Filed Pursuant to Rule 424(b)(4)
Registration No. 333-257809

6,666,667 Shares

Class A Common Stock

This is the initial public offering of shares of Class A common stock of Rani Therapeutics Holdings, Inc., par value $0.0001. We are offering 6,666,667 shares of our Class A common stock.

Prior to this offering, there has been no public market for our Class A common stock. The public offering price for our Class A common stock is $11.00 per share. Our Class A common stock has been approved for listing on the Nasdaq Global Market under the symbol "RANI."

We will use the net proceeds that we receive from this offering to purchase from Rani Therapeutics, LLC, or Rani LLC, newly issued common membership interests of Rani LLC, which we refer to as the LLC Interests. There is no public market for the LLC Interests. The purchase price for the newly issued LLC Interests will be equal to the initial public offering price of our Class A common stock, less the underwriting discounts and commissions referred to below. We intend to cause Rani LLC to use the net proceeds it receives from us in connection with this offering as described in the section titled "Use of Proceeds." Simultaneous with this offering, certain of the owners of membership interests in Rani LLC, whom we refer to as Former LLC Owners, will exchange their membership interests in Rani LLC for shares of Class A common stock and other holders of membership interests in Rani LLC, whom we refer to as the Continuing LLC Owners, will retain their membership interests in Rani LLC.

This offering is being conducted through what is commonly referred to as an "Up-C" structure, which is often used by partnerships and limited liability companies undertaking an initial public offering. The Up-C structure will allow the Continuing LLC Owners to retain their equity ownership in Rani LLC and to continue to realize tax benefits associated with owning interests in an entity that is treated as a partnership, or "passthrough" entity, for U.S. federal income tax purposes and may provide future tax benefits for both Rani Therapeutics Holdings, Inc., and certain of the Continuing LLC Owners if and when Continuing LLC Owners ultimately redeem or exchange their LLC Interests for shares of our Class A common stock. We are a holding company, and upon the closing of this offering and the application of proceeds therefrom our principal asset will be the noneconomic voting Class B common units and the LLC Interests we purchase from Rani LLC and acquire from the Former LLC Owners, representing an aggregate 37.8% economic interest in Rani LLC. The remaining 62.2% economic interest in Rani LLC will be owned by the Continuing LLC Owners through their ownership of LLC Interests. See the section titled "Organizational Transactions."

Following the closing of this offering, we will have three classes of common stock: Class A common stock, Class B common stock and Class C common stock. The Class B common stock, which we refer to as noneconomic voting equity interests, will have no rights to receive any distributions or dividends, whether cash or stock, and will not be publicly traded. 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 our stockholders generally. Shares of Class C common stock have no voting rights, except as otherwise required by law. Immediately following the completion of this offering, all of our Class B common stock will be held by the Continuing LLC Owners, on a one-to-one basis with the number of LLC Interests they respectively own. Immediately following the completion of this offering, the holders of our Class A common stock issued in this offering collectively will hold 35.6% of the economic interests in Rani Holdings and 2.1% of the voting power in Rani Holdings, the Former LLC Owners, through their ownership of Class A common stock, collectively will hold 64.4% of the economic interests in Rani Holdings and 3.9% of the voting power in Rani Holdings, and the Continuing LLC Owners, through their ownership of Class B common stock, collectively will hold no economic interest in Rani Holdings and the remaining 94.0% of the voting power in Rani Holdings, at the initial public offering price of $11.00 per share. Immediately following the completion of this offering, no shares of Class C common stock will be issued and outstanding.

We will be the sole managing member of Rani LLC. We will operate and control all of the business and affairs of Rani LLC and, through Rani LLC and its subsidiary.

Upon the completion of this offering, the number of shares owned by our controlling stockholder, InCube Labs, LLC, or ICL, will represent approximately 71.9% of the total voting power of our outstanding capital stock (or approximately 71.7% of the total voting power of our outstanding capital stock, if the underwriters exercise in full their option to purchase additional shares of Class A common stock). As a result of ICL's ownership of our Class B common stock following this offering, we will be a "controlled company" under the listing requirements of Nasdaq, or the Nasdaq Marketplace Rules. We do not intend to rely on the exemptions from the corporate governance requirements of the Nasdaq Marketplace Rules. See the section titled "Management—Controlled Company Status."

We are an "emerging growth company" as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our Class A common stock involves risks that are described in the "Risk Factors" section beginning on page 23 of this prospectus.

	Per Share	Total
Initial public offering price	$ 11.00	$ 73,333,337
Underwriting discounts and commissions(1)	$ 0.77	$ 5,133,334
Proceeds, before expenses, to us	$ 10.23	$ 68,200,003

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional 1,000,000 shares of Class A common stock from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The shares of Class A common stock will be ready for delivery on or about August 3, 2021.

Book-Running Managers

BofA Securities **Stifel** **Cantor** **Canaccord Genuity**

Lead Manager

BTIG

The date of this prospectus is July 30, 2021.

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We and the underwriters have not authorized anyone to provide you any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell shares of Class A common stock in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside of the United States: we have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of Class A common stock and the distribution of this prospectus outside of the United States.

BASIS OF PRESENTATION

In connection with the closing of this offering, we will effect certain organizational transactions. Unless otherwise stated or the context otherwise requires, all information in this prospectus reflects the completion of the organizational transactions and this offering, which we refer to collectively as the "Organizational Transactions." See the section titled "Organizational Transactions" for additional information regarding the Organizational Transactions.

As used in this prospectus, unless the context otherwise requires, references to:

- "we," "us," "our," the "Company," "Rani," "Rani Holdings," "Rani Therapeutics Holdings, Inc." and similar references refer: (i) following the completion of the Organizational Transactions, including this offering, to Rani Therapeutics Holdings, Inc., and, unless otherwise stated, all of its subsidiaries, including Rani Therapeutics, LLC, which we refer to as "Rani LLC," and, unless otherwise stated, its subsidiary, and (ii) on or prior to the completion of the Organizational Transactions, including this offering, to Rani Therapeutics, LLC and, unless otherwise stated, its subsidiary.

- "Continuing LLC Owners" refers to the individuals and entities that will continue to own LLC Interests (as defined below) and which may also hold noneconomic voting equity interests in the form of Class B common stock in Rani LLC after the Organizational Transactions. The Continuing LLC Owners may, following the completion of this offering, exchange or redeem their LLC Interests for shares of our Class A common stock or, if we elect in lieu of shares of Class A common stock, a cash payment as described in the section titled "Certain Relationships and Related Person Transactions—Rani LLC Agreement," in each case, together with a cancellation of the same number of their shares of Class B common stock. Certain Continuing LLC Owners will be legacy holders of Profits Interests (as defined below) who do not exchange their LLC Interests for shares of our Class A common stock in connection with the completion of this offering.

- "ICL" refers to InCube Labs, LLC, a Delaware limited liability company.

- "Former LLC Owners" refers to those individuals and entities that currently hold common units (including common issued upon conversion) and/or Profits Interests in Rani LLC that, upon the closing of this offering, will be recapitalized to LLC Interests and exchanged for shares of our Class A common stock in connection with the completion of this offering, as described in the section titled "Organizational Transactions."

- "LLC Interests" refers to the single class of common units in Rani LLC until we adopt our fifth amended and restated LLC agreement upon the closing of this offering, after which "LLC Interests" refers to economic nonvoting Class A common units.

- "Tax Receivable Agreement" refers to the tax receivable agreement to be entered into by Rani LLC and certain of the Continuing LLC Owners. See the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement."

Following completion of the Organizational Transactions and the application of net proceeds therefrom, we will be a holding company and the sole managing member of Rani LLC and our principal asset will be our interests in Rani LLC. Rani LLC is the predecessor of the issuer, Rani Holdings, for financial reporting purposes. Accordingly, this prospectus contains the historical consolidated financial statements of Rani LLC. As we will have no other interest in any operations other than those of Rani LLC and its subsidiary, the historical consolidated financial information included in this prospectus is that of Rani LLC and its subsidiary. As Rani Holdings has no business transactions or activities to date and had no assets or liabilities during the periods presented, the historical financial statements of this entity are not included in this prospectus. Following completion of this offering, the reporting entity for purposes of periodic reporting will be Rani Holdings.

The unaudited pro forma financial information of Rani Holdings presented in this prospectus has been derived by the application of pro forma adjustments to the historical consolidated financial statements of Rani LLC and its subsidiary included elsewhere in this prospectus. The unaudited pro forma condensed consolidated financial data of Rani Holdings presented in this prospectus has been derived from the application of pro forma adjustments to the historical consolidated financial statements of Rani LLC included elsewhere in this prospectus. These pro forma adjustments give effect to the Organizational Transactions as described in the section titled "Organizational Transactions," including the completion of this offering and other related transactions, as if all such transactions had occurred on January 1, 2020. See the section titled "Unaudited Pro Forma Condensed Consolidated Financial Information" for a complete description of the adjustments and assumptions underlying the unaudited pro forma condensed consolidated financial data included in this prospectus.

Numerical figures included in this prospectus have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in various tables may not be arithmetic aggregations of the figures that precede them.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and consolidated financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Organizational Transactions" and our consolidated financial statements and related notes included elsewhere in this prospectus. Some of the statements in this prospectus are forward-looking statements. See the section titled "Special Note Regarding Forward-Looking Statements." See the section titled "Glossary" for certain definitions of key scientific, technical, and other terms used in this prospectus.

Overview

We are a clinical stage biotherapeutics company advancing technologies to enable the development of orally administered biologics, which we believe will have the potential to transform medicine and improve patient outcomes. 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.

Patient aversion to injections has promoted a significant interest in the development of solutions to enable the oral delivery of biologics. Despite repeated attempts, oral delivery of biotherapeutics remains largely unsuccessful due to their rapid degradation and digestion in the GI environment. The most significant hurdle for oral biologics is the ability to achieve sufficient bioavailability, which is the proportion of a delivered dose that reaches the bloodstream and produces an intended therapeutic effect. Most prior attempts have taken a chemistry-based approach, which involves protecting the biologic from being digested and improving absorption by chemical agents. The best attempts have resulted in low bioavailability of peptides in the range of 1% or less.

In contrast to these prior attempts, the RaniPill capsule delivers biologics with high bioavailability, similar to subcutaneous injection, in the range of 40% to 78%, with high dosing accuracy. Further, the RaniPill capsule is designed to orally deliver a number of biologics, from peptides to antibodies. We also believe our technology may have application in delivering emerging cell and gene therapies.

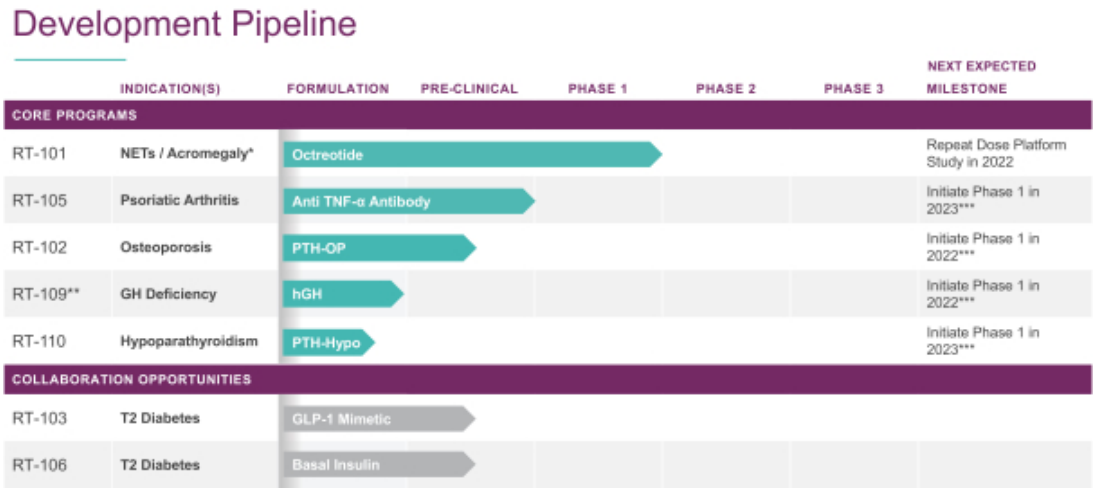
The RaniPill capsule's proprietary protective coating is designed to withstand the stomach acid and only dissolve in the jejunum, the upper half of the small intestine. Once dissolved, a microneedle containing a biologic drug is delivered into the highly vascularized wall of the small intestine so that the biologic can enter the bloodstream.

We have tested our most advanced product candidate in a Phase 1 clinical trial conducted in Australia, and we are further optimizing the formulation in preparation for a regulatory submission to FDA to initiate subsequent trials. Based on discussions with the FDA and the guidance we have received from CDRH in a pre-IDE meeting, we expect to be able to conduct further testing in humans in the contemplated IDE study of the RaniPill in the United States. In this study, we will evaluate the safety and tolerability of the RaniPill capsule, independent of any drug or biologic. This will be followed by a more standard regulatory pathway for each of our pipeline candidates. Our current pipeline includes well-characterized biologics that have been in clinical use for several years. We believe that we may be able to leverage the FDA's prior conclusions of safety, purity and

potency for certain approved biologic products in our own BLA submissions. The degree to which we may be able to reduce the burden on our own development will depend on whether the API is the same as the original approved product, particularly for products originally approved as NDAs and now deemed to be biologics. We intend to have this clarified on a product-by-product basis in pre-IND meetings with the FDA.

Our Pipeline

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. Below is a summary of our product candidate pipeline.



RT-XXX refers to the RaniPill capsule containing a biologic in a proprietary Rani formulation
*Each of these indications will require separate trials
**CCHN will have limited opportunity to negotiate for rights within China
***To follow submission and clearance of IND

RT-101: Octreotide for the treatment of NETs and acromegaly

We are developing RT-101, our most advanced candidate, for oral administration of octreotide for acromegaly and NETs. Octreotide is currently approved by the FDA and EMA for the symptomatic treatment of acromegaly, a disorder involving the secretion of excessive growth hormone, as well as carcinoid syndrome, a condition involving NETs of the GI tract. Current treatment using octreotide involves painful subcutaneous injections administered three to four times daily or an extended release formulation via painful, deep intramuscular injections every four weeks. Despite the inconvenience of the current route of administration, the worldwide market for octreotide in 2020 was approximately $2.7 billion. By introducing an oral version of octreotide, we aim to improve patients' quality of life, eliminate the burden and pain of these injections, and enable patients to more conveniently manage their disease.

We have completed a Phase 1 clinical trial in which bioavailability of RT-101 was 65% relative to the IV group. We believe this is the first demonstration of such high bioavailability of an oral biologic in humans. To date, the best published bioavailability for oral octreotide is approximately 1%. The results of the RT-101 Phase 1 clinical trial support the utility of the RaniPill capsule to deliver octreotide orally. In addition, we believe the results support the utility of the RaniPill capsule for other biologics. We are further optimizing the formulation in preparation for subsequent clinical trials with RT-101. We have worldwide commercial rights to RT-101.

RT-105: Anti-TNF-alpha antibody for the treatment of psoriatic arthritis

We are developing RT-105 as an oral anti-TNF-alpha antibody for a host of inflammatory conditions. Several TNF-alpha antibodies such as adalimumab have been approved by the FDA and EMA to treat a range of autoimmune conditions, including psoriasis, rheumatoid arthritis and Crohn's disease. Humira is a well-known brand of adalimumab and the world's best-selling drug, with worldwide sales of approximately $20.0 billion in 2019. Patients who use adalimumab administer the drug through a painful subcutaneous injection once every two weeks. We believe RT-105 represents a substantial global market opportunity.

We embarked on this program using commercially available TNF-alpha inhibitors (adalimumab and biosimilar) to conduct preclinical and clinical feasibility and proof of concept studies. To date, we have developed a formulation of a TNF-alpha inhibitor suitable for use with the RaniPill capsule and have conducted a series of preclinical studies and an early clinical study which we believe provide compelling evidence of our ability to reliably achieve therapeutic serum concentrations of the antibody via direct injection into the intestinal wall. We plan to initiate a Phase 1 clinical trial of RT-105 in healthy volunteers in 2023 and develop it for the treatment of psoriatic arthritis. Later, we plan to expand RT-105 to other indications for which TNF-alpha inhibitors are approved. We have worldwide commercial rights to RT-105.

RT-102: Parathyroid hormone for the treatment of osteoporosis

We are developing RT-102 for oral administration of PTH for the treatment of osteoporosis. PTH is approved by the FDA for the treatment of osteoporosis, a bone-loss disease, as well as for other conditions. While there are several medications available for the prevention or treatment of osteoporosis, the bone-building treatments, such as PTH, require frequent painful subcutaneous injections. Approximately 10.0 million Americans suffer from osteoporosis; however, we estimate only a small fraction of this population is being treated with PTH. While there may be other reasons for this, we believe that patients' aversion to daily injections may be a factor. As a result, non-bone-building and less effective antiresorptive drugs are used as first line therapies because they are available in oral form. We believe an oral version of PTH would advance treatment of osteoporosis and has the potential to expand this market.

We have optimized our PTH formulation for use in the RaniPill capsule for the treatment of osteoporosis and are currently conducting preclinical studies with RT-102. We plan to initiate a Phase 1 clinical trial with RT-102 in healthy volunteers in 2022. We have worldwide commercial rights to RT-102.

RT-109: HGH for the treatment of growth hormone deficiency

We are developing RT-109 for oral administration of hGH for the treatment of growth hormone deficiency. HGH is approved by the FDA for the treatment of growth hormone deficiency. Current treatment with hGH involves daily painful subcutaneous injections. Despite this, worldwide sales of hGH totaled approximately $6.0 billion in 2020. We believe that both pediatric and adult patients suffering from growth hormone deficiency would prefer once-daily oral administration.

We are finalizing our hGH formulation for the RaniPill capsule and are conducting preclinical PK studies. We plan to initiate a Phase 1 clinical trial in healthy volunteers in 2022. We have worldwide commercial rights to RT-109. We have entered into an Evaluation and First Right of Refusal Agreement with Changchun High & New Technology Industries, or CCHN, which includes limited rights to negotiate commercialization rights for RT-109 in China.

RT-110: Parathyroid hormone for the treatment of hypoparathyroidism

We are developing RT-110 for oral administration of a novel formulation of PTH for the treatment of hypoparathyroidism. PTH is approved by the FDA for the treatment of hypoparathyroidism, a rare condition that affects approximately 115,000 people in the United States; however, treatment requires painful daily injections and we believe there is an unmet need for a more convenient delivery method. We believe that RT-110, through providing the convenience of oral administration, may be able to meet this need.

We plan to initiate preclinical PK studies once our PTH formulation has been optimized. We have worldwide commercial rights to RT-110.

RT-103: GLP-1 mimetic for the treatment of Type 2 diabetes

We are developing RT-103 for oral administration of a GLP-1 mimetic for the treatment of Type 2 diabetes. We believe that RT-103 would be appealing to patients that currently use injectable versions of GLP-1 mimetics, and plan to pursue opportunities with large pharmaceutical companies to co-develop and commercialize RT-103.

RT-106: Basal insulin for the treatment of Type 2 diabetes

We are developing RT-106 for oral administration of basal insulin for the treatment of Type 2 diabetes. We believe that RT-106 would have significant benefit to the millions of people living with Type 2 diabetes. We intend to pursue partnership opportunities with large pharmaceutical companies to co-develop and commercialize RT-106.

Our Solution: The RaniPill Capsule

A Summary Description of the RaniPill Capsule

The RaniPill capsule is a versatile, orally ingestible pill for the administration of a broad range of biologics. Unlike chemistry-based approaches to the oral delivery of biologics, the RaniPill capsule is designed to autonomously inject biologics from the capsule into the intestinal wall.

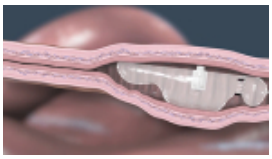
The RaniPill capsule (purple) next to fish oil pills (yellow) and calcium pills (white).
Image does not depict actual size of capsule or pills.

How the RaniPill Capsule Works

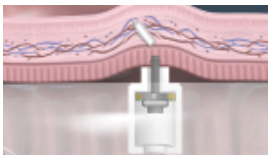
The RaniPill capsule is covered with a protective coating, which resists dissolution in the acidic environment of the stomach. Once the capsule enters the small intestine, dissolution of the protective coating leads to a series of steps that result in delivery of the biologic into the intestinal wall. These steps are illustrated in the figures below.

Cross Section of Intestinal Wall Illustrating Deployment of the RaniPill Capsule

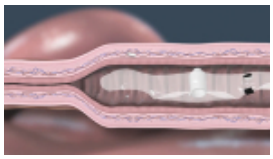
A: RaniPill capsule with protective coating in intestine.



B: Outer shell dissolves and the balloon starts to inflate as the reaction begins.



C: Pressure in the balloon pushes the dissolving microneedle into the intestinal wall.



D: Balloon deflates and is the only remnant that passes through, with the rest of the RaniPill absorbed or dissolved in its current version.

Panel A: As the RaniPill capsule exits the stomach and enters the small intestine, the higher pH environment of the small intestine causes the dissolution of the protective coating.

Panel B: After sustained exposure at a pH of around 6.5, the capsule dissolves, exposing a self-inflating balloon that is separated into two compartments. Reactants in the two compartments are separated by a pinch-valve, which dissolves upon exposure to intestinal fluids. The reactants mix upon dissolution of the pinch-valve to produce carbon dioxide, which inflates the balloon.

Panel C: Inflation of the balloon orients a microneedle contained within the balloon perpendicular to the intestinal wall. The pressure in the balloon injects the microneedle, which is smaller than a grain of rice, into the intestinal wall. In the moist tissue environment, the microneedle dissolves and the drug is rapidly absorbed into the bloodstream.

Panel D: The balloon immediately deflates upon microneedle delivery and is excreted through normal digestive processes.

Our Strategy

Our strategic vision is to disrupt and expand the approximately $269.0 billion injectable biologics therapeutics industry by developing and advancing oral biologics therapies. We are committed to delivering oral biologic solutions for patients living with burdensome chronic diseases. We believe that the RaniPill capsule will improve the lives of millions of patients with chronic diseases who currently depend on biologics available only as injections.

The key elements of our strategy include:

- **Pursue validated and commercially established market opportunities**. We intend to pursue high-value markets with biologics that are already approved where we can develop our own differentiated products. We believe that these products will take market share from available

therapies, while also expanding existing markets by reaching new patient populations that otherwise are not being treated by injectable biologics. We have designed our platform to be drug-agnostic, which could enable us to expand into additional markets beyond our current pipeline.

- **Establish the RaniPill capsule as a platform technology with regulatory authorities**. Initially, we plan to demonstrate the safety and tolerability of the RaniPill capsule through clinical studies, independent of any drug or biologic. Data from these studies will be used to support subsequent product applications.

- **Expand in-house manufacturing of the RaniPill capsule**. We have vertically integrated our manufacturing, and plan to continue to scale and optimize our manufacturing processes by expanding our use of automation. In addition, we are filing patents to protect our novel manufacturing processes.

- **Invest in RaniPill platform capabilities**. We intend to become a leader in oral biologics by continuing to invest in our technology, by expanding payload capacity and developing novel biologic formulations in order to maximize the number of therapeutic targets and addressable markets.

- **Expand our reach by selectively entering into strategic partnerships**. We are opportunistically exploring strategic partnerships to enable us to expand our commercial reach and enable oral administration of a broader array of biologics.

- **Continue to strengthen our intellectual property portfolio**. Our patent portfolio has helped establish us as a leading oral biologics company. We plan to continue to innovate and expand our intellectual property by developing novel formulations and new applications of the RaniPill capsule.

Clinical Development and Regulatory Pathway of the RaniPill Capsule

Based on the guidance we have received from CDRH and OCP, we will study the initial safety and tolerability of the RaniPill capsule in an IDE study, in an effort to enable a more standard regulatory pathway for our pipeline of product candidates.

While CBER and CDER may ask for additional testing for a specific biotherapeutic or disease, our initial goal is to evaluate the safety of the RaniPill capsule independent of any drug. In a pre-submission meeting with CDRH and OCP and representatives from CDER, we reached agreement on the initial requirements for establishing safety and tolerability of the RaniPill capsule for further clinical evaluation. Preclinical studies and clinical trials will be conducted with the RaniPill capsule containing an inert tracer in place of a drug, to determine the reliability of delivery and the initial safety of the platform. In support of the IDE study, we will first conduct a repeat-dose GLP study in canines to assess the safety and tolerability of the RaniPill capsule. We would then conduct the IDE study to evaluate the safety and tolerability of the RaniPill capsule in an eight-week healthy volunteer study (n=40) with daily administration of the RaniPill capsule. The study will also evaluate the effect of food on the delivery performance of the RaniPill capsule. After completion of the IDE study, we plan to create a Master File for the RaniPill capsule with CDRH. The information in the RaniPill Master File will be applicable to any biologic and would be incorporated by reference in subsequent applications to CDER or CBER for our future product candidates.

Our current pipeline consists of well-characterized biologics that have been in clinical use for several years. The degree to which we may be able to reduce the burden on our own development will depend on whether the API is the same as the original approved product, particularly for products originally approved as NDAs and now deemed to be biologics. We intend to have this clarified on a product-by-product basis in pre-IND meetings with the FDA.

Our Team

We are led by an experienced management team with substantial scientific, formulation and drug development expertise in a number of therapeutic areas including immunology, gastroenterology, cardiology, metabolic diseases and oncology. The development and manufacturing of the RaniPill capsule is led by a highly experienced team with deep expertise in engineering, material science, anatomy, physiology, manufacturing and automation. Our management team members have held successful and diverse roles leading research, clinical development, product development, strategy, corporate development and operational functions at companies such as GlaxoSmithKline plc., Gilead Sciences, Inc., VIVUS Inc., Edwards Lifesciences Corp., Danaher Corp., Affymetrix, Inc. and Elan Corporation plc. Members of our leadership team have been involved in the discovery, development and commercialization of multiple marketed products across various therapeutic areas, including Tykerb, Romozin, Avodart, Zyban, Ranexa and Lexiscan. We were founded by Mir Imran, our Executive Chairman and former President and Chief Executive Officer. With background in medicine and engineering, Mir Imran began his career as a healthcare entrepreneur in the late 1970s and has founded more than 20 life sciences companies since, more than half of which have been acquired. Mir Imran's passion is creating novel technologies that have the potential to positively impact the lives of millions of patients, and he has become one of the leading inventors and entrepreneurs in the field. Mir Imran is perhaps most well-known for his pioneering contributions to the first FDA-approved automatic implantable cardioverter defibrillator. Our Chief Scientific Officer, Mir Hashim, a veteran of the pharma industry, has a Ph.D. in pharmacology and led research and development teams at GSK from 1990 to 2008. Our leadership is complemented by a team of biologists, engineers, manufacturing and automation experts, many with post-graduate degrees.

Summary of the Organizational Transactions

Rani Holdings was incorporated as a Delaware corporation on April 6, 2021 and is the issuer of the Class A common stock being offered in this offering. This offering is being conducted through what is commonly referred to as an "Up-C" structure, which is often used by partnerships and limited liability companies when they decide to undertake an initial public offering. To implement the Up-C structure, we will effect certain organizational changes, which we refer to collectively as the Organizational Transactions. Unless otherwise stated or the context otherwise requires, all information in this prospectus reflects the completion of these Organizational Transactions.

Key terms of the Up-C Structure are:

- The Up-C structure will allow the Continuing LLC Owners to retain their equity ownership in Rani LLC and to continue to realize tax benefits associated with owning interests in an entity that is treated as a partnership, or "passthrough" entity, for U.S. federal income tax purposes following the completion of the offering.

- Investors in this offering will, by contrast, hold their equity ownership in Rani Holdings, a Delaware corporation that is a domestic corporation for U.S. federal income tax purposes, in the form of shares of Class A common stock.

- The Former LLC Owners will hold their equity ownership in Rani Holdings in the form of shares of Class A common stock.

- The Continuing LLC Owners will hold LLC Interests, and certain of the Continuing LLC Owners will also hold noneconomic voting equity interests in the form of Class B common stock in Rani Holdings. One of the tax benefits to the Continuing LLC Owners associated with this structure is that future taxable income of Rani LLC that is allocated to the Continuing LLC Owners will be taxed on a

flow-through basis and therefore will not be subject to corporate taxes at the entity level. Additionally, the Continuing LLC Owners may redeem or exchange their LLC Interests for shares of our Class A common stock on a one-for-one basis or, at our option, for cash. The Up-C structure also provides the Continuing LLC Owners with potential liquidity that holders of non-publicly traded limited liability companies are not typically afforded. If we ever generate sufficient taxable income to utilize the tax benefits, Rani Holdings expects to benefit from the Up-C structure because, in general, we expect cash tax savings in amounts equal to 15% of certain tax benefits arising from such redemptions or exchanges of the Continuing Owners' LLC Interests for Class A common stock or cash and certain other tax benefits covered by the Tax Receivable Agreement discussed in the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement." See the section titled "Risk Factors—Risks Related to Our Organizational Structure."

In connection with the closing of this offering, we will consummate the following organizational transactions:

- we will amend and restate the limited liability company agreement of Rani LLC, or the Rani LLC Agreement, to, among other things, appoint Rani Holdings as the sole managing member of Rani LLC and effectuate a recapitalization of all outstanding (i) convertible preferred, automatic or net exercised warrants to purchase preferred and common units, and common units of Rani LLC into a single class of economic nonvoting Class A units and an equal number of voting noneconomic Class B units of Rani LLC and (ii) Profits Interests into a single class of economic nonvoting Class A units of Rani LLC based on an exchange ratio to be calculated based off of the initial public offering price of Rani Holdings Class A common stock. We will otherwise operate as a holding company. Rani Holdings will include Rani LLC in its consolidated financial statements;

- we have amended and restated Rani Holdings' certificate of incorporation to, among other things, provide for Class A common stock, each share of which entitles its holders to one vote per share, and Class B common stock, each share of which entitles its holders to 10 votes per share on all matters presented to Rani Holdings' stockholders, and Class C common stock, will have no voting rights, except as otherwise required by law;

- generally, we expect the majority of Profits Interests, other than those held by directors, officers and vice president-level executives, will be exchanged for Class A common stock of Rani Holdings on a one-for-one basis at the election of the holder;

- we expect to assume stock options to purchase an aggregate of 1,210,981 shares of Class A common stock with an exercise price set at $9.45 per share;

- generally, the Former LLC Owners will exchange their LLC Interests for shares of Class A common stock, representing (i) approximately 3.88% of the combined voting power of all of Rani Holdings' common stock (or approximately 3.86%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and (ii) approximately 64.4% of the economic interest in Rani Holdings (or approximately 61.2%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- the Continuing LLC Owners will continue to own the LLC Interests they receive in exchange for their outstanding common units in Rani LLC, representing approximately 62.2% of the economic interest in the business of Rani LLC and its subsidiary (or approximately 61.0%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock), and Continuing LLC Owners who received voting noneconomic Class B units in the recapitalization will contribute those

Class B units to Rani Holdings in exchange for a corresponding number of shares of Class B common stock, each share of which entitles its holder to 10 votes per share;

- the LLC Interests, following the completion of this offering, will be redeemable, at the Continuing LLC Owners' election, for newly issued shares of Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications) in accordance with the terms of the Rani LLC Agreement; 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 Class A common stock for each LLC Interest redeemed in accordance with the terms of the Rani LLC Agreement. Shares of Class B common stock will be cancelled on a one-for-one basis if we, at the election of the Continuing LLC Owners that hold Class B common stock, redeem or exchange such holders' LLC Interests pursuant to the terms of the Rani LLC Agreement;

- Rani Holdings will enter into (i) the Tax Receivable Agreement with certain of the Continuing LLC Owners, and (ii) a registration rights agreement, or the Registration Rights Agreement, with certain of the Continuing LLC Owners;

- Rani Holdings will issue 6,666,667 shares of Class A common stock to the purchasers in this offering (or 7,666,667 shares of our Class A common stock if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- Rani Holdings will use all of the net proceeds from this offering (including any net proceeds received upon exercise of the underwriters' option to purchase additional shares of Class A common stock) to acquire newly issued LLC Interests from Rani LLC at a purchase price per interest equal to the initial public offering price per share of Class A common stock, less underwriting discounts and commissions, collectively representing 13.5% of Rani LLC's outstanding LLC Interests (or 15.2%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock); and

- Rani LLC will use the proceeds from the sale of LLC Interests to Rani Holdings as described in the section titled "Use of Proceeds."

Upon the completion of this offering, the purchasers in this offering (i) will own 6,666,667 shares of Class A common stock, representing approximately 2.1% of the combined voting power of all of Rani Holdings' common stock (or 7,666,667 shares of Class A common stock representing approximately 2.5%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock), (ii) will own 35.6% of the economic interest in Rani Holdings (or 38.8%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and (iii) through Rani Holdings' ownership of LLC Interests, indirectly will hold (applying the percentages in the preceding clause (ii) to Rani Holdings' percentage economic interest in Rani LLC) approximately 13.5% of the economic interest in Rani LLC (or 15.2% if the underwriters exercise in full their option to purchase additional shares of Class A common stock).

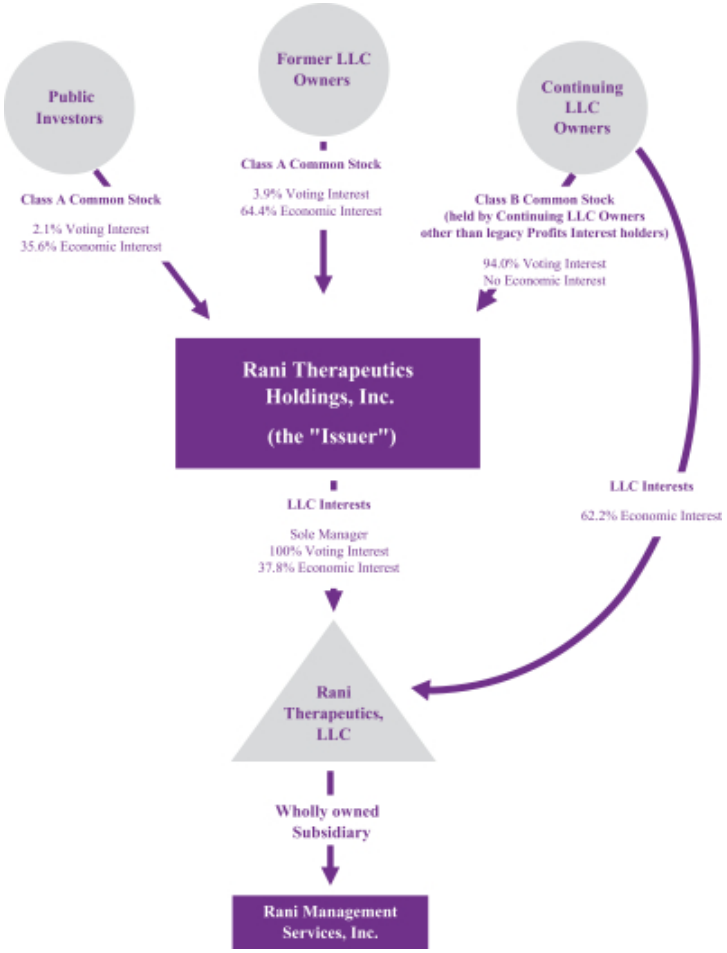
We refer to the foregoing Organizational Transactions collectively as the "Organizational Transactions." For more information regarding our structure after the completion of the Organizational Transactions, including this offering, see the section titled "Organizational Transactions."

Immediately following the completion of this offering, Rani Holdings will be a holding company and its principal asset will be our interests in Rani LLC and acquires from the Former LLC Owners. As the sole managing member of Rani LLC, Rani Holdings will operate and control all of the business and affairs of Rani LLC and, through Rani LLC and its subsidiary, conduct our business. Accordingly, Rani Holdings will have the

sole voting interest in, and control the management of, Rani LLC. As a result, we will consolidate Rani LLC in our consolidated financial statements and will report a non-controlling interest related to the LLC Interests held by the Continuing LLC Owners on our consolidated financial statements.

See the section titled "Description of Capital Stock" for more information about our amended and restated certificate of incorporation and the terms of the Class A common stock, Class B common stock and Class C common stock. See the section titled "Certain Relationships and Related Person Transactions" for more information about (i) the Rani LLC Agreement, including the terms of the LLC Interests and the redemption right of the Continuing LLC Owners; (ii) the Tax Receivable Agreement; and (iii) the Registration Rights Agreement. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Source of Liquidity" for more information about expected payments under the Tax Receivable Agreement.

The diagram below depicts our organizational structure after giving effect to the Organizational Transactions, including this offering, assuming no exercise by the underwriters of their option to purchase additional shares of Class A common stock.



Risks Associated with Our Business

There are a number of risks related to our business, this offering and our Class A common stock that you should consider before you decide to participate in this offering. You should carefully consider all the information presented in the section entitled "Risk Factors" in this prospectus. Some of the principal risks related to our business include the following:

- 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 product revenue, which makes it difficult to assess our future prospects and financial results.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us 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, 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 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. In addition, one of our clinical trials was conducted outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such a trial, in which case we may need to conduct additional clinical 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. 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.
- 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 will be a holding company following the completion of this offering. Our principal asset after the completion of this offering will be our interest in Rani LLC, and, accordingly, we will depend on distributions from Rani LLC to pay our taxes, expenses (including payments under the Tax Receivable Agreement) and dividends. Rani LLC's ability to make such distributions may be subject to various limitations and restrictions.
- Rani LLC 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 with those stockholders who held our voting units prior to the completion of this offering, including our executive officers, employees and directors and their affiliates, 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 after this offering and will be able to exert significant control over matters subject to stockholder approval.

These and other risks are more fully described in the section titled "Risk Factors" in this prospectus. If any of these risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. As a result, you could lose all or part of your investment in our Class A common stock.

Our Capital Structure

Upon the completion of this offering, we will have three classes of common stock. Our Class A common stock, which is the stock we are offering by means of this prospectus, will have one vote per share, our Class B common stock will have 10 votes per share, and our Class C common stock will have no voting rights, except as otherwise required by law.

Upon the completion of this offering, all shares of Class B common stock will be held by certain Continuing LLC Owners. Accordingly, upon completion of this offering, the shares beneficially owned by the Continuing LLC Owners will represent 94.0% of the total voting power of our outstanding capital stock. The Continuing LLC Owners will be able to determine or significantly influence any action requiring the approval of our stockholders, including the election of our board of directors, the adoption of amendments to our certificate of incorporation and bylaws, and the approval of any merger, consolidation, sale of all or substantially all of our assets, or other major corporate transaction.

Shares of our Class C common stock, which entitle the holder to zero votes per share, will not be issued and outstanding at the closing of the offering and we have no current plans to issue shares of Class C common stock. These shares will be available to be used in the future to further strategic initiatives, such as financings or acquisitions, or issue future equity awards to our service providers. Because the shares of Class C common stock have no voting rights (except as otherwise required by law), the issuance of such shares will not result in further dilution to the voting power held by the Continuing LLC Owners.

The multi-class structure of our common stock is intended to ensure that, for the foreseeable future, the Continuing LLC Owners continue to control or significantly influence our governance which we believe will permit us to continue to prioritize our long-term goals rather than short-term results, to enhance the likelihood of stability in the composition of our board of directors and its policies, and to discourage certain types of transactions that may involve an actual or threatened acquisition of us.

Potential Insider Participation

Our existing investor South Lake One LLC and its affiliates have indicated an interest in purchasing approximately $69.3 million of shares (or 6,300,000 shares) in the aggregate of our Class A common stock in this offering at the initial public offering price. Immediately following the closing of this offering, South Lake One LLC and its affiliates will beneficially own approximately 24.1% of our stock, representing approximately 3.7% of our voting power (or approximately 23.6% of our stock, representing approximately 3.7% of our voting power if the underwriters exercise in full their option to purchase additional shares of Class A common stock). However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

General Corporate Information

Our office is located at 2051 Ringwood Avenue, San Jose, California 95131. Our telephone number is 408-457-3700. Our website address is https://www.ranitherapeutics.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus. We are a holding company and all of our business operations are conducted through, and substantially all of our assets are held by, our direct and indirect subsidiaries.

The information in this prospectus is based on our estimate that, in the Organizational Transactions, an aggregate of 6,666,667 shares of our Class A common stock will be issued to holders of units in the LLC entity based on the initial public offering price per share of our Class A common stock of $11.00.

We use Rani, Rani Therapeutics, RaniPill, the Rani Therapeutics logo, the R logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names

referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than $1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of this offering.

As a result of this status, we elected to take advantage of reduced reporting requirements in the registration statement of which this prospectus forms a part and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

The Offering	
Issuer	Rani Therapeutics Holdings, Inc.
Class A common stock offered by us	6,666,667 shares.
Underwriters' option to purchase additional shares of Class A common stock	The underwriters have a 30-day option to purchase up to 1,000,000 additional shares of Class A common stock from us as described under the heading "Underwriting."
Class A common stock to be issued to Former LLC Owners	12,072,015 shares.
Class A common stock to be outstanding immediately after this offering	18,738,682 shares (or 19,738,682 shares if the underwriters exercise in full their option to purchase additional shares of Class A common stock).
Class B common stock to be outstanding immediately after this offering	29,269,540 shares, all of which will be owned by the Continuing LLC Owners.
Class C common stock to be outstanding immediately after this offering	None.
Voting Rights	Holders of our Class A common stock and Class B common stock will vote together as a single class on all matters presented to stockholders for their vote or approval, except as otherwise required by law. Each share of Class A common stock will entitle its holder to one vote per share, and each share of Class B common stock will entitle its holder to 10 votes per share on all such matters. Holders of our Class C common stock will have no voting rights, except as otherwise required by law. See the section titled "Description of Capital Stock."
Voting power held by purchasers in this offering	2.1% (or 2.5% if the underwriters exercise in full their option to purchase additional shares of Class A common stock).
Voting power held by the Former LLC Owners	3.88% (or 3.86% if the underwriters exercise in full their option to purchase additional shares of Class A common stock).
Voting power held by all holders of Class A common stock after giving effect to this offering	6.0% (or 6.3% if the underwriters exercise in full their option to purchase additional shares of Class A common stock).

Voting power held by all holders of Class B common stock after giving effect to this offering	94.0% (or 93.7% if the underwriters exercise in full their option to purchase additional shares of Class A common stock).
Voting power held by all holders of Class C common stock after giving effect to this offering	None.
Ratio of shares of Class A common stock to LLC Interests	Our amended and restated certificate of incorporation requires and the Rani LLC Agreement will require that we at all times maintain a ratio of one LLC Interest owned by us for each outstanding share of Class A common stock (subject to certain exceptions for treasury shares and shares underlying certain convertible or exchangeable securities) and Rani LLC at all times maintain a one-to-one ratio between the number of shares of Class A common stock issued by us and the number of LLC Interests owned by us, as well as a one-to-one ratio between the number of shares of Class B common stock owned by certain of the Continuing LLC Owners and the number of LLC Interests owned by certain of the Continuing LLC Owners.
Reserved Share Program	At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors and officers and certain other related parties to us. If these persons purchase reserved shares, it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately $64.1 million (or approximately $74.3 million if the underwriters exercise in full their option to purchase additional shares of Class A common stock). We intend to use the net proceeds that we receive from this offering (including any net proceeds from the underwriters' exercise of their option to purchase additional shares of Class A common stock) to purchase 6,666,667 newly issued LLC Interests (or 7,666,667 LLC Interests if the underwriters exercise in full their option to purchase additional shares of Class A common stock) directly from Rani LLC at a purchase price per interest equal to the initial public offering price per share of Class A common stock, less underwriting discounts and commissions.

We intend to cause Rani LLC to use such proceeds (together with any additional proceeds it may receive if the underwriters exercise their

	option to purchase additional shares of Class A common stock), after deducting estimated offering expenses, together with our existing cash and cash equivalents to advance our internal pipeline, to advance manufacturing scale-up and automation, to repay in full our outstanding approximately $1.3 million PPP Loan with Comerica Bank, to advance research and development programs, and for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for additional information.
Redemption rights of holders of LLC Interests	The Continuing LLC Owners, from time to time following the completion of this offering, may (subject to the terms of the Rani LLC Agreement) require Rani LLC to redeem all or a portion of their LLC Interests for newly issued shares of Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications) in accordance with the terms of the Rani LLC Agreement; provided that, at Rani Holdings' election, it 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. See the section titled "Certain Relationships and Related Person Transactions—Rani LLC Agreement." Shares of our Class B common stock will be cancelled on a one-for-one basis, if applicable, if we, at the election of the Continuing LLC Owners, redeem or exchange our LLC Interests pursuant to the terms of the Rani LLC Agreement.
Registration Rights Agreement	Pursuant to the Registration Rights Agreement, we will, subject to the terms and conditions thereof, agree to register the resale of the shares of our Class A common stock that are issuable to the Continuing LLC Owners upon redemption or exchange of their LLC Interests and the shares of our Class A common stock that are issued to the Former LLC Owners in connection with the Organizational Transactions. See the section titled "Certain Relationships and Related Person Transactions—Registration Rights Agreement."
Controlled company	Following the completion of this offering, we will be a "controlled company" within the meaning of the corporate governance rules of Nasdaq. See the section titled "Management —Controlled Company Status."
Dividend policy	We do not anticipate declaring or paying any cash dividends on our Class A common stock for the foreseeable future. See the section titled "Dividend Policy."
Tax Receivable Agreement	We will enter into the Tax Receivable Agreement with Rani LLC and certain of the Continuing LLC Owners that will provide for the payment by us to certain of the Continuing LLC Owners of 85% of the amount of 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 LLC resulting from (a) any future redemptions or exchanges of LLC Interests described above under " —The Offering—Redemption rights of holders 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. Actual tax benefits realized by Rani Holdings may differ from tax benefits calculated under the Tax Receivable Agreement as a result of the use of certain assumptions in the Tax Receivable Agreement, including the use of an assumed weighted-average state and local income tax rate to calculate tax benefits. This payment obligation is an obligation of Rani Holdings, but not of Rani LLC. See the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement."
Risk factors	Investing in our Class A common stock involves a high degree of risk. See the section titled "Risk Factors" elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Class A common stock.
Nasdaq Global Market trading symbol	"RANI"

The number of shares of Class A common stock to be outstanding after this offering is based on the units of Rani LLC outstanding as of March 31, 2021, and excludes:

- 500,000 shares of Class A common stock, plus future increases, reserved for issuance under the 2021 Employee Stock Purchase Plan, or the ESPP, which became effective upon the execution of the underwriting agreement for this offering;
- 5,500,000 shares of Class A common stock reserved for future issuance under the 2021 Equity Incentive Plan, or our 2021 Plan, which became effective upon the execution of the underwriting agreement for this offering;
- 30,813,262 shares of Class A common stock issuable upon the exchange or redemption of outstanding LLC Interests; and
- 1,210,981 stock options to purchase shares of Class A common stock granted to certain of our employees, executive officers and directors based on awards assumed from Rani LLC with an exercise price of $9.45 per share.

Unless otherwise indicated, this prospectus assumes or gives effect to:

- no conversion of the loan and security agreement described above;
- the completion of the Organizational Transactions as described in the section titled "Organizational Transactions;"
- no exercise by the underwriters of their option to purchase additional shares of Class A common stock;
- the issuance of 177,471 shares of Class A common stock issuable upon the exchange of outstanding LLC Interests by Continuing LLC Owners or Former LLC Owners related to the automatic conversion or net exercise of warrants to purchase common and preferred units of Rani LLC, based on the initial public offering price of $11.00 per share;

- the issuance of 12,072,015 shares of Class A common stock issuable upon exchange of outstanding LLC Interests by Former LLC Owners;
- the shares of Class A common stock are offered at $11.00 per share; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws.

Summary Consolidated Historical and Pro Forma Financial Data

The following tables present the summary consolidated historical and pro forma financial data for Rani LLC and its subsidiary for the periods and at the dates indicated. Rani LLC is the predecessor of the issuer, Rani Holdings, for financial reporting purposes. The summary consolidated statements of operations and comprehensive loss data for the three months ended March 31, 2020 and 2021 and the summary consolidated balance sheet data as of March 31, 2021 are derived from the Rani LLC unaudited condensed consolidated financial statements included elsewhere in this prospectus. The summary consolidated statement of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 and the summary consolidated balance sheet data as of December 31, 2019 and 2020 have been derived from the audited consolidated financial statements and notes of Rani LLC and its subsidiary included elsewhere in this prospectus. You should read this data together with our audited consolidated financial statements and related notes and unaudited condensed consolidated financial statements and related notes appearing elsewhere in this prospectus and the information in the sections titled “Capitalization,” “Unaudited Pro Forma Condensed Consolidated Financial Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of our future results and results of interim periods are not necessarily indicative of results for the entire year.

The summary unaudited pro forma condensed consolidated financial data of Rani Holdings presented below have been derived from our unaudited pro forma condensed consolidated financial statements included elsewhere in this prospectus. The summary unaudited pro forma balance sheet data as of March 31, 2021 gives effect to the Organizational Transactions as described in the section titled “Organizational Transactions,” including the completion of this offering, as if all such transactions had occurred on that date and the summary unaudited pro forma statement of operations and comprehensive loss data for the year ended December 31, 2020 and three months ended March 31, 2021 gives effect to the Organizational Transactions, as if all such transactions had occurred on January 1, 2020. The unaudited pro forma financial information includes various estimates which are subject to material change and may not be indicative of what our operations or financial position would have been had this offering and related transactions taken place on the dates indicated, or that may be expected to occur in the future. See the section titled “Unaudited Pro Forma Condensed Consolidated Financial Information” for a complete description of the adjustments and assumptions underlying the summary unaudited pro forma condensed consolidated financial data.

The summary consolidated historical data of Rani Holdings have not been presented, as Rani Holdings is a newly incorporated entity, has had no business transactions or activities to date and had no assets or liabilities during the periods presented in this section.

(in thousands, except share and unit amounts and per share and per unit amounts)	Historical Rani LLC Year Ended December 31, 2019	Historical Rani LLC Year Ended December 31, 2020	Historical Rani LLC Three Months Ended March 31 2020 (Unaudited)	Historical Rani LLC Three Months Ended March 31 2021 (Unaudited)	Pro Forma Rani Holdings Year Ended December 31, 2020 (Unaudited)	Pro Forma Rani Holdings Three Months Ended March 31, 2021 (Unaudited)
Consolidated Statements of Operations and Comprehensive Loss Data:						
Contract revenue	$ 979	$ 462	$ 83	$ 756	$ 462	$ 756
Operating expenses						
Research and development	24,579	12,044	4,060	3,347	22,364	3,347
General and administrative	3,465	4,962	1,407	2,607	9,034	2,607
Total operating expenses	28,044	17,006	5,467	5,954	31,398	5,954
Loss from operations	(27,065)	(16,544)	(5,384)	(5,198)	(30,936)	(5,198)
Other income (expense), net						
Interest income	423	63	62	47	63	47
Interest expense and other, net	(10)	(124)	—	(188)	(124)	(188)
Change in estimated fair value of preferred unit warrant	65	(63)	(17)	(216)	—	—
Loss before income taxes	(26,587)	(16,668)	5,339	(5,555)	(30,997)	(5,339)
Income tax expense	—	(35)	(11)	(43)	(35)	(43)
Net loss and comprehensive net loss	$ (26,587)	$ (16,703)	$ (5,350)	$ (5,598)	$ (31,032)	$ (5,382)
Net loss attributable to non-controlling interest					(19,297)	(3,347)
Net loss attributable to Rani Therapeutics Holdings, Inc.					$ (11,735)	$ (2,035)
Net loss per unit, basic and diluted	$ (0.57)	$ (0.36)	$ (0.11)	$ (0.12)		
Weighted average common units outstanding, basic and diluted	46,890,280	46,890,280	46,890,280	46,895,880		
Per Share Data (1)						
Pro forma weighted average shares of Class A common stock outstanding, basic and diluted:					10,599,496	18,462,713
Pro forma net loss available to Class A common stock per share, basic and diluted:					$ (1.11)	$ (0.11)

(1) See the unaudited pro forma consolidated statement of operations in "Unaudited Pro Forma Condensed Consolidated Financial Information" for the description of the assumptions underlying the pro forma net loss per share calculations.

(in thousands)	Historical Rani LLC As of December 31, 2019	Historical Rani LLC As of December 31, 2020	Historical Rani LLC As of March 31, 2021 (Unaudited)	Pro Forma Rani Holdings(2) As of March 31, 2021 (Unaudited)
Consolidated Balance Sheet Data:				
Cash and cash equivalents	$ 16,536	$ 73,058	$ 76,662	$ 139,150
Working capital (1)	13,446	69,637	69,716	133,883
Total assets	23,022	79,415	82,077	143,780
Long-term debt, net of current portion	—	2,412	1,892	1,822
Total liabilities	4,153	8,040	9,514	7,229
Convertible preferred units	115,505	184,714	191,034	—
Total members' (deficit)/stockholders' equity	(96,636)	(113,339)	(118,471)	136,551

(1) Working capital is defined as current assets less current liabilities.
(2) The consolidated pro forma balance sheet data gives effect to the Organizational Transactions, pursuant to which new Class A units of Rani LLC will be acquired using the proceeds from the sale of 6,666,667 shares of Class A common stock of Rani Holdings based on the initial public offering price of $11.00 per share.

RISK FACTORS

Investing in our Class A common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all of the other information contained in this prospectus, 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, and you may lose some or all of your investment.

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, RT-105, RT-102, RT-109, RT-110, RT-108, RT-103, and RT-106, 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 years ended December 31, 2019 and 2020 and the three months ended March 31, 2021 was approximately $26.6 million, $16.7 million and $5.6 million, respectively. As of March 31, 2021, we had an accumulated deficit of $119.6 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 RT-105, RT-102, RT-108, RT-103, and RT-106. We plan to initiate Phase 1 clinical trials of RT-102 and RT-109 in 2022 and RT-105 and RT-110 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 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.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us 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 preclinical studies of RT-108 and RT-105, are in the process of conducting preclinical studies for RT-102, RT-109, RT-110, RT-108, RT-103, and RT-106, and are preparing to conduct Phase 1 clinical trials of RT-102 and RT-109, 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 this offering, 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. 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, RT-105, RT-102, RT-109, RT-110, RT-108, RT-103, and RT-106, are still in the formulation and preclinical stages. We intend to initiate Phase 1 clinical trials for RT-102 and RT-109 in 2022 and RT-105 and RT-110 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 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 IRB or 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, RT-105, RT-102, RT-109, RT-110, RT-108, RT-103, and RT-106, are still in the formulation or preclinical stages. We intend to initiate Phase 1 clinical trials for RT-102 and RT-109 in 2022 and RT-105 and RT-110 in 2023. 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, for RT-102 and RT-109. 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 GCP regulations; 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 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 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.

We have entered into evaluation agreements with Novartis Pharmaceuticals Corporation, or Novartis, Takeda and CCHN concerning the formulation and manufacture of oral versions of a confidential molecule of Novartis, Factor VIII and hGH, respectively. Such 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 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 RT-105, RT-102, RT-108, RT-103, and RT-106. We plan to initiate Phase 1 clinical trials of RT-102 and RT-109 in 2022 and RT-105 and RT-110 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, or 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, or 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 March 31, 2021, we had 71 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 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 will be a holding company following the completion of this offering. Our principal asset after the completion of this offering will be our interest in Rani LLC, and, accordingly, we will depend on distributions from Rani LLC to pay our taxes, expenses (including payments under the Tax Receivable Agreement) and dividends. Rani LLC's ability to make such distributions may be subject to various limitations and restrictions.

Upon the closing of this offering, we will be a holding company and will have no material assets other than our ownership of LLC Interests of Rani LLC. As such, we will 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, will be dependent upon the financial results and cash flows of Rani LLC and its subsidiary and distributions we receive from Rani LLC. Rani LLC 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 LLC 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, including us. Accordingly, we will incur income taxes on our allocable share of any net taxable income of Rani LLC and will also incur expenses related to our operations, including payments under the Tax Receivable Agreement, which we expect could be significant. See the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement." Furthermore, our allocable share of Rani LLC'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 LLC 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 LLC and (ii) cover our operating expenses, including payments under the Tax Receivable Agreement. However, Rani LLC'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 LLC is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering Rani LLC 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 LLC 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. See the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement." In addition, if Rani LLC does not have sufficient funds to make distributions, our ability to declare and pay cash dividends will also be restricted or impaired. See the section titled "Risk Factors—Risks Related to this Offering and Ownership of Our Class A Common Stock" and "Dividend Policy."

Rani LLC 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.

Following the completion of this offering, we will receive a portion of any distributions made by Rani LLC. 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 LLC Agreement requires Rani LLC 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 LLC 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 LLC, 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 LLC or from holders of LLC Interests) at a price based on the market price of our Class A common stock at the time. See the section titled “Certain Relationships and Related Person Transactions—Rani LLC Agreement” and “Dividend Policy” for further information.

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.

Upon the closing of this offering, we will be 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 LLC resulting from (a) any future redemptions or exchanges of LLC Interests described under “Certain Relationships and Related Person Transactions—Rani LLC Agreement—LLC Interest Redemption Right,” and (b) payments under the Tax Receivable Agreement and (ii) certain other tax benefits arising from payments under the Tax Receivable Agreement. See the section titled “Certain Relationships and Related Person Transactions—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 LLC attributable to our interests in Rani LLC, 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. See the section titled "Certain Relationships and Related Person Transactions—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 LLC, 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 LLC, we will control and operate Rani LLC. On that basis, we believe that our interest in Rani LLC 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 LLC, our interest in Rani LLC could be deemed an "investment security" for purposes of the 1940 Act.

We and Rani LLC 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 so after the completion of this offering 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 after completion of this offering. 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 LLC as well as allocations of expenses based upon Rani LLC'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.

Immediately following the completion of this offering and the application of net proceeds from this offering, certain of the Continuing LLC Owners will control approximately 94.0% 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. See the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement."

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 with those stockholders who held our voting units prior to the completion of this offering, including our executive officers, employees and directors and their affiliates, 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, which is the stock we are offering in this offering, has one vote per share and Class C common stock has no voting rights, except as required by law. Upon the completion of this offering, holders of our outstanding Class A common stock will collectively hold approximately 6.0% of the voting power of our outstanding capital stock, holders of our outstanding Class B common stock will collectively hold approximately 94.0% of the voting power of our outstanding capital stock. No shares of Class C common stock will be outstanding upon the completion of this offering. Because of the 10-to-one voting ratio between our Class B common stock and Class A common stock, after the completion of this offering, the holders of our Class B common stock will collectively continue to control a majority of the combined voting power of our capital stock and therefore be 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 yours and may vote in a way with which you disagree and which may be adverse to your 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. For a description of the multi-class structure, see the section titled "Description of Capital Stock."

Risks Related to This Offering and Ownership of Our Class A Common Stock

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our Class A common stock.

Prior to this offering there has been no market for shares of our Class A common stock, Class B common stock or Class C common stock. Although our Class A common stock has been approved for listing on Nasdaq, an active trading market for our shares may never develop or be sustained following the completion of this offering. The initial public offering price for our Class A common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our Class A common stock after this offering. This initial public offering price may vary from the market price of our Class A common stock after the offering. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. 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 existing investors (including any shares purchased in this offering), who will be subject to lock-up agreements expiring 180 days from the date of this prospectus (except that the lock-up will not apply to any shares purchased in this offering and will include other exemptions). As a result of these and other factors, you may be unable to resell your 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 prospectus, 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 Takeda, Novartis, CCHN or 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 expected 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 this offering, Mir Imran will beneficially own approximately 80.4% 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.

You will experience immediate and substantial dilution in the net tangible book value of the shares of Class A common stock you purchase in this offering.

The initial public offering price of our Class A common stock is substantially higher than the pro forma net tangible book value per share of our Class A common stock immediately after this offering. If you purchase shares of our Class A common stock in this offering, you will suffer immediate dilution of $8.24 per share, or $8.10 per share if the underwriters exercise in full their option to purchase additional shares of Class A common stock, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to the sale of Class A common stock in this offering. To the extent outstanding warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

We will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.

We will have broad discretion over the use of the net proceeds from this offering. Investors may not agree with our decisions, and our use of the net proceeds may not yield any return on your investment. We currently intend to use the net proceeds from this offering to (i) advance our internal pipeline, (ii) advance manufacturing scale-up and automation, (iii) repay the outstanding PPP Loan with Comerica Bank, (iv) advance research and development programs, and the remainder will be used for working capital and general corporate purposes. Our failure to apply the net proceeds from this offering effectively could impair our ability to pursue our growth strategy or could require us to raise additional capital. In addition, pending their use, the net proceeds of this offering may be placed in investments that do not produce income or that may lose value. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 following the closing of this offering, 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.

Based on shares of Class A common stock outstanding as of March 31, 2021, upon the closing of this offering, we will have outstanding a total of 18,738,682 shares of Class A common stock. Of these shares, only the shares of Class A common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following the completion of this offering.

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 the date of this prospectus, 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 as described in the section of this prospectus titled "Shares Eligible for Future 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.

After this offering, Continuing LLC Owners will be 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 after this offering and will be able to exert significant control over matters subject to stockholder approval and may prevent new investors from influencing significant corporate decisions.

As of June 30, 2021, our named executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 79.3% of our stock and, upon the closing of this offering, that same group will hold approximately 78.7% of our outstanding stock, representing approximately 85.4% of our voting power. Therefore, even after this offering these stockholders will 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.

Upon closing of this offering, new public investors will own approximately 2.1% of the combined voting power of our common stock. Existing 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. Some of these persons or entities may have interests different than those of investors purchasing shares in this offering. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from 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, investors 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 will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

We will 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 will need to devote 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 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 will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. 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. See the

section of this prospectus titled "Description of Capital Stock—Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws" for additional information.

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 result of being 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 will be 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 will need 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 your ability to sell or purchase our Class A common stock when you 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 following our initial public offering. 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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 prospectus 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;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;
- our expectations regarding the timing and consummation of the Organizational Transactions; and
- our anticipated use of the net proceeds from this offering.

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 prospectus and are subject to a number of risks, uncertainties, and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. 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 until after we distribute this prospectus, 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 prospectus, 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.

MARKET, INDUSTRY, AND OTHER DATA

This prospectus contains estimates, projections, and other information concerning our industry, our business, and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the market, industry, and other data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. All of the market, industry, and other data used in this prospectus involves a number of assumptions and limitations. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the information from these industry research, publications, surveys and studies is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate, based on the initial public offering price of $11.00 per share of our Class A common stock, we will receive net proceeds from this offering of approximately $64.1 million (or $74.3 million if the underwriters exercise in full their option to purchase additional shares of Class A common stock), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use all of the net proceeds to us from this offering to purchase 6,666,667 newly issued LLC Interests (or 7,666,667 LLC Interests if the underwriters exercise in full their option to purchase additional shares of Class A common stock) directly from Rani LLC at a purchase price per LLC Interest equal to the initial public offering price per share of Class A common stock less the underwriting discounts and commissions.

We intend to cause Rani LLC to use such proceeds (together with any additional proceeds it may receive if the underwriters exercise their option to purchase additional shares of Class A common stock), after deducting estimated offering expenses, together with our existing cash and cash equivalents, as follows:

(i) approximately $45.0 million to $55.0 million to advance our internal pipeline;

(ii) approximately $25.0 million to $35.0 million to advance manufacturing scale-up and automation;

(iii) approximately $1.3 million to repay the outstanding PPP Loan with Comerica Bank, which has a fixed interest rate of 1.0% and a maturity date two years from the April 13, 2020 date of the note; and

(iv) use the remaining proceeds for working capital and other general corporate purposes.

We believe, based on our current operating plan, our existing cash and cash equivalents as of June 30, 2021, together with the net proceeds from this offering, will be sufficient to fund our operations for at least the next 12 months. We believe that the net proceeds from this offering will allow us to initiate our planned clinical development to the end of 2023, which includes initiating a repeat dose platform study for RT-101 and initiating Phase 1 clinical trials for RT-105, RT-102, RT-109 and RT-110.

We will need to raise additional capital from equity offerings or debt financings, collaboration agreements, or other arrangements with other companies, or through other sources of financing to fund regulatory approval and commercialization of our product candidates.

Our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above.

As of the date of this prospectus, since we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, our management will have broad discretion over the use of any net proceeds from this offering that are to be applied for general corporate purposes. Pending the use of the proceeds from this offering, we intend to invest the net proceeds in short-term, interest-bearing, investment grade securities, certificates of deposit or governmental securities.

DIVIDEND POLICY

We do not anticipate declaring or paying any cash dividends to holders of our Class A common stock in the foreseeable future. We currently intend to retain future earnings, if any, to finance the growth of our business. If we decide to pay cash dividends in the future, the declaration and payment of such dividends will be at the sole discretion of our board of directors and may be discontinued at any time. Holders of our Class B common stock are not entitled to participate in any dividends declared by our board of directors. In determining the amount of any future dividends, our board of directors will take into account any legal or contractual limitations, our actual and anticipated future earnings, cash flow, debt service and capital requirements and other factors that our board of directors may deem relevant.

Upon the completion of this offering, Rani Holdings will be a holding company and will have no material assets other than its ownership of LLC Interests. Accordingly, we will depend on distributions from Rani LLC to pay our taxes and expenses, including payments under the Tax Receivable Agreement. The limited liability company agreement of Rani LLC that will be in effect at the closing of this offering provides that certain distributions intended to cover the taxes of Rani LLC's owners will be made based upon assumed tax rates and other assumptions provided in the Rani LLC Agreement. See the section titled "Certain Relationships and Related Person Transactions—Rani LLC Agreement." Additionally, in the event Rani Holdings declares any cash dividends, we intend to cause Rani LLC to make distributions to Rani Holdings in an amount sufficient to cover such cash dividends declared by us. If Rani LLC makes such distributions to Rani Holdings, the Continuing LLC Owners will also be entitled to receive the respective equivalent pro rata distributions in accordance with the percentages of their respective LLC Interests. See the section titled "Risk Factors—Risks Related to Our Organizational Structure." To the extent that the tax 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.

Rani LLC's ability to make such distributions may be subject to various limitations and restrictions. In addition, Rani LLC is generally prohibited under Delaware law from making a distribution to a member to the extent that, at the time of the distribution, after giving effect to the distribution, liabilities of Rani LLC (with certain exceptions) exceed the fair value of its assets. Rani LLC's subsidiary is generally subject to similar legal limitations on its ability to make distributions to Rani LLC.

ORGANIZATIONAL TRANSACTIONS

Existing Organization

Prior to the completion of this offering and the Organizational Transactions described below, the Former LLC Owners and the Continuing LLC Owners were the only owners of Rani LLC. Rani LLC is treated as a partnership for U.S. federal income tax purposes and, as such, generally is not subject to any U.S. federal entity-level income taxes (with the exception of its subsidiary, which is subject to entity-level income taxes). Rather, taxable income or loss is included in the U.S. federal income tax returns of Rani LLC's members.

Rani Holdings was incorporated as a Delaware corporation on April 6, 2021 and is the issuer of the Class A common stock being offered in this offering.

Organizational Transactions

In connection with the closing of this offering, we will consummate the following organizational transactions, which we refer to as the "Organizational Transactions":

- we will amend and restate the Rani LLC Agreement to, among other things, appoint Rani Holdings as the sole managing member of Rani LLC and effectuate a recapitalization of all outstanding (i) convertible preferred, automatic or net exercised warrants to purchase preferred units, and common units into a single class of economic nonvoting Class A units and an equal number of voting noneconomic Class B units of Rani LLC and (ii) Profits Interests into a single class of economic nonvoting Class A units of Rani LLC based on an exchange ratio to be calculated based off of the initial public offering price of Rani Holdings Class A common stock. We will otherwise operate as a holding company. Rani Holdings will include Rani LLC in its consolidated financial statements;

- we have amended and restated Rani Holdings' certificate of incorporation to, among other things, provide for Class A common stock, each share of which entitles its holders to one vote per share, Class B common stock, each share of which entitles its holders to 10 votes per share on all matters presented to Rani Holdings' stockholders, and Class C common stock, will have no voting rights, except as otherwise required by law;

- generally, we expect the majority of Profits Interests, other than those held by directors and officers, will be exchanged for Class A common stock of Rani Holdings on a one-for-one basis at the election of the holder;

- we expect to assume stock options to purchase an aggregate of 1,210,981 shares of Class A common stock with an exercise price set at $9.45 per share;

- generally, the Former LLC Owners will exchange their LLC Interests for shares of Class A common stock, representing (i) approximately 3.88% of the combined voting power of all of Rani Holdings' common stock (or approximately 3.86%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and (ii) approximately 64.4% of the economic interest in Rani Holdings (or approximately 61.2%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- the Continuing LLC Owners will continue to own the LLC Interests they receive in exchange for their outstanding common units in Rani LLC, representing approximately 62.2% of the economic interest in the business of Rani LLC and its subsidiary (or approximately 61.0%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock), and

Continuing LLC Owners who received voting noneconomic Class B units in the recapitalization will contribute those Class B units to Rani Holdings in exchange for a corresponding number of shares of Class B common stock, each share of which entitles its holder to 10 votes per share;

- the LLC Interests, following the completion of this offering, will be redeemable, at the Continuing LLC Owners' election, for newly issued shares of Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications) in accordance with the terms of the Rani LLC Agreement; 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 Class A common stock for each LLC Interest redeemed in accordance with the terms of the Rani LLC Agreement. Shares of Class B common stock will be cancelled on a one-for-one basis if we, at the election of the Continuing LLC Owners that hold Class B common stock, redeem or exchange such holders' LLC Interests pursuant to the terms of the Rani LLC Agreement;

- Rani Holdings will enter into (i) the Tax Receivable Agreement, with certain of the Continuing LLC Owners, and (ii) a registration rights agreement, or the Registration Rights Agreement, with certain of the Continuing LLC Owners;

- Rani Holdings will issue 6,666,667 shares of Class A common stock to the purchasers in this offering (or 7,666,667 shares of our Class A common stock if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- Rani Holdings will use all of the net proceeds from this offering (including any net proceeds received upon exercise of the underwriters' option to purchase additional shares of Class A common stock) to acquire newly issued LLC Interests from Rani LLC at a purchase price per interest equal to the initial public offering price per share of Class A common stock, less underwriting discounts and commissions, collectively representing 13.5% of Rani LLC's outstanding LLC Interests (or 15.2%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock). Following the completion of this offering, Rani Holdings will hold a number of LLC Interests that is equal to the number of shares of Class A common stock that it has issued, a relationship that we believe fosters transparency because it results in a single share of Class A common stock representing the same percentage ownership in Rani LLC as a single unit of LLC Interests; and

- Rani LLC will use the proceeds from the sale of LLC Interests to Rani Holdings as described in the section titled "Use of Proceeds."

Organizational Structure Following This Offering

Immediately following the completion of the Organizational Transactions, including this offering:

- Rani Holdings will be a holding company and the principal asset of Rani Holdings will be our interests in Rani LLC;

- Rani Holdings will be the sole managing member of Rani LLC and will control the business and affairs of Rani LLC and its subsidiary;

- Rani Holdings' amended and restated certificate of incorporation requires and the Rani LLC Agreement will require that we and Rani LLC at all times maintain a one-to-one ratio between the number of shares of Class A common stock issued by us and the number of LLC Interests owned by us, as well as a one-to-one ratio between the number of shares of Class B common stock owned by certain of the Continuing LLC Owners and the number of LLC Interests owned by such Continuing LLC Owners;

- Rani Holdings will own LLC Interests representing 37.8% of the economic interest in Rani LLC (or 39.0%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- the purchasers in this offering (i) will own 6,666,667 shares of Class A common stock, representing approximately 2.1% of the combined voting power of all of Rani Holdings common stock (or 7,666,667 shares of Class A common stock, representing approximately 2.5%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock), (ii) will own 35.6% of the economic interest in Rani Holdings (or 38.8%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and (iii) through Rani Holdings ownership of LLC Interests, indirectly will hold (applying the percentages in the preceding clause (ii) to Rani Holdings percentage economic interest in Rani LLC) approximately 13.5% of the economic interest in Rani LLC (or 15.2% if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- the Former LLC Owners (i) will own 12,072,015 shares of Class A common stock, representing approximately 3.88% of the combined voting power of all of Rani Holdings common stock (or approximately 3.86%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock), (ii) will own 64.4% of the economic interest in Rani Holdings (or 61.2%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and (iii) through Rani Holdings ownership of LLC Interests, indirectly will hold (applying the percentages in the preceding clause (ii) to Rani Holdings percentage economic interest in Rani LLC) approximately 24.4% of the economic interest in Rani LLC (or 23.9%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock);

- the Continuing LLC Owners will own (i) through their ownership of Class B common stock, if relevant, approximately 94.0% of the voting power in Rani Holdings (or approximately 93.7%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and (ii) LLC Interests, representing 62.2% of the economic interest in Rani LLC (or 61.0%, if the underwriters exercise in full their option to purchase additional shares of Class A common stock). Following the completion of the offering, each LLC Interest held by the Continuing LLC Owners will be redeemable, at their election (subject to the terms of the Rani LLC Agreement), for newly issued shares of Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications) in accordance with the terms of the Rani LLC Agreement; provided that, at Rani Holdings election, Rani Holdings may effect a direct exchange of such Class A common stock or a cash payment equal to a volume weighted average market price of one share of Class A common stock for each LLC Interest redeemed in accordance with the terms of the Rani LLC Agreement. Shares of Class B common stock will be cancelled on a one-for-one basis if we, at the election of the Continuing LLC Owners, redeem or exchange its LLC Interests pursuant to the terms of the Rani LLC Agreement. See the section titled “Certain Relationships and Related Person Transactions—Rani LLC Agreement;” and

- Rani Holdings will enter into (i) the Tax Receivable Agreement with certain of the Continuing LLC Owners and (ii) the Registration Rights Agreement with certain of the Continuing LLC Owners.

Our corporate structure following the completion of this offering, as described below, is commonly referred to as an umbrella partnership-C-corporation, or Up-C, structure, which is often used by partnerships and limited liability companies when they undertake an initial public offering of their business. The Up-C structure will allow the Continuing LLC Owners to retain their equity ownership in Rani LLC and to continue to realize tax benefits associated with owning interests in an entity that is treated as a partnership, or “passthrough” entity, for U.S. federal income tax purposes following the completion of the offering. Investors in this offering will, by contrast, hold their equity ownership in Rani Holdings, a Delaware corporation that is a domestic corporation for

U.S. federal income tax purposes, in the form of shares of Class A common stock. The Former LLC Owners will hold their equity ownership in Rani Holdings in the form of shares of Class A common stock. The Continuing LLC Owners will hold LLC Interests and, in the case of Continuing LLC Owners other than Continuing LLC Owners who are legacy holders of Profits Interests who do not exchange their LLC Interests for shares of our Class A common stock in connection with the completion of this offering, an equal number of shares of Class B common stock in Rani Holdings. One of the tax benefits to the Continuing LLC Owners associated with this structure is that future taxable income of Rani LLC that is allocated to the Continuing LLC Owners will be taxed on a flow-through basis and therefore will not be subject to corporate taxes at the entity level. Additionally, the Continuing LLC Owners may redeem or exchange their LLC Interests for newly issued shares of our Class A common stock on a one-for-one basis or, at our option, for cash. The Up-C structure also provides the Continuing LLC Owners with potential liquidity that holders of non-publicly traded limited liability companies are not typically afforded. If we generate sufficient taxable income, Rani Holdings expects to benefit from the Up-C structure because, in general, we expect cash tax savings in amounts equal to 15% of the tax benefits, as described above, arising from such redemptions or exchanges of the Continuing Owners' LLC Interests for Class A Common Stock or cash and certain other tax benefits covered by the Tax Receivable Agreement discussed in the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement." See the section titled "Risk Factors —Risks Related to Our Organizational Structure."

Immediately following the completion of this offering and the application of net proceeds therefrom, Rani Holdings will be a holding company and our principal asset will be the noneconomic voting Class B common units and the LLC Interests we purchase from Rani LLC and acquire from the Former LLC Owners. As a result, Rani Holdings will have no independent means of generating revenue. As the sole managing member of Rani LLC, Rani Holdings will operate and control all of the business and affairs of Rani LLC and, through Rani LLC and its subsidiary, conduct our business. Accordingly, we will have the sole voting interest in, and control the management of, Rani LLC. As a result, Rani Holdings will consolidate Rani LLC in our consolidated financial statements and will report a non-controlling interest related to the LLC Interests held by the Continuing LLC Owners on our consolidated financial statements. Rani Holdings will have a board of directors and executive officers and employees.

Rani LLC will be treated as a partnership for U.S. federal income tax purposes and, as such, will generally not be subject to U.S. federal income tax. Instead, taxable income will be allocated to holders of LLC Interests, including Rani Holdings. Accordingly, Rani Holdings will incur income taxes on its allocable share of any net taxable income of Rani LLC. Pursuant to the Rani LLC Agreement, Rani LLC will make cash distributions to the owners of LLC Interests in an amount sufficient to fund their tax obligations in respect of the cumulative taxable income in excess of cumulative taxable losses of Rani LLC that is allocated to them, to the extent previous tax distributions from Rani LLC have been insufficient. In addition to tax expenses, Rani Holdings also will incur expenses related to its operations, plus payments under the Tax Receivable Agreement, which Rani Holdings expects will be significant. Rani Holdings intends to cause Rani LLC to make distributions or, in the case of certain expenses, payments in an amount sufficient to allow Rani Holdings to pay its taxes and operating expenses, including distributions to fund any ordinary course payments due under the Tax Receivable Agreement.

As the sole managing member of Rani LLC, Rani Holdings will have the right to determine when distributions will be made to the holders of LLC Interests in Rani LLC and the amount of any such distributions (subject to the requirements with respect to the tax distributions described above). If Rani Holdings authorizes a distribution, such distribution will be made to the holders of LLC Interests, including Rani Holdings, pro rata in accordance with their respective ownership of Rani LLC, provided that Rani Holdings as sole managing member will be entitled to non-pro rata distributions for certain fees and expenses.

As noted above, certain of the Continuing LLC Owners will also hold a number of shares of our Class B common stock initially equal to the number of LLC Interests held by such person. Although these shares have no economic rights, they will allow such Continuing LLC Owners to directly exercise voting power at Rani Holdings, the sole managing member of Rani LLC. Under Rani Holdings' amended and restated certificate of incorporation, each share of Class B common stock will be entitled to 10 votes per share.

The Rani LLC Agreement will provide that as a general matter a Continuing LLC Owner will not have the right to exchange LLC Interests if Rani Holdings determines that such exchange would be prohibited by law or regulation or would violate other agreements with us to which the Continuing LLC Owner may be subject, including the Rani LLC Agreement. Additionally, the Rani LLC Agreement contains restrictions on redemptions and exchanges intended to prevent Rani LLC from being treated as a "publicly traded partnership" for U.S. federal income tax purposes. These restrictions are modeled on certain safe harbors provided for under applicable U.S. federal income tax law. Rani Holdings may impose additional restrictions on exchange that Rani Holdings determines to be necessary or advisable so that Rani LLC is not treated as a "publicly traded partnership" for U.S. federal income tax purposes. As a holder redeems or exchanges LLC Interests, the number of LLC Interests held by Rani Holdings is correspondingly increased, and if the redeeming or exchanging Continuing LLC Owner holds Class B common stock, a corresponding number of such shares of Class B common stock are cancelled. See the section titled "Certain Relationships and Related Person Transactions—Rani LLC Agreement."

Following This Offering

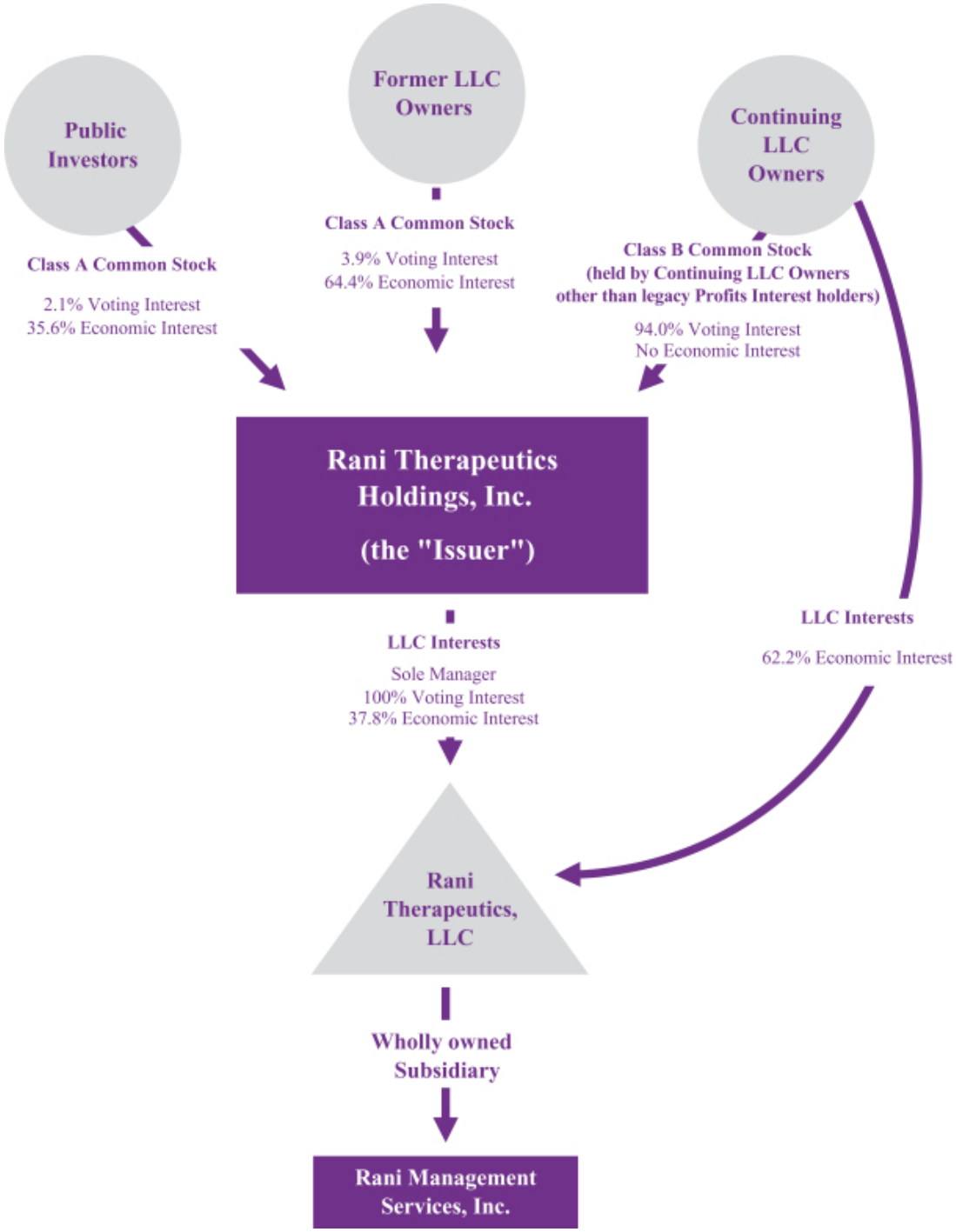
The Continuing LLC Owners of Rani LLC, from time to time following the completion of this offering, may, subject to the terms of the Rani LLC Agreement, exchange their LLC Interests for common stock on a one to one basis in accordance with the terms of the Rani LLC Agreement, and if the redeeming or exchanging Continuing LLC Owner holds Class B common stock, a corresponding number of such shares of Class B common stock will be cancelled; 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 Class A common stock for each LLC Interest redeemed in accordance with the terms of the Rani LLC Agreement. Any shares of Class B common stock will be cancelled on a one-for-one basis if we, 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 are expected to 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.

Rani Holdings will enter into a Tax Receivable Agreement with certain of the Continuing LLC Owners that will provide for the payment by Rani Holdings of 85% of the amount of the calculated tax savings, if any, that Rani Holdings realizes, or in some circumstances is deemed to realize, as a result of this existing and increased tax basis and certain other tax benefits related to it entering into the Tax Receivable Agreement, including tax benefits attributable to payments under the Tax Receivable Agreement. These payment obligations are obligations of Rani Holdings and not of Rani LLC. See the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement" for additional information.

Rani Holdings may accumulate cash balances in future years resulting from distributions from Rani LLC exceeding its tax or other liabilities. To the extent Rani Holdings does not use such cash balances to pay a dividend on or repurchase shares of Class A common stock and instead decides to hold or recontribute such cash balances to Rani LLC for use in its operations, Continuing LLC Owners who exchange LLC Interests and, if applicable, shares of Class B common stock for shares of Class A common stock in the future could also benefit from any value attributable to such accumulated cash balances.

See the section titled "Description of Capital Stock" for more information about our amended and restated certificate of incorporation and the terms of the Class A common stock, Class B common stock and Class C common stock. See the section titled "Certain Relationships and Related Person Transactions" for more information about (i) the Rani LLC Agreement, including the terms of the LLC Interests and the redemption right of the Continuing LLC Owners; (ii) the Tax Receivable Agreement; and (iii) the Registration Rights Agreement. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Source of Liquidity" for more information about expected payments under the Tax Receivable Agreement.

The diagram below depicts our organizational structure after giving effect to the Organizational Transactions, including this offering, assuming no exercise by the underwriters of their option to purchase additional shares of Class A common stock:


Public Investors
Class A Common Stock
2.1% Voting Interest
35.6% Economic Interest
Former LLC Owners
Class A Common Stock
3.9% Voting Interest
64.4% Economic Interest
Continuing LLC Owners
Class B Common Stock
(held by Continuing LLC Owners other than legacy Profits Interest holders)
94.0% Voting Interest
No Economic Interest
Rani Therapeutics Holdings, Inc.
(the "Issuer")
LLC Interests
Sole Manager
100% Voting Interest
37.8% Economic Interest
LLC Interests
62.2% Economic Interest
Rani Therapeutics, LLC
Wholly owned Subsidiary
Rani Management Services, Inc.

CAPITALIZATION

The following table sets forth the cash and cash equivalents and consolidated capitalization as of March 31, 2021:

- of Rani LLC and its subsidiary on an actual basis; and
- of Rani Holdings on a pro forma basis, after giving effect to:
  - the conversion and exchange of all outstanding units of our convertible preferred units as of March 31, 2021 into 14,733,226 shares of a single class of economic nonvoting Class A units and an equal number of voting noneconomic Class B units and the related reclassification of the carrying value of our convertible preferred units converted to our common units as permanent equity;
  - the repayment in full of our outstanding PPP Loan with Comerica Bank which, as of March 31, 2021, had an outstanding principal balance of $1.3 million;
  - the Organizational Transactions, including our issuance and sale of 6,666,667 shares of Class A common stock in this offering after (x) deducting the underwriting discounts and commissions and estimated offering expenses payable by us and (y) the application of the proceeds from the offering, each as described under “Use of Proceeds”; and
  - the issuance of 177,471 shares of Class A common stock issuable upon the exchange of outstanding LLC Interests by Continuing LLC Owners and Former LLC Owners related to the automatic conversion or net exercise of warrants to purchase exchanged units of Rani LLC, based on the initial public offering price of $11.00 per share.

You should read this information together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth in the sections titled “Prospectus Summary—Summary Consolidated Historical and Pro Forma Financial Data,” “Organizational Transactions,” “Use of Proceeds,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

(in thousands, except share and unit amounts and par value)	As of March 31, 2021		
	Historical Rani LLC	Pro Forma for the Organizational Transactions (1)	Pro Forma As Adjusted for the Organizational Transactions and the Offering
		(unaudited)	
Cash and cash equivalents	$ 76,662	$ 76,662	$ 139,150
Long-term debt	$ 1,892	$ 1,892	$ 1,822
Convertible preferred units, 32,620,000 units authorized, issued and 27,629,804 outstanding actual; no units authorized, issued or outstanding pro forma or pro as forma adjusted	191,034	—	—
Member's deficit / stockholders' equity:			
Common units, 101,000,000 units authorized and 46,896,280 units issued and outstanding; no units authorized, issued or outstanding pro forma or pro as forma adjusted	1,130	—	—
Preferred stock, $0.0001 par value per share, no shares authorized, issued or outstanding, on an actual basis; 20,000,000 shares authorized; no shares issued and outstanding, on a pro forma basis; 20,000,000 shares authorized; no shares issued and outstanding, on a pro forma as adjusted basis	—	—	—
Class A common stock, $0.0001 par value per share, no shares authorized, issued or outstanding, on an actual basis; 800,000,000 shares authorized, 12,072,015 shares issued and outstanding, on a pro forma basis; 800,000,000 shares authorized; 18,738,682 shares issued and outstanding, on a pro forma as adjusted basis	—	5	5
Class B common stock, $0.0001 par value per share, no shares authorized, issued or outstanding, on an actual basis; 40,000,000 shares authorized; 29,269,540 shares issued and outstanding, on a pro forma basis; 40,000,000 shares authorized; 29,269,540 shares issued and outstanding, on a pro forma as adjusted basis	—	3	3
Class C common stock, $0.0001 par value per share, no shares authorized, issued or outstanding, on an actual basis; 20,000,000 shares authorized; no shares issued and outstanding, on a pro forma basis; 20,000,000 shares authorized; no shares issued and outstanding, on a pro forma as adjusted basis	—	—	—
Additional paid-in-capital	—	147,236	176,675
Accumulated deficit	(119,601)	(119,601)	(125,044)
Non-controlling interest(1)	—	45,456	84,912
Total members' (deficit)/stockholders' equity	(118,471)	73,099	136,551
Total capitalization	$ 74,445	$ 74,991	$ 138,373

(1) On a pro forma as adjusted basis, includes the Rani LLC interests not owned by us, which represents 62.2% of Rani LLC's LLC Interests. The Continuing LLC Owners will hold the non-controlling economic interest in Rani LLC. Rani Holdings will hold 37.8% of the economic interest in Rani LLC.

The number of shares of Class A common stock to be outstanding after this offering is based on the units of Rani LLC outstanding as of March 31, 2021 and excludes:

- 500,000 shares of Class A common stock, plus future increases, reserved for issuance under the ESPP, which became effective upon the execution of the underwriting agreement for this offering;

- 5,500,000 shares of Class A common stock reserved for future issuance under our 2021 Plan which became effective upon the execution of the underwriting agreement for this offering;
- 30,813,262 shares of Class A common stock issuable upon the exchange or redemption of outstanding LLC Interests; and
- 1,210,981 stock options to purchase shares of Class A common stock granted to certain of our employees, executive officers and directors based on awards assumed from Rani LLC with an exercise price of $9.45 per share.

DILUTION

The Continuing LLC Owners will maintain their LLC Interests in Rani LLC after the Organizational Transactions. Because the Continuing LLC Owners do not own any Class A common stock or have any right to receive distributions from Rani Holdings, we have presented dilution in pro forma net tangible book value per share after this offering assuming the Continuing LLC Owners had their LLC Interests redeemed or exchanged for newly issued shares of Class A common stock on a one-for-one basis (rather than for cash), and the cancellation for no consideration of all of its shares of Class B common stock (which are not entitled to distributions from Rani Holdings), in order to more meaningfully present the dilutive impact on the investors in this offering. We refer to the assumed redemption or exchange of all LLC Interests owned by the Continuing LLC Owners for shares of Class A common stock as described in the previous sentence as the "Assumed Redemption." We also note that the effect of the Assumed Redemption is to increase the assumed number of shares of Class A common stock outstanding before the offering, thereby decreasing the pro forma net tangible book value per share before the offering and correspondingly increasing the dilution per share to new Class A common stock investors.

Dilution is the amount by which the offering price paid by the purchasers of the Class A common stock in this offering exceeds the pro forma net tangible book value per share of Class A common stock after the offering. Pro forma net tangible book value is determined at any date by subtracting our total liabilities from the total book value of our tangible assets, after giving effect to the Organizational Transactions and the Assumed Redemption. Net tangible book value per share is determined at any date by subtracting our total liabilities from the total book value of our tangible assets and dividing the difference by the number of shares of Class A common stock deemed to be outstanding at that date, after giving effect to the Organizational Transactions and the Assumed Redemption. Rani LLC's pro forma net tangible book value as of March 31, 2021 was $72.3 million or $1.69 per share of Class A common stock.

If you invest in our Class A common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma net tangible book value per share of our Class A common stock after this offering.

Pro forma as adjusted net tangible book value per share is determined at any date by subtracting our total liabilities from the total book value of our tangible assets and dividing the difference by the number of shares of Class A common stock, after giving effect to the Organizational Transactions, including this offering, and the Assumed Redemption. Our pro forma as adjusted net tangible book value as of March 31, 2021 would have been $136.6 million, or $2.76 per share of Class A common stock. This amount represents an immediate increase in pro forma net tangible book value of $1.07 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of $8.24 per share to new investors purchasing shares of Class A common stock in this offering. We determine dilution by subtracting the pro forma net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of Class A common stock. The following table illustrates this dilution:

Initial public offering price per share		$11.00
Pro forma net tangible book value per share as of March 31, 2021(1)(2)	$1.69	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common shares in this offering	1.07	
Pro forma as adjusted net tangible book value per share after this offering		2.76
Dilution per share to new investors purchasing shares of Class A common stock in this offering		$ 8.24

(1) The computation of pro forma net tangible book value per share as of March 31, 2021 before this offering and after the Assumed Redemption is set forth below (in thousands except per share data):

Numerator:	
Book value of tangible assets	$ 81,292
Less: total liabilities	(8,978)
Pro forma net tangible book value[(a)]	$ 72,314
Denominator:	
Shares of Class A common stock outstanding immediately prior to this offering and after giving effect to the Organizational Transactions and the Assumed Redemption	42,885,277
Pro forma net tangible book value per share	$ 1.69

(a) Gives pro forma effect to the Organizational Transactions (other than this offering) and the Assumed Redemption.

(2) The computation of pro forma net tangible book value per share as of March 31, 2021 before this offering and before the Assumed Redemption is set forth below:

Numerator:	
Book value of tangible assets	$ 81,292
Less: total liabilities	(8,978)
Pro forma net tangible book value[(a)]	$ 72,314
Denominator:	
Shares of Class A common stock outstanding immediately prior to this offering and after giving effect to the Organizational Transactions but prior to any Assumed Redemption	12,072,015
Pro forma net tangible book value per share	$ 5.99

(a) Gives pro forma effect to the Organizational Transactions (other than this offering) and excludes the Assumed Redemption.

If the underwriters exercise in full their option to purchase additional shares of our Class A common stock in this offering, the pro forma as adjusted net tangible book value after the offering would be $2.90 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $1.21 and the dilution per share to new investors would be $8.10 per share.

The following table summarizes, as of March 31, 2021 after giving effect to this offering, the Organizational Transactions and the differences between the Continuing LLC Owners and Former LLC Owners and new investors in this offering with regard to:

- the number of shares of Class A common stock purchased from us by investors in this offering and the number of shares issued to the Continuing LLC Owners and Former LLC Owners after giving effect to the Assumed Redemption,
- the total consideration paid to us in cash by investors purchasing shares of Class A common stock in this offering and by the Continuing LLC Owners and Former LLC Owners, and
- the average price per share of Class A common stock that such Continuing LLC Owners and Former LLC Owners and new investors paid.

The table below is based on the initial public offering price of $11.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares of Class A Common Stock Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Continuing and Former LLC Owners	42,885,277	86.5	$191,591,786	72.3%	$ 4.47
New investors in this offering	6,666,667	13.5	73,333,337	27.7%	11.00
Total	49,551,944	100.0%	$264,925,123	100.0%	

Except as otherwise indicated, the discussion and the tables above assume no exercise of the underwriters' option to purchase additional shares of Class A common stock. The number of shares of our Class A common stock outstanding after this offering as shown in the tables above is based on the units of Rani LLC outstanding as of March 31, 2021, and excludes:

- 500,000 shares of Class A common stock, plus future increases, reserved for issuance under the ESPP, which became effective upon the execution of the underwriting agreement for this offering;
- 5,500,000 shares of Class A common stock reserved for future issuance under the 2021 Plan, which became effective upon the execution of the underwriting agreement for this offering; and
- 1,210,981 stock options to purchase shares of Class A common stock granted to certain of our employees, executive officers and directors based on awards assumed from Rani LLC with an exercise price of $9.45 per share.

To the extent that any outstanding warrants are exercised or other equity awards are issued under our equity incentive plans, or we issue additional equity or convertible debt securities in the future, there will be further dilution to new investors participating in this offering.

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED FINANCIAL INFORMATION

The unaudited pro forma condensed consolidated balance sheet as of March 31, 2021 and the unaudited pro forma condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2021 and the year ended December 31, 2020 present our consolidated financial position and results of operations after giving pro forma effect to:

(1) The Organizational Transactions described under the section titled "Organizational Structure," as if such transactions occurred on March 31, 2021 for the unaudited pro forma condensed consolidated balance sheet and on January 1, 2020 for the unaudited pro forma condensed consolidated statements of operations and comprehensive loss;

(2) The effects of the Tax Receivable Agreement, as described under the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement;" and

(3) This offering and the application of the estimated net proceeds from this offering as described under the section titled "Use of Proceeds."

Our historical consolidated financial information has been derived from the consolidated financial statements of Rani LLC and its subsidiary and accompanying notes to the consolidated financial statements included elsewhere in this prospectus. Rani Holdings was incorporated on April 6, 2021 and has no material assets or results of operations until the completion of this offering. Therefore, its historical financial information is not included in the unaudited pro forma condensed consolidated financial information.

The unaudited pro forma condensed consolidated financial information has been prepared on the basis that we will be taxed as a corporation for U.S. federal and state income tax purposes and, accordingly, will become a taxpaying entity subject to U.S. federal, state and foreign income taxes. The unaudited pro forma condensed consolidated financial information were prepared in accordance with Article 11 of SEC Regulation S-X as amended by the final rule, Release No. 33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses." Release No. 33-10786 replaces the existing pro forma adjustment criteria with simplified requirements to depict the Organizational Transactions and present the reasonably estimable transaction effects that have occurred or reasonably expected to occur. See the accompanying notes to the Unaudited Pro Forma Condensed Consolidated Financial Information for a discussion of assumptions made.

The unaudited pro forma condensed consolidated financial information is not necessarily indicative of financial results that would have been attained had the described transactions occurred on the dates indicated above or that could be achieved in the future. The unaudited pro forma condensed consolidated financial information also does not give effect to the potential impact of any anticipated synergies, operating efficiencies or cost savings that may result from the transactions or any integration costs that result from the Organizational Transactions or any costs that do not have a continuing impact. Future results may vary significantly from the results reflected in the unaudited pro forma condensed consolidated statements of operations and comprehensive loss and should not be relied on as an indication of our results after the consummation of this offering and the other transactions contemplated by such unaudited pro forma condensed consolidated financial information. However, our management believes that the assumptions provide a reasonable basis for presenting the significant effects of the transactions as contemplated and that the pro forma adjustments give appropriate effect to those assumptions and are properly applied in the unaudited pro forma condensed consolidated financial information.

As a public company, we will be implementing additional procedures and processes for the purpose of addressing the standards and requirements applicable to public companies. We expect to incur additional annual expenses related to these steps and, among other things, additional directors' and officers' liability insurance,

director fees, costs to comply with the reporting requirements of the SEC, transfer agent fees, hiring of additional accounting, legal and administrative personnel, increased auditing and legal fees and similar expenses. We have not included any pro forma adjustments relating to these costs.

For purposes of the unaudited pro forma condensed consolidated financial information, we have assumed that we will issue 6,666,667 shares of Class A common stock at a price per share equal to $11.00, and, as a result, immediately following the completion of this offering, the ownership percentage represented by LLC Interests not held by us will be 62.2%, and the net loss attributable to LLC Interests not held by us will accordingly represent 62.2% of our net loss. Except as otherwise indicated, the unaudited pro forma condensed consolidated financial information presented assumes no exercise by the underwriters of their option to purchase additional shares of Class A common stock.

As described in greater detail under the section titled “Certain Relationships and Related Person Transactions—Tax Receivable Agreement,” in connection with the consummation of this offering, we will enter into the Tax Receivable Agreement with Rani LLC and certain of the Continuing LLC Owners that will provide for the payment by Rani Holdings to such Continuing LLC Owners of 85% of the amount of tax benefits, if any, that Rani Holdings are 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 LLC Interests described above under “—The Offering—Redemption rights of holders 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. Actual tax benefits realized by Rani Holdings may differ from tax benefits calculated under the Tax Receivable Agreement as a result of the use of certain assumptions in the Tax Receivable Agreement, including the use of an assumed weighted-average state and local income tax rate to calculate tax benefits. This payment obligation is an obligation of Rani Holdings, but not of Rani LLC. See the section titled “Certain Relationships and Related Person Transactions—Tax Receivable Agreement.”

If we ever generate sufficient taxable income to utilize the tax benefits from the Organizational Transactions, we expect to benefit from the remaining 15% of cash savings, if any, that we realize. We do not expect to record a liability under the Tax Receivable agreement as result of the Organizational Transactions and the purchase of newly issued LLC Interests from Rani LLC with a portion of the net proceeds from this offering. This is because the purchase of the LLC Interests will not result in a taxable transaction and we currently expect to record a full valuation allowance against the deferred tax asset created through the purchase of the LLC Interests. Due to the uncertainty in the amount and timing of future redemptions or exchanges of LLC Interests by certain of the Continuing LLC Owners and purchases of LLC Interests from certain of the Continuing LLC Owners, the unaudited pro forma condensed consolidated financial information assumes that no future redemptions or exchanges or purchases of LLC Interests have occurred and therefore no increases in tax basis in the Rani LLC assets or other tax benefits that may be realized thereunder have been assumed in the unaudited pro forma condensed consolidated financial information. However, if certain of the Continuing LLC Owners were to redeem or exchange or sell us all of their LLC Interests, we would recognize a deferred tax asset of approximately $120.7 million and a liability under the Tax Receivable Agreement of approximately $102.6 million, assuming: (i) all exchanges or purchases occurred on the same day; (ii) a constant corporate tax rate of 27.98%; (iii) that we will have sufficient taxable income to utilize the tax benefits and (iv) no material changes in tax law. For each 5% increase (decrease) in the amount of LLC Interests exchanged by or purchased from certain of the Continuing LLC Unitholders (or their transferees of LLC Interests or other assignees), our deferred tax asset would increase (decrease) by approximately $6.0 million and the related liability would increase (decrease) by approximately $5.1 million, assuming that the price per share of Class A common stock and corporate tax rate remain the same. These amounts are estimates and have been prepared for illustrative purposes only. The actual amount of deferred tax assets and liability under the Tax Receivable Agreement that we will recognize will differ based on, among other things, the timing of the exchanges and purchases, the price of our shares of Class A common stock at the time of the exchange or purchase, our ability to utilize the tax benefits from the Organizational Transactions, and the tax rates then in effect. The unaudited pro forma condensed consolidated financial information should be read together with the sections titled “Risk Factors,”

"Organizational Transactions," "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements of Rani LLC and related notes thereto as well as the interim unaudited condensed consolidated financial statements of Rani LLC and related notes thereto included elsewhere in this prospectus.

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED BALANCE SHEET

AS OF MARCH 31, 2021

(In thousands, except share and unit amounts)	Rani Therapeutics, LLC As Reported	Organizational Transactions		Rani Therapeutics Holdings, Inc. Pro Forma
Assets				
Current assets:				
Cash and cash equivalents	$ 76,662	$ 62,488	(1) (4) (7)	$ 139,150
Prepaid expenses	140	—		140
Total current assets	76,802	62,488		139,290
Deferred financing costs	785	(785)	(4)	—
Property and equipment, net	4,490	—		4,490
Total assets	$ 82,077	$ 61,703		$ 143,780
Liabilities, Redeemable Convertible Preferred Units and Members' Deficit/Stockholders' Equity				
Current liabilities:				
Accounts payable	943	—		943
Related party payable	346	—		346
Accrued expenses	1,890	(483)	(1)	1,407
Deferred revenue	1,961	—		1,961
Current portion of long-term debt	1,946	(1,196)	(7)	750
Total current liabilities	7,086	(1,679)		5,407
Long-term liabilities:				
Preferred unit warrant liability	536	(536)	(6)	—
Long-term debt, less current portion	1,892	(70)	(7)	1,822
Total liabilities	$ 9,514	$ (2,285)		$ 7,229
Commitments and contingencies				
Convertible preferred units, 32,620,000 units authorized and 27,629,804 units issued and outstanding	191,034	(191,034)	(5)	—
Members' Deficit/Stockholders' Equity:				
Common units, 101,000,000 units authorized and 46,896,280 units issued and outstanding	1,130	(1,130)	(5) (6)	—
Preferred stock, par value $0.0001 per share	—	—	(3)	—
Class A common stock, par value $0.0001 per share	—	5	(1) (6)	5
Class B common stock, par value $0.0001 per share	—	3	(2)	3
Class C common stock, par value $0.0001 per share, authorized and no shares issued and outstanding	—	—	(3)	—
Additional paid-in-capital	—	176,675	(4) (9) (10)	176,675
Accumulated deficit	(119,601)	(5,443)	(4) (8) (10)	(125,044)
Noncontrolling interest attributable to Rani Therapeutics, LLC members	—	84,912	(8)	84,912
Total members' (deficit) / stockholders' equity	(118,471)	255,022		136,551
Total liabilities, redeemable convertible preferred units, and members' (deficit) / stockholders' equity	$ 82,077	$ 61,703		$ 143,780

See Notes to the Unaudited Pro Forma Condensed Consolidated Financial Information

NOTES TO UNAUDITED PRO FORMA CONDENSED CONSOLIDATED BALANCE SHEET

(1) We estimate that the net proceeds to us from this offering will be approximately $64.1 million (or $74.3 million if the underwriters exercise in full their option to purchase additional shares of Class A common stock), based on the initial public offering price of $11.00 per share, after deducting $5.1 million of underwriting discounts and commissions (or $5.9 million if the underwriters exercise in full their option to purchase additional shares of Class A common stock) and $3.8 million of estimated, previously unpaid offering expenses, and $0.5 million of which were recorded in accrued expense as of March 31, 2021. We intend to use the net proceeds from this offering to (i) acquire newly issued LLC Interests, (ii) pay expenses incurred in connection with this offering. The remaining proceeds received from the sale of these shares will be used for general corporate purposes. For more information, see the section titled “Use of Proceeds.”

(2) Reflects the issuance of Class B common stock to LLC Interest holders in return for LLC Interests, on a one-to-one basis with the number of LLC Interests they own, as described in greater detail under “Organizational Transactions.”

(3) Reflects the authorization of our Class C common stock, which entitle the holder to zero votes per share, and with preferred stock, both of which will not be issued and outstanding at the closing of the offering, as described in greater detail under “Organizational Transactions.”

(4) We are deferring certain costs associated with this offering. These costs primarily represent legal, accounting and other costs directly associated with this offering and are recorded in other assets in our combined consolidated balance sheet. Upon completion of this offering, these deferred costs will be charged against the proceeds from this offering with a corresponding reduction to additional paid-in capital. Of the total $0.8 million of deferred offering costs, $0.3 million was paid as of March 31, 2021. After March 31, 2021, we incurred an additional $0.6 million of costs associated with this offering that were not eligible for capitalization. These costs were expensed as incurred and were recorded to accrued expenses and accumulated deficit.

(5) Reflects the conversion of all 74,526,084 outstanding convertible preferred and common units into a single class of economic nonvoting Class A common units and an equal number of voting noneconomic Class B common units of Rani LLC and the related reclassification of the carrying value of convertible preferred units converted to common units as permanent equity.

(6) Reflects the automatic conversion or net exercise of the convertible preferred and common units warrants into Class A common stock of Rani Holdings in connection with the Organizational Transactions.

(7) Represents the repayment of $1.3 million for the small business loan received in April 2020 under the Paycheck Protection Program (“PPP”) in connection with COVID-19 pandemic relief efforts, $0.1 million of which was recorded in long-term debt, net of current portion.

(8) As a result of the Organizational Transactions, the limited liability company agreement of Rani LLC has been amended and restated to, among other things, designate Rani Holdings as the sole managing member of Rani LLC. As sole managing member, Rani Holdings will exclusively operate and control the business and affairs of Rani LLC. The LLC Interests owned by LLC Interest holders will be considered noncontrolling interests in the consolidated financial statements of Rani Holdings. The adjustment to noncontrolling interest of $84.9 million, additional paid-in capital of $(93.9) million, and accumulated deficit of $8.9 million reflects the pro forma proportional interest in the pro forma consolidated total equity of Rani LLC held by the Continuing LLC Owners (62.2%).

(9) The following table is a reconciliation of the adjustments impacting additional paid-in-capital:

Net proceeds from offering of Class A common stock	$ 64,082	(1)
Purchase of LLC Interests from Rani Therapeutics, LLC		(1)
	(68,200)	(8)
Contributed capital reclassification	192,692	(6)
Adjustment for vesting of Profits Interests	13,762	(10)
Adjustment to noncontrolling interest	(25,661)	(8)
Net additional paid-in capital pro forma adjustment	$ 176,675	

(10) Represents an adjustment of $13.8 million to accumulated deficit and additional paid-in capital to reflect the acceleration of vesting of Profits Interests in connection with the IPO.

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED STATEMENT OF INCOME

FOR THE THREE MONTHS ENDED MARCH 31, 2021

(in thousands, except unit/share and per unit/share data)	Rani Therapeutics, LLC As Reported	Organizational Transactions		Rani Therapeutics Holdings, Inc. Pro Forma
Contract revenue	$ 756	$ —		$ 756
Operating expenses				
Research and development	3,347	—		3,347
General and administrative	2,607	—		2,607
Total operating expenses	5,954	—		5,954
Loss from operations	(5,198)	—		(5,198)
Other income (expense), net				
Interest income	47	—		47
Interest expense and other, net	(188)	—		(188)
Change in estimated fair value of preferred unit warrant liability	(216)	216	(5)	—
Loss before income taxes	(5,555)	216		(5,339)
Income tax expense	(43)	—	(1)	(43)
Net loss and comprehensive loss	(5,598)	216		(5,382)
Net loss attributable to noncontrolling interest	—	(3,347)	(2)	(3,347)
Net (loss) income attributable to Rani Therapeutics Holdings, Inc.	$ (5,598)	$ 3,563	(2)	$ (2,035)
Proforma net loss per Class A common share, basic and diluted				$ (0.11)
Proforma weighted-average common Class A common shares outstanding, basic and diluted			(3)	18,462,713

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

FOR THE YEAR ENDED DECEMBER 31, 2020

(in thousands, except share and unit amounts and per share and per unit amounts)	Rani Therapeutics, LLC	Organizational Transactions		Rani Therapeutics Holdings, Inc.
Contract revenue	$ 462	$ —		$ 462
Operating expenses				
Research and development	12,044	10,320	(4)	22,364
General and administrative	4,962	4,072	(4) (6)	9,034
Total operating expenses	17,006	14,392		31,398
Loss from operations	(16,544)	(14,392)		(30,936)
Other income (expense), net				
Interest income	63	—		63
Interest expense and other, net	(124)	—		(124)
Change in estimated fair value of preferred unit warrant liability	(63)	63	(5)	—
Loss before income taxes	(16,668)	(14,329)		(30,997)
Income tax expense	(35)	—	(1)	(35)
Net loss	(16,703)	(14,329)		(31,032)
Net loss attributable to noncontrolling interest	—	(19,297)	(2)	(19,297)
Net (loss) income attributable to Rani Therapeutics Holdings, Inc.	$ (16,703)	4,968	(2)	$ (11,735)
Proforma net loss per Class A common share, basic and diluted				$ (1.11)
Proforma weighted-average Class A common shares outstanding, basic and diluted			(3)	10,599,496

NOTES TO UNAUDITED PRO FORMA CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(1) Following the Organizational Transactions and offering, Rani Holdings will be subject to U.S. federal income taxes, in addition to state, and local taxes. We have determined it is more-likely-than-not the tax benefits associated with the deferred tax assets arising from the Organizational Transactions and this offering will not be realized. As a result, the pro forma consolidated statement of operations and comprehensive loss does not reflect an adjustment for deferred tax benefits.

(2) Following the Organizational Transactions, Rani Holdings will become the sole managing member of Rani LLC, and upon consummation of this offering, Rani Holdings will initially own approximately 37.8% of the economic interest in Rani LLC but will have 4.1% of the voting power and control the management of Rani LLC. The ownership percentage held by the noncontrolling interest will be approximately 62.2%. Net loss attributable to the noncontrolling interest will represent approximately 62.2% of net loss.

(3) The weighted average number of shares underlying the basic loss per share calculation reflects only the 18,738,682 shares of Class A common stock outstanding after the offering as they are the only outstanding shares which participate in distributions or dividends by Rani Holdings. The net proceeds from the sale of 6,666,667 shares of Class A common stock in the IPO will be used to (i) acquire newly issued 6,666,667 LLC Interests, (ii) pay expenses incurred in connection with this offering. Pro forma diluted loss per share is computed by adjusting pro forma net loss attributable to Rani Holdings and the weighted average shares of Class A common stock outstanding to give effect to potentially dilutive securities that qualify as participating securities using the treasury stock method, as applicable. However, as Rani Holdings is in a net loss position, all securities are considered antidilutive, as they would only further reduce the net loss per share. Shares of Class B common stock are not participating securities and therefore are not included in the calculation of pro forma basic earnings per share.

30,813,262 LLC Interests, together with 29,269,540 shares of Class B common stock from the Continuing LLC Owners, may be redeemed, at the option of the Continuing LLC Owners, for shares of our Class A common stock or, at our election, for cash. After evaluating the potential dilutive effect under the if-converted method, the outstanding LLC Interests for the assumed exchange of noncontrolling interest were determined to be antidilutive and thus were excluded from the computation of diluted earnings per share.

The diluted weighted average share calculation assumes that certain equity awards were issued and outstanding at the beginning of the period. The following table sets forth a reconciliation of the numerators and denominators used to compute pro forma basic and diluted loss per share.

	For the Three Months Ended March 31, 2021	For the Year Ended December 31, 2020
Loss per share of Class A common stock		
Numerator:		
Net loss attributable to Rani Therapeutics Holdings, Inc.'s shareholders (basic and diluted)	$ (2,035)	(11,735)
Denominator:		
Weighted average of shares of Class A common stock outstanding (basic)	18,462,713	10,599,496
Weighted average of shares of Class A common stock outstanding (diluted)	18,462,713	10,599,496
Basic and diluted loss per share of Class A common stock	$ (0.11)	(1.11)

(4) Reflects the recognition of compensation expense totaling $13.8 million to reflect the acceleration of vesting of Profits Interests in connection with the IPO.

(5) To eliminate other expense related to the revaluation of the preferred unit warrant liability related to preferred unit warrants, which will automatically convert and be exchanged into Class A common stock of Rani Holdings in connection with the Organizational Transactions.

(6) After March 31, 2021, the Company incurred an additional $0.6 million of costs associated with this offering that were not eligible for capitalization. These costs were expensed as incurred and were recorded to accrued expenses and accumulated deficit.

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

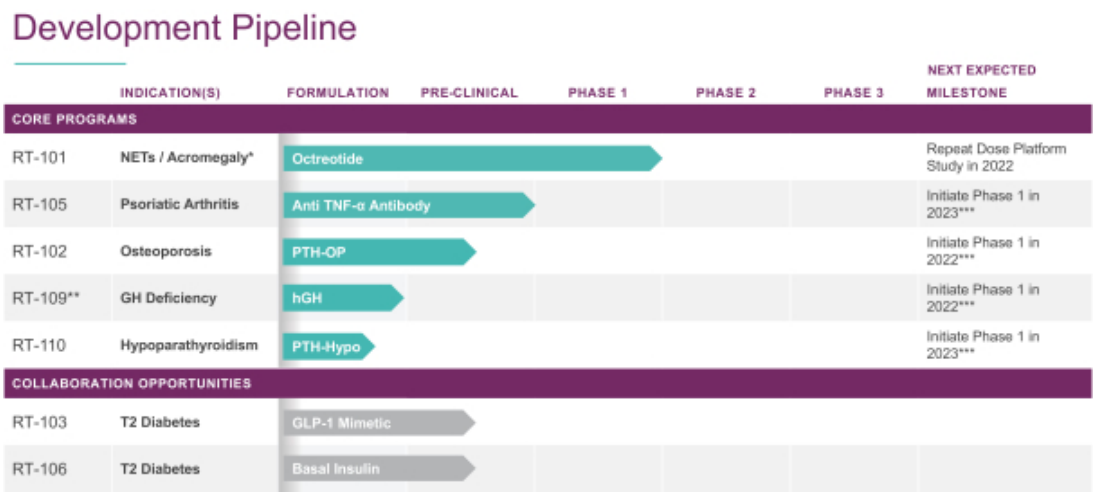
You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and unaudited interim condensed consolidated financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, 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 prospectus 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 does not give effect to the Organizational Transactions. See the sections titled "Organizational Transactions" and "Unaudited Pro Forma Condensed Consolidated Financial Information" included elsewhere in this prospectus for a description of the Organizational Transactions and their effect on our historical results of operations.

The following discussion contains references to calendar year 2019, calendar year 2020 and the first quarter of 2021, which represents the consolidated financial results of our predecessor Rani Therapeutics, LLC ("Rani LLC") and subsidiary for the years ended December 31, 2019 and December 31, 2020 and the three months ended March 31, 2020 and March 31, 2021, respectively. Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," and "Rani" and similar references refer: (1) on or following the consummation of the Organizational Transactions, including this offering, to Rani Therapeutics Holdings, Inc. ("Rani Holdings") and its consolidated subsidiaries, including Rani LLC, and (2) prior to the consummation of the Organizational Transactions, including this offering, to Rani LLC and its consolidated subsidiary.

Overview

We are a clinical stage biotherapeutics company advancing technologies to enable the development of orally administered biologics, which we believe will have the potential to transform medicine and improve patient outcomes. 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. Below is a summary of our product candidate pipeline.



RT-XXX refers to the RaniPill capsule containing a biologic in a proprietary Rani formulation
* Each of these indications will require separate trials
**CCHN will have a limited opportunity to negotiate for rights within China
***To follow submission and clearance of IND

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 private placements of our preferred units and the issuance of convertible promissory notes, with aggregate gross proceeds of $208.8 million, as well as revenue generated from evaluation agreements. As of March 31, 2021, we had cash and cash equivalents of $76.7 million. 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 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 $26.6 million and $16.7 million for the years ended December 31, 2019 and 2020, respectively, and $5.4 million and $5.6 million for the three months ended March 31, 2020 and 2021, respectively. As of March 31, 2021, we had an accumulated deficit of $119.6 million. We expect to continue to incur significant losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. As a result, we will require substantial additional capital to develop the RaniPill capsule and related product candidates and fund

operations for the foreseeable future. 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.

As a result of the COVID-19 pandemic, in April 2020 we implemented a reduction in force, certain activities related to the pre-clinical and clinical studies were put on hold and, our ability to travel was strictly

limited. We expect that COVID-19 precautions will directly or indirectly impact the timeline for some of our planned clinical trials and we are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations.

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.

As a result of the COVID-19 pandemic, or similar pandemics and outbreaks, we have and may in the future experience severe disruptions, including:

- interruption of or delays in receiving materials or services from the third parties due to staffing shortages, production slowdowns or stoppages, or disruptions in delivery systems, which interruption or delay may impact our ability to continue our research programs;
- limitations on our business operations by the local, state, or federal government that could impact our ability to continue our research programs;
- business disruptions caused by workplace closures, travel limitations, communication or mass transit disruptions; or an increased reliance on employees working from home with concomitant cyber security concerns and data accessibility limits; and
- limitations on employee resources that would otherwise be focused on the conduct of our activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

Evaluation Agreements

Rani has entered into evaluation agreements with Takeda (formerly Shire), Novartis and CCHN. Our evaluation agreements focus on testing specific molecules of interest using the RaniPill capsule. The drugs being evaluated are Factor VIII with Takeda; human growth hormone with CCHN; and two confidential molecules with Novartis. The evaluations include formulation development of the pharmaceutical companies' drugs and testing for delivery with the RaniPill capsule in preclinical studies. We work with these pharmaceutical companies to define the scope of preclinical studies that will help determine the feasibility of the RaniPill route of administration for specific drug(s). As part of these agreements, the pharmaceutical companies have funded the studies and have also made equity investments in Rani. We have recognized contract revenue in the amount of $1.0 million and $0.5 million for the years ended December 31, 2019 and 2020, respectively, and $0.1 million and $0.8 million for the three months ended March 31, 2020 and 2021, respectively. See the section titled "Evaluation Agreements" for a more detailed description of these and our other license agreements.

Organizational Transactions

Rani Holdings was incorporated in April 2021 and formed for the purpose of this offering and has engaged to date only in activities in contemplation of this offering. Rani Holdings will be a holding company and its sole material asset will be a controlling ownership interest in Rani LLC. For more information regarding our reorganization and holding company structure, see the section titled "Organizational Transactions." Upon completion of this offering, all of our business will be conducted through Rani LLC and its consolidated subsidiary, and the financial results of Rani LLC and its consolidated subsidiary will be included in the consolidated financial statements of Rani Holdings.

Rani LLC has been treated as a pass-through entity for U.S. federal and state income tax purposes and accordingly has not been subject to U.S. federal or state income tax. The wholly owned subsidiary of Rani LLC, 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. After consummation of this offering, Rani LLC will continue to be treated as a pass-through entity for U.S. federal and state income tax purposes, and our wholly owned subsidiary will continue to be 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 LLC, Rani Holdings will become subject to U.S. federal, state and local income taxes with respect to its allocable share of any taxable income of Rani LLC and will be taxed at the prevailing corporate tax rates. In addition to tax expenses, we also will incur expenses related to our operations and we will be 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 are likely to 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. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources— Source of Liquidity” for more information about expected payments under the Tax Receivable Agreement.

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 our evaluation agreements, which are recorded as contract revenue. We expect that our revenue for the next several years will be derived primarily from our current evaluation agreements and any additional 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 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 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 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.

Noncontrolling Interest

In connection with the Organizational Transactions, Rani Holdings will be appointed as the sole managing member of Rani LLC pursuant to the amended and restated LLC Operating Agreement. Because we will manage and operate the business and control the strategic decisions and day-to-day operations of Rani LLC and will also have a substantial financial interest in Rani LLC, we will consolidate the financial results of Rani LLC, and a portion of our net loss will be allocated to the noncontrolling interest to reflect the entitlement of the noncontrolling interest holders to Rani LLC's net loss. We will hold approximately 38.0% of the outstanding LLC Interests of Rani LLC (or approximately 39.2% of the outstanding LLC Interests of Rani LLC if the underwriters exercise their option to purchase additional shares in full), and the outstanding Class B Interests of Rani LLC will be held by Rani Holdings.

Income Tax Expense

Rani LLC is currently, and will through consummation of the Organizational Transactions, be treated as a partnership for U.S. federal and most applicable state and local income tax purposes. As a partnership, its taxable income or loss is passed through to and included in the tax returns of its members, including us. Certain wholly owned subsidiaries of Rani LLC are organized and treated as corporations for U.S. federal and most applicable state, local income tax and foreign tax purposes. Accordingly, the consolidated financial statements of Rani LLC included in this prospectus include a tax provision for federal, state, local and foreign income taxes.

For a description of the Tax Receivable Agreement, see the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement."

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 was again amended in June 2021, effective January 2021, to extend the term for an additional year and automatically renew annually for an additional year, unless terminated by ICL or the Company. 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 years ended December 31, 2019 and 2020, and the three months ended March 31, 2021. Costs are billed on a monthly basis and based upon the hours incurred by ICL employees working on behalf of Rani LLC, as well as allocations of expenses based upon Rani LLC's utilization of ICL's facilities and equipment. Effective January 1, 2020, the ICL personnel that were substantially dedicated to providing services to Rani were hired by RMS as full-time employees. In addition, under the service agreement, RMS bills ICL on the same cost basis described above certain hours incurred by RMS employees performing services on behalf of ICL. For the year ended December 31, 2020, RMS charged ICL $0.4 million for services performed, and for the three months ended March 31, 2020 and 2021, $0.1 million and $0.2 million, respectively and such amounts charged were recorded as a reduction to research and development expense in the consolidated statement of operations and comprehensive loss.

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 our employees, including our named executive officers, who satisfy certain eligibility requirements.

All of Rani LLC's facilities are owned by an entity affiliated with one of our directors, who is also the owner of ICL. Rani LLC 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 (in thousands):

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Research and development	$17,129	$535	$184	$ 33
General and administrative	3,308	1,826	244	182
Total	**$20,437**	**$2,361**	**$428**	**$215**

Financing activity

From inception to December 31, 2017, Rani LLC advanced funds to ICL, and ICL made payments directly to certain vendors on behalf of Rani LLC. Rani LLC has reimbursed ICL for all such payments at cost on a monthly basis. In June 2017, Rani LLC converted the outstanding advances of $6.6 million to ICL into notes receivable. The notes provide for interest at 1.97% compounded annually, loan fees of 2.75% and are payable upon demand to Rani LLC any time after January 1, 2024. During 2019 and 2020, the Company received $1.0 million and $0.2 million, respectively, in payments for interest and repayment of principal on the ICL notes receivable. During the three months ended March 31, 2020, payments for interest and repayment of principal on the ICL note receivable was insignificant. During the three months ended March 31, 2021, the Company received $1.7 million for interest and principal on the ICL notes receivable. As of December 31, 2019 and 2020, $1.9 million and $1.7 million, respectively, of the notes were outstanding. As of March 31, 2021, the outstanding balance, including all accrued interest, was fully repaid.

In December 2020, Rani LLC amended the terms of certain expired warrants to purchase Series B units, or the Series B Warrants, issued to InCube Ventures II, LP, or 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 LLC issued 51,341 Series B units. There were no Series B Warrants outstanding at March 31, 2021.

Exclusive License Agreement

In June 2012, we entered into an Intellectual Property Agreement and an Exclusive License Agreement with ICL, which were each amended in June 2013, pursuant to which ICL assigned to us certain intellectual property made by ICL during the course of providing services to us that relates primarily to, or has application primarily within, the field of oral delivery of biotherapeutic agents such as peptides, proteins and antibodies and excluding swallowable devices that do not deliver such drugs (the "Field of Use"). ICL also granted to us a fully-paid, royalty-free, sublicensable, exclusive license under the intellectual property made by ICL during the course of providing services to us that is useful in the Field of Use but does not relate primarily to, or have application primarily within, the Field of Use to make, have made, use, offer to sell, sell and import products and services that are covered by such intellectual property within the Field of Use. We are obligated to diligently develop and commercialize such products and services and to reimburse ICL for its costs to prosecute and maintain the patents that are licensed to us, which reimbursement will be a pro rata portion if ICL grants licenses under such patents to other licensees. 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, 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.

Future Public Company Expenses

We expect our operating expenses to increase when we become a public company following the completion of this offering. 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 March 31, 2020 and 2021

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

	Three Months Ended March 31,	
	2020	2021
Contract revenue	$ 83	$ 756
Operating expenses		
Research and development	4,060	3,347
General and administrative	1,407	2,607
Total operating expense.	$ 5,467	$ 5,954
Loss from operations	(5,384)	(5,198)
Other income (expense), net		
Interest income	62	47
Interest expense and other, net	—	(188)
Change in estimated fair value of preferred unit warrant	(17)	(216)
Loss before income taxes	(5,399)	(5,555)
Income tax expense	(11)	(43)
Net loss and comprehensive net loss	$ (5,350)	$ (5,598)

Contract Revenue

Contract revenue was $0.1 million and $0.8 million for the three months ended March 31, 2020 and 2021, respectively, which was primarily attributable to our evaluation agreement with Takeda. The increase was primarily related to timing of work performed. In May 2021, the Company received notice from Takeda as to their intent to terminate the contract for convenience. The termination of the contract is considered a modification of an arrangement, and the deferred revenue remaining under this agreement will be recognized in the second quarter of 2021 when this modification occurred.

Research and Development Expenses

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

	Three Months Ended March 31,	
	2020	2021
Payroll and related benefits	$ 1,990	$ 2,195
Facility, materials and supplies	705	683
Third-party services	1,356	187
Other	9	282
	$ 4,060	$ 3,347

Research and development expenses were $4.1 million for the three months ended March 31, 2020, compared to $3.3 million for the three months ended March 31, 2021. The change in research and development expense was primarily related to a reduction in third-party services of $1.2 million associated with the development of our manufacturing processes that occurred in 2020 and did not recur in 2021, $0.2 million associated with equity-based compensation expense from a secondary sales transaction, offset by an increase of $0.2 million in salaries and related costs due to an increase in headcount.

General and Administrative Expenses

General and administrative expenses were $1.4 million for the three months ended March 31, 2020, compared to $2.6 million for the three months ended March 31, 2021. During the three months ended March 31, 2021, our payroll and related benefits increased by $0.3 million due to an increase in headcount, $0.2 million associated with equity-based compensation expense from a secondary sales transaction and the professional and consulting services expense increased by $0.7 million primarily due to the costs associated with preparing to operate as a public company.

Other Income (Expense), Net

Other income, net was nominal for the three months ended March 31, 2020, compared to a net expense of $0.4 million for the three months ended March 31, 2021. The change in other income, net, was primarily due to the change in fair value of our Series E warrants and interest expense on the debt incurred at the end of 2020.

Comparison of the Years Ended December 31, 2019 and 2020

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

	Years Ended December 31,	
	2019	2020
Contract revenue	$ 979	$ 462
Operating expenses		
Research and development	24,579	12,044
General and administrative	3,465	4,962
Total operating expense	$ 28,044	$ 17,006
Loss from operations	(27,065)	(16,544)
Other income (expense), net		
Interest income	423	63
Interest expense and other, net	(10)	(124)
Change in estimated fair value of preferred unit warrant	65	(63)
Loss before income taxes	(26,587)	(16,668)
Income tax expense	—	(35)
Net loss and comprehensive net loss	$ (26,587)	$ (16,703)

Contract Revenue

Contract revenue was $1.0 million and $0.5 million for the years ended December 31, 2019 and 2020, respectively, which was primarily attributable to our evaluation agreement with Takeda. The decrease was primarily related to timing of work performed for our evaluation agreement with Takeda.

Research and Development Expenses

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

	Years Ended December 31,	
	2019	2020
Payroll and related benefits	$ 17,249	$ 6,794
Facility, materials and supplies	4,364	2,449
Third-party services	2,057	2,690
Other	909	111
	$ 24,579	$ 12,044

Research and development expenses were $24.6 million for the year ended December 31, 2019, compared to $12.0 million for the year ended December 31, 2020. The change in research and development expense was primarily related to a decrease in payroll and related benefits expenses due to a reduction in force that was completed in April 2020, as well as a decrease in materials and supplies expense associated with our preclinical studies and clinical trial activities due in large part because of the COVID-19 pandemic, which disrupted our ability to perform certain research and development activities, as well as impacting the timing of our ability to raise capital.

General and Administrative Expenses

General and administrative expenses were $3.5 million for the year ended December 31, 2019, compared to $5.0 million for the year ended December 31, 2020. During the year ended December 31, 2020, our

payroll and related benefits increased by $0.2 million, our patent costs increased by $0.3 million, partially offset by a decrease in consulting services of $0.2 million and a decrease in travel expense of $0.3 million.

Other Income (Expense), Net

Other income, net was $0.5 million for the year ended December 31, 2019, compared to a net expense of $0.1 million for the year ended December 31, 2020. The change in other income, net, was primarily due to a decrease in interest income of $0.4 million in 2020 as a result of lower average cash and cash equivalent balances throughout most of 2020.

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 private placement of our preferred units and convertible promissory notes, and revenue generated from evaluation agreements. Since our inception, we have received aggregate gross proceeds of $208.8 million from the sales and issuances of our preferred units and convertible promissory notes. As of March 31, 2021, we had cash and cash equivalents of $76.7 million.

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. The loan and accrued interest are forgivable as long as the loan proceeds are used for eligible purposes; however, while we believe the loan would be eligible for forgiveness, we intend to pay back the loan and accrued interest in full with the proceeds from this offering.

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 March 31, 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 three months ended March 31, 2021. As of March 31, 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 January 31, 2021, we had issued the total authorized amount at a price of $7.1471 for gross proceeds of $75.0 million.

After completion of this offering, Rani Holdings will be a holding company and will have 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 LLC that will be in effect at the closing of this 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. As described in the section titled "Certain Relationships and Related Person Transactions—Tax Receivable Agreement," in connection with the Organizational Transactions we will enter into the Tax Receivable Agreement with certain of the Continuing LLC Owners. 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. For example, if we acquired all of the LLC Interests of certain of the Continuing LLC Owners in taxable transactions as of this offering, based on the initial public offering price of $11.00 per share and on certain assumptions, including that (i) there are no material changes in relevant tax law and (ii) we earn sufficient taxable income in each year to realize on a current basis all tax benefits that are subject to the Tax Receivable Agreement, we expect that the resulting reduction in tax payments for us, as determined for purposes of the Tax Receivable Agreement, would aggregate to approximately $120.7 million, substantially all of which would be realized over the next 15 years, and we would be required to pay certain of the Continuing LLC Owners 85% of such amount, or $102.6 million, over the same period. The actual increases in tax basis with respect to future taxable redemptions, exchanges or purchases of LLC Interests, as well as the amount and timing of any payments we are required to make under the Tax Receivable Agreement in respect of the acquisition of LLC Interests from certain of Continuing LLC Owners in connection with this offering or future taxable redemptions, exchanges or purchases of LLC Interests, may differ materially from the amounts set forth above because the potential future reductions in our tax payments, as determined for purposes of the Tax Receivable Agreement, and the payments we will be required to make under the Tax Receivable Agreement, will each depend on a number of factors, including the market value of our Class A common stock at the time of redemption or exchange, the prevailing federal tax rates applicable to us over the life of the Tax Receivable Agreement. See "Certain Relationships and Related Person Transactions—Tax Receivable Agreement" and "Certain Relationships and Related Person Transactions—Rani LLC Agreement."

Future Funding Requirements

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 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 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):

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Net cash used in operating activities	$ (26,267)	$ (14,960)	$ (6,122)	$ (4,048)
Net cash used in investing activities	(1,532)	(1,200)	(900)	(99)
Net cash provided by financing activities	852	72,682	—	7,751
Net (decrease) increase in cash and cash equivalents	$ (26,947)	$ 56,522	$ (7,022)	$ 3,604

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2021 was $4.0 million, which was primarily attributable to a net loss of $5.6 million, non-cash depreciation and amortization of $0.1 million, and change in the fair value of preferred unit warrant liability of $0.2 million, equity-based compensation expense from a secondary sales transaction of $0.5 million, partially offset by an increase in operating assets and liabilities of $0.7 million.

Net cash used in operating activities for the three months ended March 31, 2020 was $6.1 million, which was primarily attributable to a net loss of $5.4 million and non-cash depreciation and amortization of $0.2 million, partially offset by payment of the related party payable balance of $1.5 million.

In 2020, net cash used in operating activities was $15.0 million, which consisted of a net loss of $16.7 million, partially offset by $0.7 million in non-cash charges and a net change of approximately $1.0 million in our net operating assets and liabilities. The non-cash charges primarily consisted of depreciation of $0.6 million. The net change in our operating assets and liabilities was primarily due to an increase in deferred revenue of $2.5 million resulting from the amendment of the evaluation agreement with Takeda, partially offset by a net reduction of $1.8 million resulting from paying down our related party payable balance.

For the year ended December 31, 2019, net cash used in operating activities was $26.3 million, which consisted of a net loss of $26.6 million, partially offset by $0.5 million in non-cash charges and a net change of $0.2 million in our net operating assets and liabilities. The non-cash charges primarily consisted of depreciation of $0.6 million. The net change in our operating assets and liabilities was primarily due to a net increase in related party payables and accrued expenses of $0.4 million, partially offset by a net decrease in prepaid expenses, accounts payable, and deferred revenue of approximately $0.5 million resulting from our evaluation agreement with Takeda.

Investing Activities

For the three months ended March 31, 2021, net cash used in investing activities was $0.1 million, consisting solely of purchases of property and equipment.

For the three months ended March 31, 2020, net cash used in investing activities was $0.9 million, consisting solely of purchases of property and equipment.

For the year ended December 31, 2020, net cash used in investing activities was $1.2 million, consisting solely of purchases of property and equipment of $1.2 million.

For the year ended December 31, 2019, net cash used in investing activities was $1.5 million, consisting primarily of purchases of property and equipment of $1.6 million.

Financing Activities

For three months ended March 31, 2021, cash provided by financing activities was approximately $7.8 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.

For three months ended March 31, 2020, there were no financing activities.

For the year ended December 31, 2020, cash provided by financing activities was approximately $72.7 million, consisting of the sale and issuance of 9.6 million units of our Series E Preferred Units, for net proceeds of $68.5 million, $1.3 million of proceeds relating to our PPP Loan, and net proceeds of $2.8 million relating to our Avenue Loan Agreement.

For the year ended December 31, 2019, cash provided by financing activities was approximately $0.9 million, consisting of principal by a related party against their related party notes receivable.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations and commitments as of March 31, 2021 (in thousands):

	Payments due by period		
	Total	Less than one year	1 to 3 years
PPP Loan (1)	$1,279	$ 1,209	$ 70
Loan and Security Agreement (2)	3,000	750	2,250
Service Agreement (3)	579	579	—
Total	$4,858	$ 2,538	$ 2,320

(1) In April 2020, we received loan proceeds in the amount of approximately $1.3 million under the PPP loan, established pursuant to the CARES Act which we plan to repay in 2021.

(2) In September 2020, we entered into the Avenue Loan Agreement. As of December 31, 2020, we had drawn $3.0 million, which is payable by September 2023. We repaid the full balance of this loan in July 2021.

(3) Effective December 31, 2020, the term of our service agreement with ICL, which includes leasing of the office space, laboratories and manufacturing facilities, expired. We are party to a services agreement with ICL. Under the terms of this agreement we pay for the use of office space, laboratory and manufacturing facilities as well as certain services provided by ICL's personal. The agreement auto renews annually unless terminated by the parties.

We have also entered into other contracts in the normal course of business with certain CROs and other third parties for preclinical studies, clinical trials, non-clinical studies and testing, and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations for our service providers, up to the date of cancellation.

Critical Accounting Policies, Significant Judgments and Use of Estimates

This management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of these consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The economic uncertainty in the current environment caused by the COVID-19 pandemic could limit our ability to accurately make and evaluate our estimates and judgments.

Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in Note 2 to our consolidated financial statements at the end of this prospectus, we believe that the following accounting policies are the most critical to understanding and evaluating our reported financial results.

Revenue Recognition

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, we perform 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.

We perform evaluation services for our biopharmaceutical customers utilizing the RaniPill capsule. These contract revenue evaluation services typically represent a single performance obligation as we perform evaluation and testing of the customer's drug molecule delivery using the RaniPill capsule. Revenue for an individual contract is recognized at the related transaction price, which is the amount we expect to be entitled to in exchange for transferring these services. The terms of the evaluation services agreements usually include payments for evaluation services. 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. 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.

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 contract receivable when it has an unconditional right to consideration. No contract asset balance has been recorded for any periods presented.

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, 2019, December 31, 2020 and March 31, 2021, the contract liabilities were $0.2 million, $2.7 million and $2.0 million, respectively. The Company expects to recognize all of the remaining transaction price for the contract liability recorded as deferred revenue at March 31, 2021 within the next 12 months.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses to date 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. 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. Clinical and preclinical costs are a component of research and development expense. 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.

We accrue 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. We determine 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. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each reporting period in our consolidated financial statements based on facts and circumstances at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of research and development expenses.

Estimated Fair Value of Preferred Unit Warrant Liability

We have issued freestanding warrants to purchase shares of our preferred units. These freestanding warrants are classified as liabilities in the consolidated balance sheet and remeasured at each reporting period at fair value as they contain terms for redemption that are outside our control and do not meet the criteria for equity classification. We estimate the fair value of preferred unit warrants at each reporting period, using a hybrid between the probability weighted expected return and option pricing methods, estimating the probability weighted value across multiple scenarios, but using the option pricing method to estimate the allocation of value within one or more of those scenarios, until the earlier of the exercise of the preferred unit warrants, at which

time the liability will be revalued and reclassified to members' deficit, the expiration of the preferred unit warrants or the completion of a liquidation event, including the completion of an initial public offering ("IPO"). The determination of fair value of these preferred unit warrants requires management to make certain assumptions regarding subjective input variables such as estimated fair value of the underlying convertible preferred units at the measurement date, timing and likelihood of achieving a liquidity event, risk free interest rates, expected volatility, and a discount for lack of marketability reflective of the different rights of the preferred unit warrant holders. We re-measure the fair value of all warrants at each financial reporting date with any changes in fair value being recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. We will continue to re-measure the fair value of the preferred unit warrant liabilities until exercise or expiration of the related preferred unit warrants.

Equity-Based Compensation

We have granted equity-based awards to our employees and or consultants and certain employees of ICL in the form of non-vested units, or Profits Interests. These Profits Interests are considered to be a substantive class of equity. All awards of Profits Interests are measured based on the fair value of the award on the date of grant and are subject vest based the service of the grantee and only upon a non IPO liquidation event or Rani meeting certain revenue hurdles. We evaluate the probability of achieving each performance condition at each reporting date and recognize expense over the requisite service period when it is deemed probable that a performance condition will be met using the accelerated attribution method over the requisite service period. Equity-based compensation expenses are classified in the consolidated statements of operations and comprehensive loss based on the job functions of the related employees. Forfeitures are recognized when they occur.

Profits Interests and Preferred Unit Valuation

As there has been no public market for the fair value of our units, the fair value our preferred units, which is an input into the estimated fair value of our preferred unit warrants, and Profits Interests has been determined by our board of directors with the assistance of management and an independent third-party valuation specialist. We believe our board of directors has the relevant experience and expertise to determine the fair value of our preferred units and Profits Interests. In determining the fair value of the preferred units and Profits Interests, the methodologies used to estimate the enterprise values were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* ("AICPA Accounting and Valuation Guide"). In accordance with the AICPA Accounting and Valuation Guide, our board of directors considered the following methods:

- *Current value method*. Under the Current Value Method, our value is determined based on our balance sheet. This value is then first allocated based on the liquidation preference associated with preferred units issued as of the valuation date, and then any residual value is assigned to the common units and Profits Interests.

- *Option-pricing method*. Under the option-pricing method, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred units, common units and Profits Interests are inferred by analyzing these options.

- *Probability-weighted expected return method*. The probability-weighted expected return method, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each unit class.

The assumptions we use in the valuation model are based on future expectations combined with management's judgment. In the absence of a public trading market, our board of directors, with input from

management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of the preferred units and Incentive Units as of the date of reporting period or each award, including the following factors:

- independent valuations performed at periodic intervals by an independent third-party valuation firm;
- the prices at which we sold shares of preferred units and the superior rights and preferences of the preferred units relative to our common units at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common units, preferred units or preferred unit warrants;
- the likelihood of achieving a liquidity event, such as an IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented our board of directors and management develop best estimates based on application of these approaches and the assumptions underlying these valuations, giving careful consideration to the advice from our third-party valuation expert. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

As of March 31, 2021, the aggregate value of our unvested Profits Interests subject to a service and performance condition was $14.0 million based on the $11.00 initial public offering price per share of the Company's Class A common stock. As of March 31, 2021, we had $14.9 million of unrecognized compensation expense related to Profits Interests subject to a performance condition.

Off-Balance Sheet Arrangements

As of March 31, 2021, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Recently Adopted Accounting Standards

See Note 2 to our consolidated financial statements in this prospectus for more information about recent accounting standards, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our consolidated financial condition and consolidated results of operations.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The market risk inherent in our consolidated financial instruments and in our financial condition represents the potential loss arising from adverse changes in interest rates or exchange rates. As of December 31, 2019, December 31, 2020, and March 31, 2021, we had cash, and cash equivalents of $16.5 million, $73.1 million, and $76.7 million, respectively.

Our PPP Loan bears interest at a fixed rate of 1.00% and therefore, is not subject to interest rate variability. Additionally, as of March 31, 2021, the principal amount owed under our Avenue Loan Agreement, was $3.0 million. The Avenue Loan Agreement bears interest at a variable rate interest per annum equal to the sum of the greater of the Prime Rate (which is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal) and 3.25%, plus 8.00%.

Our cash and cash equivalents and interest payments in respects of our Avenue Loan Agreement are subject to market risk due to changes in interest rates. We do not believe that an increase or decrease in interest rate of 100 basis points would have a material effect on our business, consolidated financial condition or consolidated results of operations.

Foreign Currency Risk

All of our employees and our operations are currently located in the United States. We have, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

We do not believe that inflation had a material effect on our business, financial condition or results of operations during the periods presented.

Emerging Growth Company Status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We are an “emerging growth company” as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by us of more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of this offering.

As a result of this status, we elected to take advantage of reduced reporting requirements in the registration statement, of which this prospectus forms a part and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for

complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

BUSINESS

Overview

We are a clinical stage biotherapeutics company advancing technologies to enable the development of orally administered biologics, which we believe have the potential to transform medicine and improve patient outcomes. 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.

Biologics refers to a broad class of therapeutics that are derived from proteins and human genes and is the fastest growing segment of the pharmaceutical industry. In 2019, sales of biologics were estimated to have reached $269.0 billion and are projected to reach approximately $465.0 billion by 2023. Eight of the 10 highest-revenue-producing drugs in the world are biologics, including adalimumab, the best-selling drug globally in 2019. Adalimumab, sold under the brand name Humira, generated approximately $20.0 billion in sales in 2019.

Biologics, while effective, must generally be administered either through IV, intramuscular, or subcutaneous injection. This long term use of injectable drugs represents a serious burden to patients which impacts quality of life and compliance with therapy. Fear of needles and the associated pain often leads patients to delay taking their injections and even deliberately miss treatments. Such lack of adherence to dosing results in ineffective therapy and compromises the effective management of chronic diseases. Patient aversion to injections has promoted a significant interest in the development of solutions to enable the oral delivery of biologics. Despite repeated attempts, oral delivery of biotherapeutics remains largely unsuccessful due to their rapid degradation and digestion in the GI environment. The most significant hurdle for oral biologics is the ability to achieve sufficient bioavailability, which is the proportion of delivered dose that reaches the bloodstream, to produce an intended therapeutic effect. Most prior attempts have taken a chemistry-based approach, which involves protecting the biologic from being digested and improving absorption by chemical agents. The best attempts have resulted in low bioavailability of peptides up to 1%.

In contrast to these prior attempts, our studies conducted to date have demonstrated high mean bioavailability via the RaniPill capsule, similar to subcutaneous injection, in the mean range of 47% to 78%, with high dosing accuracy. Our studies have indicated that the RaniPill capsule can orally deliver a number of biologics, from peptides to antibodies. We also believe our technology may have application in delivering emerging cell and gene therapies.

The RaniPill capsule's proprietary protective coating is designed to withstand the stomach acid and only dissolve in the jejunum, the upper half of the small intestine. Once dissolved, a microneedle containing a biologic drug is delivered into the highly vascularized wall of the small intestine so that the biologic can enter the bloodstream.

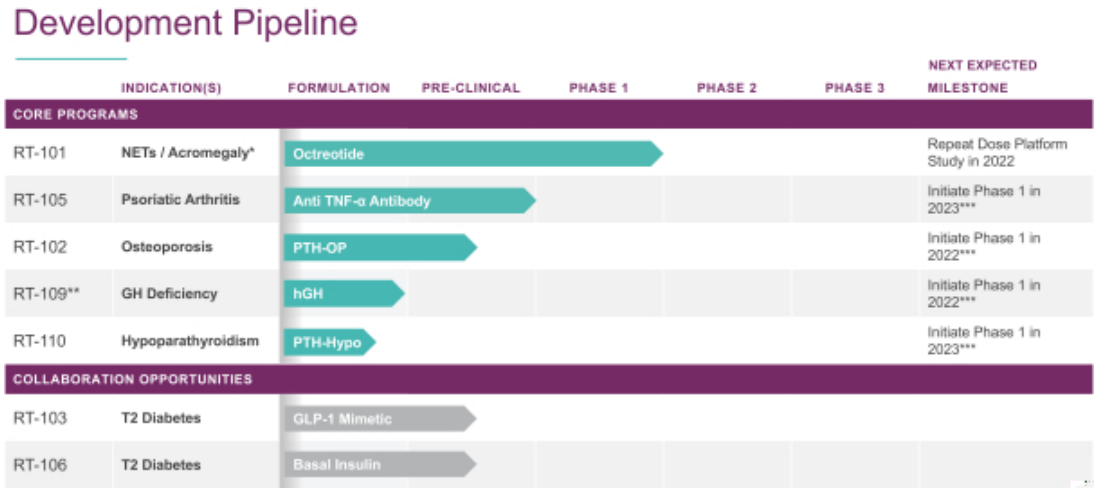
We have tested our most advanced product candidate in a Phase 1 clinical trial conducted in Australia, and we are further optimizing the formulation in preparation for a regulatory submission to FDA to initiate subsequent trials. Based on discussions with the FDA and the guidance we have received from CDRH in a pre-IDE meeting, we expect to be able to conduct further testing in humans in the contemplated IDE study of the RaniPill in the United States. In this study, we will evaluate the safety and tolerability of the RaniPill capsule, independent of any drug or biologic. This will be followed by a more standard regulatory pathway for each of our pipeline pipeline candidates. Our current pipeline includes well-characterized biologics that have been in clinical use for several years. We believe that we may be able to leverage the FDA's prior conclusions of safety, purity and potency for certain approved biologic products in our own BLA. The degree to which we may be able to

reduce the burden on our own development will depend on whether the API is the same as the original approved product, particularly for products originally approved as NDAs and now deemed to be biologics. We intend to have this clarified on a product-by-product basis in pre-IND meetings with the FDA for each of the pipeline product candidates.

Our Pipeline

The broad utility of the RaniPill capsule to enable the oral delivery of biologics reliably provides us with a range of attractive development opportunities. We have prioritized development of these opportunities based on specific scientific, developmental, regulatory and commercial considerations to optimize our portfolio of targeted product candidates. Our core internal development targets are focused on well-characterized molecules with attractive commercial characteristics. We believe selection of these targets will allow us to potentially accelerate product approval and market launch, while also broadening patient, provider and payor acceptance of the RaniPill capsule.

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. Below is a summary of our product candidate pipeline.



RT-XXX refers to the RaniPill capsule containing a biologic in a proprietary Rani formulation.
*Each of these indications will require separate trials.
**CCHN will have a limited opportunity to negotiate for rights within China.
***To follow submission and clearance of IND.

RT-101: Octreotide for the treatment of NETs and acromegaly

We are developing, RT-101, our most advanced candidate, for oral administration of octreotide for acromegaly and NETs. Octreotide is currently approved by the FDA and EMA for the symptomatic treatment of acromegaly, a disorder involving the secretion of excessive growth hormone, as well as carcinoid syndrome, a condition involving NETs of the GI tract. Current treatment using octreotide involves painful subcutaneous injections administered three to four times daily or an extended release formulation via painful, deep intramuscular injections every four weeks. Despite the inconvenience of the current route of administration, the worldwide market for octreotide in 2020 was approximately $2.7 billion. By introducing an oral version of octreotide, we aim to improve patients' quality of life, eliminate the burden and pain of these injections, and enable patients to more conveniently manage their disease.

We have completed a Phase 1 clinical trial in which bioavailability of RT-101 was 65% relative to the IV group. We believe this is the first demonstration of such high bioavailability of an oral biologic in humans. To

date, the best published bioavailability for oral octreotide is approximately 1%. The results of the RT-101 Phase 1 clinical trial support the utility of the RaniPill capsule to deliver octreotide orally. In addition, the results indicate that the RaniPill capsule may be used for other biologics. We are further optimizing the formulation in preparation for subsequent clinical trials with RT-101. We have worldwide commercial rights to RT-101.

RT-105: Anti-TNF-alpha antibody for the treatment of psoriatic arthritis

We are developing RT-105 as an oral anti-TNF-alpha antibody for a host of inflammatory conditions. Several TNF-alpha antibodies such as adalimumab have been approved by the FDA and EMA to treat a range of autoimmune conditions, including psoriasis, rheumatoid arthritis and Crohn's disease. Humira is a well-known brand of adalimumab and the world's best-selling drug, with worldwide sales of approximately $20.0 billion in 2019. Patients who use adalimumab administer the drug through a painful subcutaneous injection once every two weeks. We believe RT-105 represents a substantial global market opportunity.

We embarked on this program using commercially available TNF-alpha inhibitors (adalimumab and biosimilar) to conduct preclinical and clinical feasibility and proof of concept studies. To date, we have developed a formulation of a TNF-alpha inhibitor we believe to be suitable for use with the RaniPill capsule and have conducted a series of preclinical studies and an early clinical study which support our ability to reliably achieve therapeutic serum concentrations of the antibody via direct injection into the intestinal wall. We plan to initiate a Phase 1 clinical trial of RT-105 in healthy volunteers in 2023 and develop it for the treatment of psoriatic arthritis. Later, we plan to expand RT-105 to other indications for which TNF-alpha inhibitors are approved. We have worldwide commercial rights to RT-105.

RT-102: Parathyroid hormone for the treatment of osteoporosis

We are developing RT-102 for oral administration of PTH for the treatment of osteoporosis. PTH is approved by the FDA for the treatment of osteoporosis, a bone-loss disease, as well as for other conditions. While there are several medications available for the prevention or treatment of osteoporosis, the bone-building treatments, such as PTH, require frequent painful subcutaneous injections. Approximately 10 million Americans suffer from osteoporosis; however, we estimate only a small fraction of this population is being treated with PTH analogs. While there may be other reasons for this, we believe that patients' aversion to daily injections may be a major factor. As a result, non-bone-building and less effective antiresorptive drugs are used as first line therapies because they are available in oral form. We believe an oral version of PTH would advance treatment of osteoporosis and has the potential to expand this market.

We have optimized our PTH formulation for use in the RaniPill capsule for the treatment of osteoporosis, and are currently conducting preclinical studies with RT-102. We plan to initiate a Phase 1 clinical trial with RT-102 in healthy volunteers in 2022. We have worldwide commercial rights to RT-102.

RT-109: hGH for the treatment of growth hormone deficiency

We are developing RT-109 for oral administration of hGH for the treatment of growth hormone deficiency. HGH is approved by the FDA for the treatment of growth hormone deficiency. Current treatment with hGH involves daily painful subcutaneous injections. Despite this, worldwide sales of hGH totaled approximately $6.0 billion in 2020. We believe that both pediatric and adult patients suffering from growth hormone deficiency would prefer once-daily oral administration.

We are finalizing our hGH formulation for the RaniPill capsule and are conducting preclinical PK studies. We plan to initiate a Phase 1 clinical trial in healthy volunteers in 2022. We have worldwide commercial rights to RT-109. We have entered into an Evaluation and First Right of Refusal Agreement with Changchun High & New Technology Industries, or CCHN, which includes limited rights to negotiate commercialization rights for RT-109 in China.

RT-110: Parathyroid hormone for the treatment of hypoparathyroidism

We are developing RT-110 for oral administration of a novel formulation of PTH for the treatment of hypoparathyroidism. PTH is already approved by the FDA for the treatment of hypoparathyroidism, a rare condition that affects approximately 115,000 people in the United States; however, treatment requires painful daily injections and we believe there is an unmet need for a more convenient delivery method. We believe that RT-110, through providing the convenience of oral administration, may be able to meet this need.

We plan to initiate preclinical PK studies once our PTH formulation has been optimized. We have worldwide commercial rights to RT-110.

RT-103: GLP-1 mimetic for the treatment of Type 2 diabetes

We are developing RT-103 for oral administration of a GLP-1 mimetic for the treatment of Type 2 diabetes. We believe that RT-103 would be appealing to patients that currently use injectable versions of GLP-1 mimetics, and plan to pursue opportunities with large pharmaceutical companies to co-develop and commercialize RT-103.

RT-106: basal insulin for the treatment of Type 2 diabetes

We are developing RT-106 for oral administration of basal insulin for the treatment of Type 2 diabetes. We believe that RT-106 would have significant benefit to the millions of people living with Type 2 diabetes. We intend to pursue partnership opportunities with large pharmaceutical companies to co-develop and commercialize RT-106.

Our Strategy

Our strategic vision is to disrupt and expand the approximately $269.0 billion injectable biologics therapeutics industry by developing and advancing oral biologics therapies. We are committed to delivering oral biologic solutions for patients living with burdensome chronic diseases. We believe that the RaniPill capsule will improve the lives of millions of patients with chronic diseases who currently depend on biologics available only as injections.

The key elements of our strategy include:

- **Pursue validated and commercially established market opportunities**. We intend to pursue high-value markets with biologics that are already approved where we can develop our own differentiated products. We believe that these products will take market share from available therapies, while also expanding existing markets by reaching new patient populations that otherwise are not being treated by injectable biologics. We have designed our platform to be drug-agnostic, which could enable us to expand into additional markets beyond our current pipeline.

- **Establish the RaniPill capsule as a platform technology with regulatory authorities**. Initially, we plan to demonstrate the safety and tolerability of the RaniPill capsule through clinical studies, independent of any drug or biologic. Data from these studies will be used to support subsequent product applications.

- **Expand in-house manufacturing of the RaniPill capsule**. We have vertically integrated our manufacturing, and plan to continue to scale and optimize our manufacturing processes by expanding our use of automation. In addition, we are filing patents to protect our novel manufacturing processes.

- **Invest in RaniPill platform capabilities**. We intend to become a leader in oral biologics by continuing to invest in our technology, by expanding payload capacity and developing novel biologic formulations in order to maximize the number of therapeutic targets and addressable markets.

- **Expand our reach by selectively entering into strategic partnerships**. We are opportunistically exploring strategic partnerships to enable us to expand our commercial reach and enable oral administration of a broader array of biologics.

- **Continue to strengthen our intellectual property portfolio**. Our patent portfolio has helped establish us as a leading oral biologics company. We plan to continue to innovate and expand our intellectual property by developing novel formulations and new applications of the RaniPill capsule.

Industry Overview

The Market for Biologics

More than half of the adult population of the United States has one or more chronic diseases. The affected population is expected to continue to grow as the population ages. Chronic conditions, including cancers, cardiovascular diseases, autoimmune diseases and metabolic disorders, are increasingly being treated with biologics. Biologics include recombinant therapeutic proteins, peptides and monoclonal antibodies, as well as cell and gene therapies, and constitute one of the largest and fastest growing segments of medicines in the world, as measured by revenue. In 2019, worldwide sales of biologics, including biosimilars, were estimated to have reached approximately $269.0 billion and are projected to reach $465.0 billion by 2023. Eight of the 10 highest revenue-producing drugs in the world are biologics, including the best-selling drug globally in 2019, adalimumab, sold under the brand name Humira. We believe that oral biologics have the potential to disrupt this large and growing market and significantly improve the quality of life of millions of patients.

The Burden of Injectable Biologics for Patients

To date, most biologics require repeated, painful injections – either subcutaneously, intramuscularly, or intravenously. A regimen of injections represents a serious burden to patients, which impacts quality of life and compliance with therapy. Potential lack of compliance may influence physician treatment decisions and delay the prescribing of biologics until after the disease has progressed significantly. In diabetes, for example, basal insulin administered early in newly diagnosed pre-diabetic (insulin-resistant) and diabetic patients has been shown to slow the progression of the disease but is currently prescribed as a last line therapy due to an aversion to injections. For patients who have been prescribed a regimen of injectables, fear of needles and the associated pain often leads patients to delay taking their injections and even deliberately miss treatments. Such lack of adherence to dosing schedules, in turn, results in ineffective therapy and compromises the effective management of chronic diseases.

To reduce the burden of injections on patients and thereby improve compliance, developers of many biologics made the choice to introduce infrequent dosing regimens (weekly, bi-weekly or even monthly injections) using higher doses that would provide protracted exposures over days and weeks. Even so, compliance remains an issue. Additionally, larger doses increase therapeutic exposure and can result in high levels of the biologic in circulation within the bloodstream, which in turn can increase the potential for serious, off-target adverse reactions. From a pharmacological perspective, a preferred dosing regimen for most drugs is daily dosing, using the smallest effective dose to tightly maintain therapeutic exposures and prevent high levels of the biologic circulating in the bloodstream. Disease management is more effective with frequent small dosing, which, to date, remains elusive for biologics.

Prior Efforts to Deliver Biologics Orally

Numerous attempts have been made to deliver biologics orally but have been met with little success. Most attempts have taken a chemistry-based approach, which involve protecting the biologic from being digested and improving absorption by chemical agents. The best attempts have resulted in under 1% bioavailability. Only a few types of biologics, such as small peptides, which have long half-lives and wide clinically-desirable dosing windows, can be safely and effectively used with chemistry-based approaches. Larger molecular weight biologics, such as antibodies, are not conducive to this approach. In some cases, low bioavailability and dosing variability may be overcome by using much higher doses, such as a hundredfold the dose in the oral version as compared to the injectable, but doing so raises the risk of potential adverse effects as well as unintended health and safety consequences.

The RaniPill capsule has been designed to solve these challenges by taking an alternative approach to administering biologics orally.

Our Solution: The RaniPill Capsule

A Summary Description of the RaniPill Capsule

The RaniPill capsule is a versatile, orally ingestible pill for the administration of a broad range of biologics. Unlike chemistry-based approaches to the oral delivery of biologics, the RaniPill capsule is designed to autonomously inject biologics from the capsule into the intestinal wall.

The RaniPill capsule (purple) next to fish oil pills (yellow) and calcium pills (white).

Image depicts relative but not actual size of capsule or pills.

The RaniPill Advantage

We believe that several characteristics of the RaniPill capsule distinguish it from other technologies of which we are aware that enable the oral delivery of biologics, in development or approved. We anticipate these features will provide us with significant and sustainable competitive advantages. Differentiating attributes of the RaniPill capsule include:

- ***Drug-agnostic platform***: The RaniPill capsule is designed to enable oral delivery of a broad array of biologics, including antibodies, by injecting its microneedle into the intestinal wall. This technique enables the RaniPill capsule to protect the biologic from intestinal fluid and overcome the

body's natural mechanisms that serve to block a biologic from reaching the blood stream from the intestine. In contrast, biologics ingested orally are broken down in the harsh GI environment before they are absorbed into the blood stream. Accordingly, current technologies employed to release biologics within the intestinal lumen have been restricted to a limited number of smaller-sized molecules, typically certain peptides that offer a sufficiently wide clinically-desirable dosing window to allow for significant dosing variability.

- ***Optimized dosing regimen***: We expect that the convenience of the ingestible RaniPill capsule will enable a more frequent dosing regimen as compared to injections. For example, small daily doses can be effective to maintain therapeutic exposure within a narrow range and potentially help minimize adverse events, whereas larger less-frequent doses can lead to issues such as large variations in therapeutic exposure, which directly contributes to adverse events, loss of efficacy, and increased propensity for immunogenic response. Therefore, small frequent doses can be a preferred regimen, and we expect better compliance with the convenience of daily oral dosing with the RaniPill capsule.

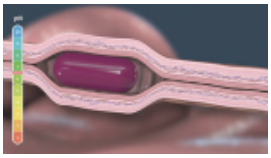
- ***High bioavailability***: Our studies conducted to date have demonstrated that the RaniPill capsule delivers biologics with high mean bioavailability, similar to subcutaneous injection, in the range of 40% to 78%, with high dosing accuracy. Bioavailability in the completed Phase 1 study was 65%. This level of bioavailability is significantly higher than that of currently marketed oral biologics, the best attempts of which have resulted in low bioavailability of peptides in the range of 1% or less. Due to the high bioavailability achievable using the RaniPill capsule, we anticipate a substantial reduction in the per-dose cost of APIs as compared to chemistry-based technologies currently used to enable the oral delivery of biologics.

- ***Patient preference***: Patient preference for an oral alternative is significantly higher than for an injection, a bias which has been confirmed through numerous published studies and patient surveys. Inconvenience, fear of needles, pain, injection site reactions and infection create significant barriers to injections and contribute to lack of compliance in treatment adherence.

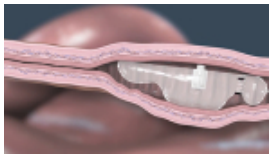
How the RaniPill Capsule Works

The RaniPill capsule is an orally ingestible capsule approximately the size of a fish oil pill. The RaniPill capsule is covered with a protective coating, which resists dissolution in the acidic environment of the stomach. Once the capsule enters the small intestine, dissolution of the protective coating leads to a series of steps that result in delivery of the biologic into the intestinal wall. These steps are illustrated in the figures below.

Cross Section of Intestinal Wall Illustrating Deployment of the RaniPill Capsule

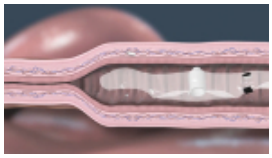


A: RaniPill capsule with protective coating in intestine.



B: Outer shell dissolves and the balloon starts to inflate as the reaction begins.

C: Pressure in the balloon pushes the dissolving microneedle into the intestinal wall.



D: Balloon deflates and is the only remnant that passes through, with the rest of the RaniPill absorbed or dissolved in its current version.

Panel A: As the RaniPill capsule exits the stomach and enters the small intestine, the higher pH environment of the small intestine causes the dissolution of the protective coating.

Panel B: After sustained exposure at a pH of around 6.5, the capsule dissolves, exposing a self-inflating balloon that is separated into two compartments. Reactants in the two compartments are separated by a pinch-valve, which dissolves upon exposure to intestinal fluids. The reactants mix upon dissolution of the pinch-valve to produce carbon dioxide, which inflates the balloon.

Panel C: Inflation of the balloon orients a microneedle contained within the balloon perpendicular to the intestinal wall. The pressure in the balloon injects the microneedle, which is smaller than a grain of rice, into the intestinal wall. In the moist tissue environment, the microneedle dissolves and the drug is rapidly absorbed into the bloodstream.

Panel D: The balloon immediately deflates upon microneedle delivery and is excreted through normal digestive processes.

Key features of the RaniPill capsule

Many of the distinguishing characteristics of the RaniPill capsule originate from internal research activities involving specific components, which have required, in many instances, multiple years to develop and optimize. We believe these efforts have enabled us to establish a broad intellectual property portfolio relating to the RaniPill capsule and the oral delivery of biologics. Several advanced features are detailed below.

- *Lubricious coating to facilitate swallowing* – The RaniPill capsule has a clear outer coating that hydrates upon interaction with saliva to become a lubricious hydrogel. This proprietary coating is designed to enhance ease-of-swallowing of the RaniPill capsule.

- *Protective coating to avoid deployment in the stomach* – Our proprietary pH-sensitive protective coating formulation enables the RaniPill capsule to maintain its integrity through the acidic environment in the stomach and to ensure that the moisture-sensitive release mechanism is protected from the moist environment of the stomach.

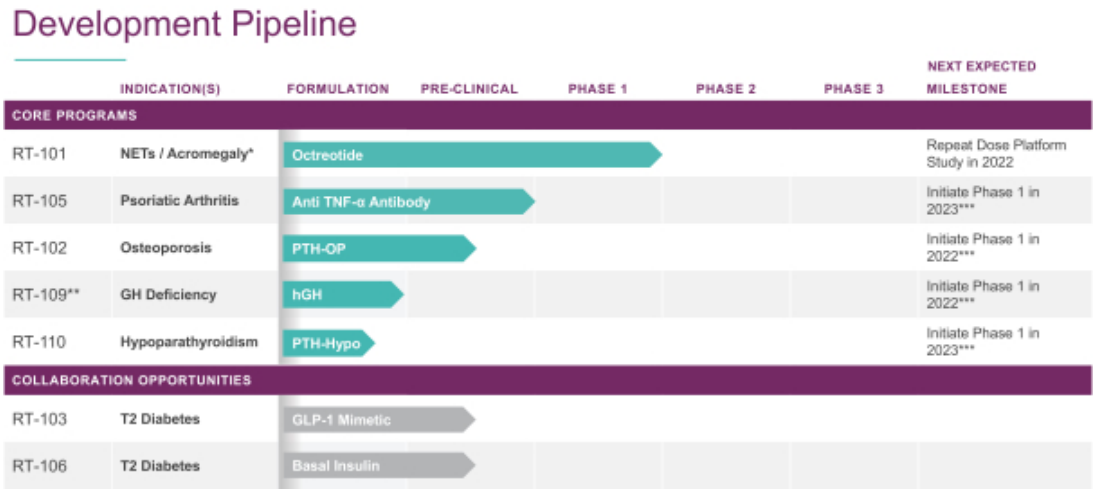
- *Drug-agnostic design to provide a standardized platform* – The RaniPill capsule is designed to deliver any molecule, including peptides, proteins or large antibodies, irrespective of molecular mass. This allows a single platform design to be used across multiple product candidates.

- *Self-inflating balloon to ensure reliable delivery* – The self-inflating balloon provides the optimal pressure to deliver the dissolvable microneedle. In addition, the novel design of the balloon positions the microneedle perpendicularly to the intestinal wall for reliable drug delivery, with up to 80% drug delivery success observed in our initial clinical study. The self-inflating balloon has been designed to minimize GI discomfort.

- *Proprietary microneedle design to preserve drug integrity and sterility* – The dissolvable microneedle is made from injectable-grade, sterile materials. The hollow microneedle is designed to accommodate the biologic formed into a microtablet of up to 3 mg. The sealed microneedle preserves the integrity and sterility of the biologic until the point of delivery.

Our Pipeline

The broad utility of the RaniPill capsule to enable the oral delivery of biologics provides us with a range of attractive development opportunities. We have prioritized these opportunities based on specific scientific, developmental, regulatory and commercial considerations to optimize our portfolio of targeted product candidates.



RT-XXX refers to the RaniPill capsule containing a biologic in a proprietary Rani formulation
*Each of these indications will require separate trials
**CCHN will have limited opportunity to negotiate for rights within China
***To follow submission and clearance of IND

Core Programs

Our five core programs are oral versions of octreotide, anti-TNF-alpha antibody, PTH-OP, hGH and PTH-Hypo. We selected these molecules because they are well-characterized and have been in clinical use for decades. We believe these drugs are compatible with our technology based on their dosage and dosing schedule. Most importantly, our core products, if approved, would give millions of patients a convenient, injection-free option to effectively manage their diseases.

RT-101: Octreotide for the treatment of NET and acromegaly

Market Overview and Currently Approved Products

Somatostatin is a peptide hormone involved in the regulation of the endocrine system. It acts as an inhibitory hormone and influences hGH release, insulin and glucagon secretion, regional blood flow, gastric acid secretion, intestinal mobility and neuronal activity. Octreotide, developed by Novartis AG and sold under the brand name Sandostatin, is a truncated and modified form of the human somatostatin that is a more potent mimetic with a significantly longer half-life than naturally occurring somatostatin. It is approved by the FDA and EMA for the symptomatic treatment of carcinoid syndrome, a condition involving NETs of the GI tract, as well as acromegaly, a disorder involving the excessive secretion of growth hormone.

The total patient population of these two disorders the United States is estimated to be around 200,000. Approximately 12,000 new cases of NETs and 3,000 new cases of acromegaly are diagnosed annually in the United States. The worldwide market for injectable somatostatin analogs is approximately $6.0 billion annually across both indications.

The current standard of care involves either multiple painful subcutaneous injections of Sandostatin daily, or an extended-release formulation of the drug delivered by a painful, deep intramuscular injection every four weeks. By introducing an oral version of octreotide, we aim to improve patients' quality of life, eliminate the burden and pain of these injections, and enable patients to more conveniently manage their disease.

Our Solution

Our most advanced product candidate, RT-101, is being developed for the treatment of NETs and acromegaly. We tested our oral formulation of octreotide in a Phase 1 clinical trial conducted in Australia, and are further optimizing the formulation in preparation for submitting an IND to initiate subsequent trials. We believe that RT-101 has the potential to expand the treatment paradigm beyond the limited reach of MYCAPSSA as we introduce this oral version of octreotide to patients. We have worldwide commercial rights to RT-101.

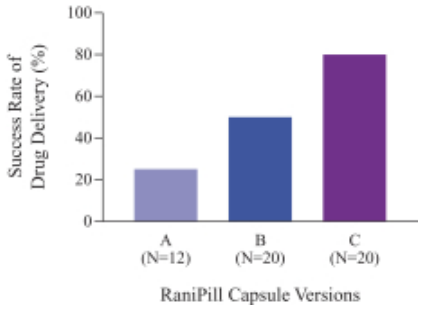
Phase 1 Octreotide Study

We conducted a Phase 1 clinical trial with the RaniPill capsule containing octreotide to evaluate safety and tolerability as primary endpoints and bioavailability as a secondary endpoint.

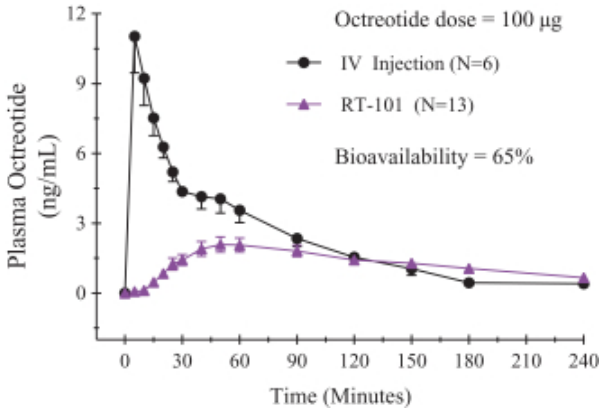
Sixty-two healthy subjects were enrolled in the Phase 1 clinical trial and 58 completed the study, six of whom received Sandostatin by IV injection (the IV group), and the remaining 52 subjects were given the RaniPill capsule containing octreotide in three separate groups (A, B and C). Three different versions of the RaniPill capsule, which were identical in all respects except for the size of the balloon, were tested in the three groups. In Groups A and B, the transit of the RaniPill capsule was tracked by taking several X-ray images at 15 to 20-minute intervals as needed to ascertain the time of deployment, which was followed by serial blood sampling for drug level analysis. In Group C, the primary objective was to determine the success rate of drug delivery. Thus, frequent fluoroscopic imaging was not conducted in Group C and blood samples were collected hourly between two and 10 hours after swallowing the RaniPill capsule. The drug delivery via RaniPill was considered successful when the presence of octreotide was confirmed in one or more of the hourly blood samples. This protocol greatly helped to reduce the subjects' exposure to radiation, as only a single X-ray image was taken between seven to eight hours after the RaniPill ingestion to verify that the device had deployed. The IV group was used as a control to enable determination of absolute bioavailability of orally delivered octreotide.

The results of the trial demonstrated that the RaniPill capsule was well tolerated by all participants, and no subjects had difficulty swallowing the pill. The capsule remnants were passed by all trial subjects by Day 7 and no serious adverse events were observed. The most common adverse events reported were lightheadedness, vasovagal syncope, diarrhea and headache, all of which were related to octreotide and resolved shortly after onset.

Results of this clinical trial also demonstrated that the RaniPill capsule was able to orally deliver levels of octreotide comparable to IV injection. The RaniPill capsule successfully delivered octreotide 25% of the time in Group A, 50% in Group B and 80% in Group C, as shown in the graph below. Based on the successful drug deliveries in Groups A and B, complete PK profiles were obtained from 13 subjects which were sufficient to compute bioavailability and PK parameters. Therefore, subjects in Group C were spared excessive exposure due to frequent X-ray imaging as additional complete PK profiles were deemed unnecessary, and only the success rate of drug delivery by the RaniPill capsule was determined in this group.



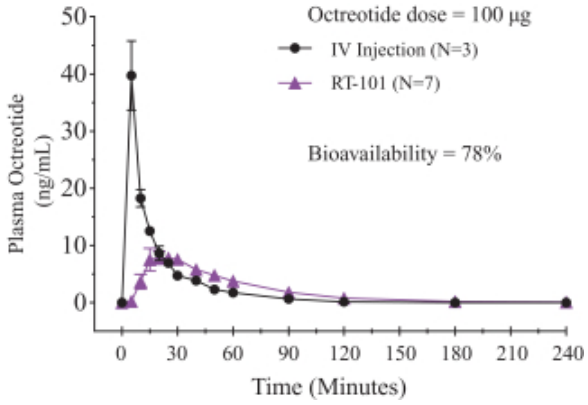
The PK data obtained with RT-101 in the study was within the same narrow range as the IV group, as is illustrated in the graph presented below.



Results of this clinical trial demonstrated that the RaniPill capsule succeeded in the oral delivery of octreotide to healthy volunteers. Bioavailability of RT-101 was determined from cohort A and B to be 65% relative to the IV group in the combined analysis of two of the three configurations test (n=13 patients from whom PK data was obtained). We believe this is the first demonstration of this high of bioavailability of an oral biologic in humans. To date, the best published bioavailability for oral octreotide is approximately 1%. We believe the results of the RT-101 Phase 1 clinical trial indicate that the RaniPill capsule can be used to deliver octreotide orally. In addition, they indicate that the RaniPill capsule may be used for other biologics.

A similar study conducted in awake canines shows that the data from the canine model, shown in the graph below, were consistent with the PK data obtained in humans. Bioavailability of RT-101 in the canine model was 78%, similar to the bioavailability obtained in humans.

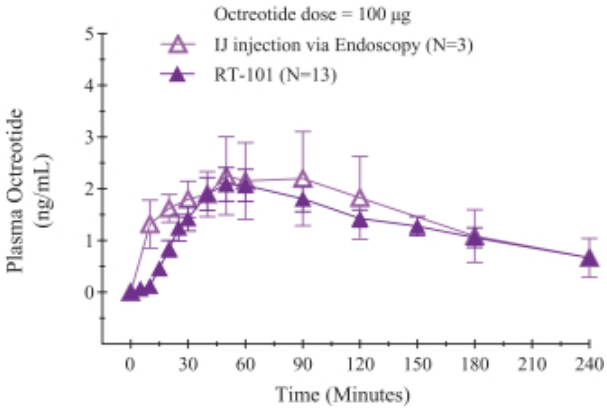
The bioavailability of octreotide in the canine model



Endoscopic delivery of octreotide into the jejunum of healthy volunteers

In addition to the Phase 1 clinical trial with RT-101, we evaluated PK of the commercial formulation of octreotide delivered via a direct injection into the jejunal wall. This study, which involved five healthy volunteers, determined the PK of octreotide injected endoscopically into the intestinal wall, mimicking the intended route of delivery by RaniPill capsule. Blood samples were taken at regular intervals for the four-hour period following drug administration. Results of the clinical trial are presented in the graphic below, showing a highly similar PK profile of octreotide delivered by a direct injection into the intestinal wall to that obtained with RT-101 in the Phase 1 clinical trial. These data also show that change in formulation of octreotide from liquid to solid form did not significantly affect the PK of the drug.

PK comparison of direct intrajejunal injection vs. RT-101



We are currently optimizing the formulation for RT-101, to potentially enable once daily dosing. Once optimized, we will test and verify the formulation in appropriate animal models. Once the formulation is validated in preclinical studies, we plan to initiate clinical trials for the development of RT-101.

RT-105: Anti-TNF-alpha antibody for the treatment of psoriatic arthritis

Market Overview and Currently Approved Products

Anti-TNF-alpha antibodies such as adalimumab are used to treat a range of inflammatory disorders and are among the largest selling class of pharmaceutical drugs globally as measured by revenue. Adalimumab, sold by AbbVie Inc. under the brand name Humira, generated sales of approximately $20.0 billion in 2019, making it the best-selling drug globally in 2019. Adalimumab is approved by the FDA and EMA to treat a range of autoimmune conditions, including psoriasis, rheumatoid arthritis and Crohn's disease. In the United States alone, there are an estimated 1.5 million patients with rheumatoid arthritis, 7 million with psoriasis and 3 million with Crohn's disease or ulcerative colitis. Currently, six Humira biosimilars have been approved by the FDA, but will not enter the U.S. market until 2023, per licensing agreements with the originator.

Patients who use adalimumab administer the drug through a painful subcutaneous injection once every two weeks. Despite the painful injections required to administer it, adalimumab is the best-selling drug globally in 2019. We believe that the development of an orally administered anti-TNF-alpha antibody represents a significant market opportunity and are actively engaged in advancing its delivery using the RaniPill capsule.

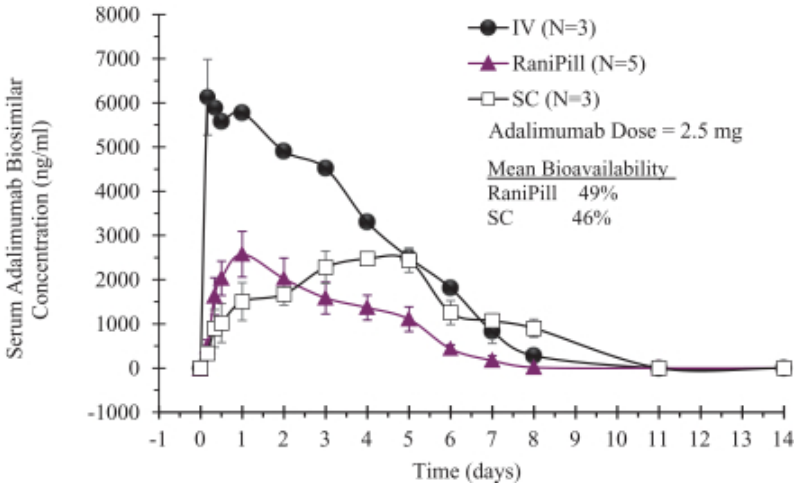
Our Solution: RT-105

We are developing RT-105 for oral administration of an anti-TNF-alpha antibody for the treatment of a host of inflammatory conditions. We have conducted preclinical studies with adalimumab (Humira) and an adalimumab biosimilar in porcine and canine models, respectively, detailed below, which confirm the bioavailability via the RaniPill capsule to be high, similar to a subcutaneous injection. We also conducted a study in healthy volunteers to assess the bioavailability of adalimumab (Humira) delivered endoscopically into the intestinal wall relative to subcutaneous injections. We are currently establishing a supply chain and plan to initiate a Phase 1 clinical trial of RT-105 in healthy volunteers in 2023. We have worldwide commercial rights to RT-105.

Preclinical and Clinical Experience

We evaluated the performance of the RaniPill capsule containing an adalimumab biosimilar in awake canines. Blood samples were collected for 28 days. The PK profile obtained with the RaniPill capsule was comparable to the profiles generated through subcutaneous administration of the adalimumab biosimilar. Bioavailability of adalimumab biosimilar via the RaniPill capsule was 49%, compared to 46% with subcutaneous injection. Data from this single dose study are presented in the following graph. These findings provide a successful demonstration of biologic delivery with high bioavailability enabled by the RaniPill capsule in awake animals, and importantly, the successful delivery of a large antibody.

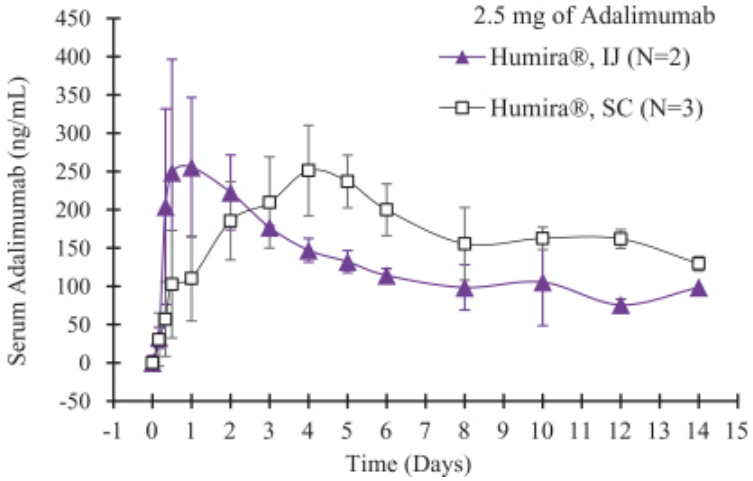
A study of adalimumab delivery comparing the RaniPill capsule to subcutaneous and IV injection



Endoscopic administration of adalimumab into the jejunum of healthy volunteers

To further investigate the absorption of adalimumab through the intestinal wall and assess whether the observations from preclinical studies translate to clinical trials, we conducted an endoscopic study in humans. The study involved 10 healthy volunteers and compared the PK of an approved formulation of adalimumab injected endoscopically into the jejunal intestinal wall, which mimics the RaniPill capsule route of administration, to that of an identical dose injected subcutaneously. Blood samples were obtained at prescribed intervals during 14-day study periods. The results of this open-label, single dose study are presented below.

PK comparisons of Humira delivered via jejunal injection and subcutaneous injection



Similar variability in serum concentrations of the drug were noted between both study groups. As shown in the graph, PK profiles were similar with no notable differences observed in either AUC or C_{max}. The mean AUC was 62.7 ± 11.4 µg/ml*day*kg/mg for the SC group and 45.0 ± 29.0 µg/ml*day*kg/mg for the IJ group. The C_{max} observed for the SC and IJ groups were 260 ± 75 ng/ml and 272 ± 115 ng/ml, respectively. T_{max} was achieved more quickly (0.75 ± 0.35 days) through the IJ route compared to that with SC route (5 ± 1 days) which is consistent with that data obtained in preclinical animal studies. No serious adverse events were noted in this study, and adverse events of headache and flu-like symptoms after IJ administration resolved within 48 hours. Similar drug exposures observed between the IJ and SC groups indicate the viability of delivering a daily oral dose of adalimumab via the RaniPill capsule, making this a potential alternative to painful SC injections.

These preclinical studies and the initial clinical study provide compelling evidence that the RaniPill capsule can maintain serum concentrations of the antibody that are comparable to the approved subcutaneous dosing method.

RT-102: Parathyroid hormone for the treatment of osteoporosis

Market Overview and Currently Approved Products

Osteoporosis is a bone disease where bone mineral density and bone mass decreases, leading to a decrease in bone strength that can increase the risk of fractures. Osteoporosis affects women and men of all races and ethnic groups. Osteoporosis can occur at any age, although the risk for developing the disease increases as you get older. For many women, the disease begins to develop a year or two before menopause. The prevalence of osteoporosis in the United States is approximately 10 million adults.

There are several medications available for the prevention or treatment of osteoporosis, however, PTH is the most-effective and the only bone-building treatment. PTH is a hormone secreted by the parathyroid glands that regulates serum calcium concentration and promotes bone growth. Teriparatide is a PTH analog administered as a once-daily injection to treat osteoporosis, first developed by Eli Lilly and Company and sold under the brand name Forteo. Another analog of PTH, Tymlos, was approved in 2017. Another teriparatide biosimilar injection, by Pfenex, Inc., was approved in 2019. Annual sales revenue of PTH analogs and biosimilars globally in 2019 was approximately $2.0 billion. In addition to the existing market, we believe there is an opportunity to expand the market by advancing RT-102 as a first line therapy for osteoporosis.

All of the existing bone-building drugs for osteoporosis are given as painful daily subcutaneous injections for up to two years. Patients often miss dosing due to the pain and inconvenience associated with injections. An oral version of PTH would have significant clinical utility in the treatment of osteoporosis. We believe an orally administered teriparatide represents a compelling development opportunity and would be life-changing for the millions of patients who depend on regular injections of PTH.

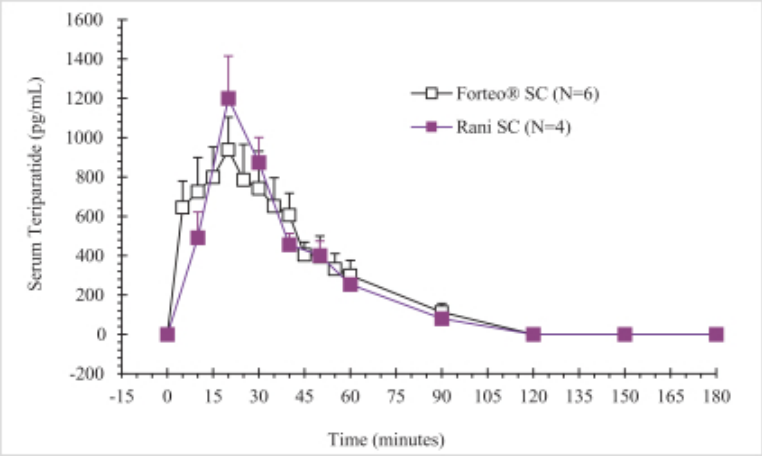
Our Solution: RT-102

We are developing RT-102 as an oral PTH for the treatment of osteoporosis. We believe our current PTH formulation is optimized for use in the RaniPill capsule for the treatment of osteoporosis, and we are currently conducting preclinical studies with RT-102. We plan to initiate a Phase 1 clinical trial with RT-102 in healthy volunteers in 2022. We have worldwide commercial rights to RT-102.

Preclinical Studies

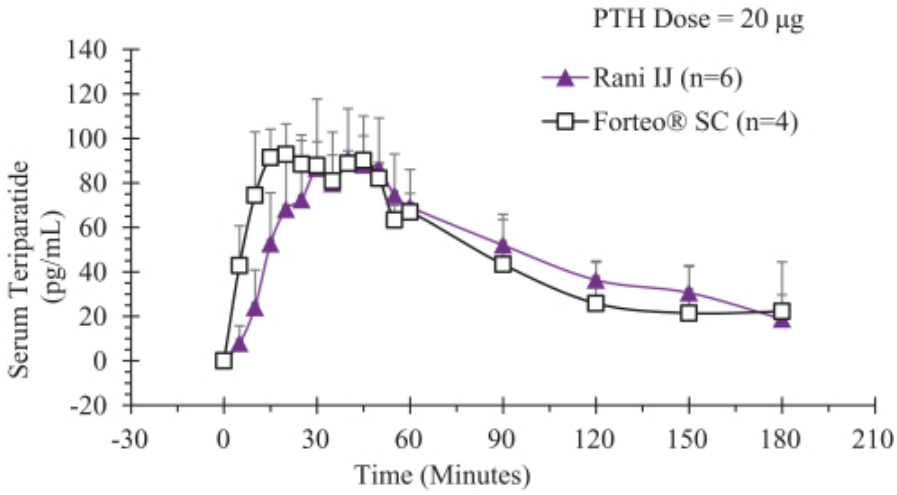
Our initial study compared the PK profile of Rani-formulated teriparatide administered subcutaneously to a control group that received an equivalent dose of commercial formulation of teriparatide, or Forteo, subcutaneously in awake canines. Serial blood samples were collected for a three-hour period following dosing. Results of this study are shown in the following graph. AUC for the Forteo SC group was 45 ± 7 and 42 ± 5 ng/ml*min-1 for the RaniPill SC group. The results of this study provided evidence that the PK profile of teriparatide prepared with our formulation was largely comparable to Forteo.

A comparison of PK profile of subcutaneous teriparatide prepared from our formulation vs. Forteo



We conducted a second preclinical study in anesthetized juvenile swine, which involved an assessment of IJ delivery of our teriparatide formulation as compared to an equivalent dose of a subcutaneous injection of Forteo. PTH was administered directly into the jejunum. The second group received an equivalent dose of Forteo via subcutaneous injection. Blood samples were collected for up to three hours after drug dosing for evaluation of serum teriparatide levels. Cmax 113 ± 8 pg/ml (n=4 Forteo) and 111 ± 27 pg/ml (n=6 IJ); AUC 8555 ± 1939 pg/ml/min (n=4 Forteo) and 8379 ± 2022 pg/ml/min (n=6 IJ) in SC and IJ groups, respectively. Data from this study are presented in the graph below. This study demonstrated that, in the porcine model, both our PTH formulation and Forteo have comparable PK profiles.

A comparison of intrajejunal and subcutaneous delivery of teriparatide in swine



We are currently characterizing the PK profile of RT-102 in awake canine models. In addition, we are conducting preclinical studies with RT-102 in an animal model of osteoporosis. In parallel, we are preparing to conduct a Phase 1 clinical trial with RT-102 in 2022. Completion of these PK and PD studies will inform the design of subsequent clinical trials.

RT-109: HGH for the treatment of growth hormone deficiency

Market Overview and Currently Approved Products

Growth hormone is a peptide that is secreted by the pituitary gland and promotes cell growth, proliferation and regeneration. This anabolic hormone also stimulates insulin-like growth factor 1 which has growth enhancing effects on a broad set of tissues. A recombinant form of hGH is used to treat juvenile growth disorders and adult growth hormone deficiency, which affect between 30,000 and 80,000 people in the United States. Treatment involves painful daily subcutaneous hGH injections often over multiple years.

Genentech, Inc., now part of Roche Holding AG, pioneered the use of recombinant hGH, receiving FDA approval for its commercial sale in 1985. HGH is currently available from a number of sources and is sold by Eli Lilly and Company under the brand name Humatrope and by Genentech, Inc. under the brand name Nutropin. Worldwide sales of hGH were $4.0 to $6.0 billion in 2019 and are projected to reach $11.0 billion by 2028.

Because patients typically need daily injections of hGH over several years, we believe that a once-daily oral version would transform treatment regimens for both pediatric and adult patients suffering from growth hormone deficiency.

Our Solution: RT-109

We are developing RT-109 for oral administration of hGH for the treatment of growth hormone deficiency. To advance our RT-109 program, we are collaborating with CCHN on creating a formulation of recombinant hGH for the RaniPill capsule. We have worldwide commercial rights to RT-109. CCHN will have a limited opportunity to negotiate with us for exclusive rights within China and has a limited right of first refusal with respect to third-party offers for rights within China.

We will initiate preclinical PK studies once our hGH formulation has been optimized.

RT-110: PTH for the treatment of hypoparathyroidism

Market Overview and Currently Approved Products

Hypoparathyroidism is a rare condition of low levels of serum PTH resulting in low calcium levels in the blood. PTH is currently approved for the treatment of hypoparathyroidism by the FDA and EMA and requires lifelong daily injections but has suboptimal efficacy. The prevalence of hypoparathyroidism in the United States is approximately 115,000 people.

Our Solution: RT-110

We are developing RT-110 for oral delivery of PTH for the treatment of hypoparathyroidism. Treatment of hypoparathyroidism requires consistent and sustained plasma levels of PTH. We intend to initiate preclinical PK studies in animals once our long-acting PTH formulation has been optimized. We have worldwide commercial rights to RT-110.

Collaboration Opportunities

We envision complementing our core programs with robust partnering activities to maximize the value inherent in the RaniPill capsule.

RT-106: Basal insulin for the treatment of Type 2 diabetes

Market Overview and Currently Approved Products

The CDC estimates that approximately 34 million Americans have diabetes (about one in 10). Of these, 90% to 95% suffer from Type 2 diabetes, which is characterized by progressive hyperinsulinemia (pre-diabetes or insulin resistance) followed by hyperglycemia as a result of the body's inability to properly respond to insulin and, eventually, produce sufficient insulin. Diabetes has no known cure and can give rise to a host of serious and often life-threatening complications, including cardiovascular disease, neuropathy, retinopathy, cognitive impairment and stroke. This results in estimated economic costs totaling over $300.0 billion in United States annually.

In addition to oral anti-diabetic medications and lifestyle changes, patients with advanced Type 2 diabetes manage their blood sugar by administering painful daily injections of one or both types of insulin: (1) a single injection of a longer-acting insulin called basal insulin, which provides a steady baseline of insulin to offset insulin resistance and reduce hyperinsulinemia; and (2) a rapid-acting insulin called mealtime insulin, which is added in the later stages of the disease and injected several times daily approximately 20 to 30 minutes before the ingestion of a meal. Worldwide sales of basal insulin totaled an estimated $11.0 billion in 2019.

The market for basal insulin would further expand in the currently unserved 'pre-diabetic' market segment if an oral version of basal insulin were available. According to the CDC, 88 million (about one in three) Americans are pre-diabetic, a health condition in which blood glucose levels are higher than normal for long periods as a result of progressing insulin resistance. Clinical research has indicated that early intervention with daily injections of basal insulin could prevent or slow down disease progression in pre-diabetic patients, as steady-state, low levels of insulin would reduce the hyperinsulinemia caused by insulin resistance. Despite this knowledge, pre-diabetic patients currently are not prescribed basal insulin or indeed any injectable as a first-line therapy, and instead advised lifestyle changes and prescribed only oral anti-diabetic medications to manage the disease. However, in a market research study we commissioned, we found that approximately 81% of surveyed endocrinologists would initiate basal insulin therapy for diabetic patients earlier if an oral option were available.

Our Solution: RT-106

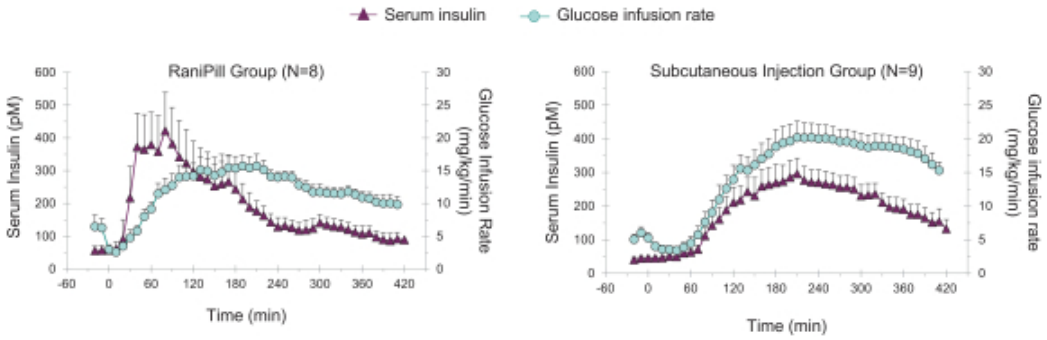
We are developing RT-106 as an oral basal insulin for the treatment of diabetes. We believe the RaniPill capsule would have significant benefit to the millions of people living with Type 2 diabetes, who inject longer-acting basal insulin on a daily basis, through the development of RT-106 as a once-daily oral basal insulin pill. Additionally, our RT-106 program aims to address a new market of unserved pre-diabetic patients who should be using basal insulin but eschew injections until their disease progression necessitates it. In both cases, basal insulin represents a compelling development opportunity for the RaniPill capsule, and our strategy is to pursue partnership opportunities with large pharmaceutical companies to co-develop and commercialize an oral version of basal insulin. Based on a survey we commisioned, we found that 87% of patients using insulin were likely to switch to a once-daily pill if available.

Several long-acting insulin biosimilars are available in the market today, as patents for both leading brands (Lantus and Levemir) have expired. We believe that any of these biosimilars may potentially be reformulated for oral delivery via the RaniPill capsule. In addition, because of the solid form of the drug in the RaniPill capsule, generic or rapid acting insulin can be converted to a long-acting formulation using conventional pharmaceutical approaches. We are currently exploring various options for the development of the oral basal insulin therapy for evaluation in both established Type 2 diabetics as well as in pre- and early diabetic patients. We currently retain all global commercial rights for RT-106, however we intend to partner with a large pharmaceutical company.

Preclinical Studies

As a proof-of-concept to demonstrate the viability of the RaniPill capsule to deliver insulin orally, we evaluated the efficacy of fast-acting human insulin delivered via the RaniPill capsule in a preclinical study, detailed below. In this study, we compared the PK and PD profiles of fast-acting human insulin delivered using the RaniPill capsule against those achieved through the subcutaneous route of administration in anesthetized juvenile swine under a euglycemic glucose clamp. Serum samples were taken at frequent intervals over a seven-hour period to quantify serum insulin levels (PK) with glucose infusion rates adjusted to maintain plasma glucose levels between 60 and 80 mg/dl (euglycemic glucose clamp). The changes in glucose infusion rates reflect the glucose disposing action of insulin (PD). The outcome of these studies is presented below.

Insulin PK/PD data in juvenile swine administered insulin via the RaniPill vs. subcutaneously. Insulin dose = 20 IU.



These data demonstrate that fast-acting insulin was successfully delivered via the RaniPill capsule, comparable to a subcutaneous injection. The AUCs for the RaniPill capsule and SC group were 83± 18 and 81 ± 10 pmol/L.min, respectively, and were not statistically different. Consistent with the results of other studies, T_{max} was shorter for the RaniPill capsule (139 ± 42 minutes) than for subcutaneous administration (227 ± 24 minutes), reflecting the more rapid uptake of drugs delivered by the RaniPill capsule as compared to the subcutaneous route.

RT-103: GLP-1 mimetic for the treatment of Type 2 diabetes

Market Overview and Currently Approved Products

GLP-1 mimetics are used to treat Type 2 diabetes by increasing insulin secretion and suppressing glucagon secretion. Several large pharmaceutical companies market GLP-1 mimetics, and the global combined sales of these were estimated to be $11.0 billion annually in 2019.

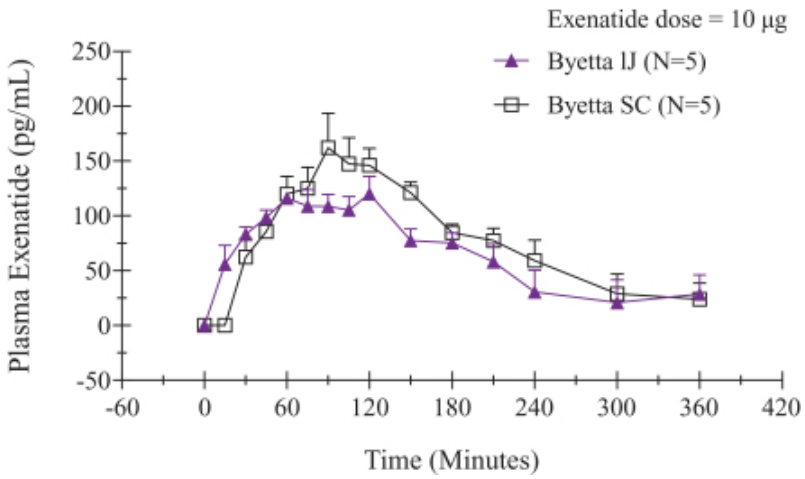
Our Solution: RT-103

We are developing RT-103 for oral administration of a GLP-1 mimetic for the treatment of Type 2 diabetes. Based on a survey we commissioned, we found that 89% of endocrinologists prescribing GLP-1 mimetics were likely to switch their prescription to a once-daily pill if available. We believe RT-103 would be more appealing to patients than the injectable form. While we continue to optimize our formulation to increase the drug half-life, we plan to pursue partnership opportunities with large pharmaceutical companies to co-develop and commercialize RT-103.

Clinical Study

We conducted an endoscopic study with Byetta, a branded form of exenatide, a GLP-1 mimetic, in humans. The study involved five healthy volunteers, who were dosed via a jejunal injection and, after a washout period, a subcutaneous injection. The results are presented below, showing nearly identical PK profiles between subcutaneous and jejunal injection, which mimics the route of administration of the RaniPill capsule. The C_{max} for the IJ group was 139 ± 6 pg/ml and 184 ± 23 pg/ml for the SC group. The AUC for the IJ group was 27 ± 3 ng/ml*min and 23 ± 2 ng/ml*min in the SC group. Jejunal wall delivery of exenatide mimicking delivery by RaniPill capsule yielded a robust PK profile. T_{max} in the two groups was highly similar (IJ: 90 ± 13 min, SC: 96 ± 11 min, p=0.8)

PK comparisons of Byetta delivered via intestinal versus subcutaneous injection



Due to the size, cost and complexity of clinical trials required to address the diabetes market, our strategy is to partner with large pharmaceutical companies to create oral versions of injected diabetes medications, such as basal insulin and GLP-1 mimetics.

Safety Studies with the RaniPill Capsule—Preclinical and Clinical Experience

Seven-day repeat-dose GLP study

Tolerability and reliability of the RaniPill capsule was assessed in a multi-day administration study in canines done under GLP guidelines. The RaniPill capsule containing octreotide was orally administered to eight animals (Test group) and another four animals received an enteric coated capsule containing nonpareil sugar (Control group), for seven consecutive days followed by a seven-day washout period. Blood samples were collected after each RaniPill capsule was administered to confirm successful payload delivery by measuring plasma concentrations of the drug. Plasma samples analyzed from test group animals showed that 77% of the devices administered successfully delivered the drug, with seven of eight animals having at least five successful payload deliveries over the seven-day dosing period. Ten percent of test articles (six capsules) were deployed in the stomach, and one of these capsules delivered the drug through the stomach rather than the intestinal tissue (which was counted as a successful delivery). The RaniPill capsule was well-tolerated by all animals in the study. There were no clinical adverse effects observed in either group throughout the study duration. The GI tract was critically evaluated in all animals and no significant macroscopic or microscopic abnormalities were observed in any animal. These results demonstrated that the RaniPill capsule can be consumed on a daily basis for seven days, deploy within the targeted region of the small intestine without causing any adverse clinical effects and its remnants can be excreted without complications.

A platform study in humans confirms reliable deployment of the RaniPill capsule in both fed and fasted states

In 2018, we conducted a clinical assessment of the RaniPill capsule to evaluate the device when orally administered and to compare device performance in fed and fasted states in 20 healthy volunteers, divided into two groups of 10. In one group, the RaniPill capsule was administered under fasting conditions, while the other group was given the RaniPill capsule 45 minutes after consumption of a standardized meal. X-ray imaging was used to monitor transit of the device as well as its deployment. The evaluation involved the use of capsules that were not equipped with a drug or needle. The goals of this study were tolerability and effects of food on the RaniPill capsule's functionality, as measured by the time required for the RaniPill capsule to reach and deploy in the small intestine.

The deployment time was longer in the fed group than in the fasted group. However, X-ray imaging indicated that this did not impact the functionality of the RaniPill capsule. No volunteers reported difficulty in swallowing the capsule, nor did any study participant experience pain or sense an awareness upon balloon deployment. Volunteers were again X-rayed between 72 and 96 hours after capsule ingestion and all RaniPill capsule remnants had been excreted. In conclusion, the results of this study indicated that the RaniPill capsule was well-tolerated in both groups and presence of food did not affect the functionality of the RaniPill capsule.

Clinical Development and Regulatory Pathway of the RaniPill Capsule

Based on the guidance we have received from CDRH and OCP, we will study the initial safety and tolerability of the RaniPill capsule in an IDE study, in an effort to enable a more standard regulatory pathway for our pipeline of product candidates.

While CBER and CDER may ask for additional testing for a specific biotherapeutic or disease, our initial goal is to evaluate the safety of the RaniPill capsule independent of any drug. In a pre-submission meeting with CDRH and OCP and representatives from CDER, we reached agreement on the initial requirements for establishing safety and tolerability of the RaniPill capsule for further clinical evaluation. Preclinical studies and clinical trials will be conducted with the RaniPill capsule containing an inert tracer in place of a drug, to determine the reliability of delivery and the initial safety of the platform. In support of the IDE study, we will first conduct a repeat-dose GLP study in canines to assess the safety and tolerability of the RaniPill capsule. We would then conduct the IDE study to evaluate the safety and tolerability of the RaniPill capsule in an eight-week healthy volunteer study (n=40) with daily administration of the RaniPill capsule. The study will also evaluate the effect of food on the delivery performance of the RaniPill capsule.

After completion of the IDE study, we plan to create a Master File for the RaniPill capsule with CDRH, which would include the following:

- Facilities and manufacturing procedures and controls;
- Verification and validation reports;
- Biocompatibility test data;
- GLP canine study data; and
- IDE clinical study data.

The information in the RaniPill Master File will be applicable to any biologic and would be incorporated by reference in subsequent applications to CDER or CBER for our future product candidates.

Our current pipeline consists of well-characterized biologics that have been in clinical use for several years. We believe that we may be able to leverage the FDA's prior conclusions of safety, purity and potency for certain approved biologic products in our own BLA. The degree to which we may be able to reduce the burden on our own development will depend on whether the API is the same as the original approved product, particularly for products originally approved as NDAs and now deemed to be biologics. We intend to have this clarified on a product-by-product basis in pre-IND meetings with the FDA. We intend to have the first of these pre-IND meetings in the second half of 2021.

Our Team

We are led by an experienced management team with substantial scientific, formulation and drug development expertise in a number of therapeutic areas including immunology, gastroenterology, cardiology, metabolic diseases and oncology. The RaniPill capsule development and manufacturing is led by a highly experienced team with deep expertise in engineering, material science, anatomy, physiology, manufacturing and automation. Our management team members have held successful and diverse roles leading research, clinical development, product development, strategy, corporate development and operational functions at companies such as GlaxoSmithKline plc., Gilead Sciences, Inc., VIVUS Inc., Edwards Lifesciences Corp., Danaher Corp., Affymetrix, Inc. and Elan Corporation plc. Members of our leadership team have been involved in the discovery, development and commercialization of multiple marketed products across various therapeutic areas, including Tykerb, Romozin, Avodart, Zyban, Ranexa and Lexiscan. We were founded by, Mir Imran, our Executive Chairman and former President and Chief Executive Officer. With background in medicine and engineering, Mir Imran began his career as a healthcare entrepreneur in the late 1970s and has founded more than 20 life sciences companies since, more than half of which have been acquired. Mir Imran's passion is creating novel technologies that have the potential to positively impact the lives of millions of patients, and he has become one of the leading inventors and entrepreneurs in the field. Mir Imran is perhaps most well-known for his pioneering contributions to the first FDA-approved automatic implantable cardioverter defibrillator. Our Chief Scientific Officer, Mir Hashim, a veteran of the pharma industry, has a Ph.D. in pharmacology and led research and development teams at GSK from 1990-2008. Our leadership is complemented by a team of biologists, engineers, manufacturing and automation experts, many with post-graduate degrees.

Evaluation Agreements

Novartis Evaluation Agreement

In May 2015, we entered into an Evaluation and First Rights Agreement, or the Novartis Agreement, with Novartis Pharmaceuticals Corporation, or Novartis, in which we agreed to perform certain specified research for Novartis to evaluate two specified Novartis compounds with our oral drug delivery technology. In August 2019 and July 2020, we amended the agreement to focus on one compound. Under the agreement, we granted Novartis an exclusive, fully paid-up license to the intellectual property it generates for the sole purpose of delivering that compound via any delivery route other than through use of any microtablet. Novartis will own intellectual property generated related to that compound and we will own all other intellectual property regardless of inventorship. We are currently in the process of completing our own internal testing of higher capacity payloads in the RaniPill capsule which will be shared with Novartis pursuant to the July 2020 amendment. We expect to provide this data by the end of 2021. Afterwards, Novartis will have a right of first negotiation to obtain rights to research, develop, manufacture and commercialize a specified class of biologics formulated with our delivery technology (Novartis Field) for a period of four months. If we and Novartis do not reach an agreement in this period, for a period of another 6 months, Novartis will have the opportunity to make a topping bid on any third-party transaction proposal in the Novartis Field. Unless earlier terminated, the Novartis Agreement will expire upon the expiration of the last-to-expire time periods for which Novartis has a right of first negotiation or a right to make a topping bid. Prior to these periods, Novartis may terminate the Novartis Agreement at any time for convenience, and we and Novartis may terminate the Novartis Agreement for the other's party's uncured breach.

Novartis has paid us an aggregate of $7.0 million and made an equity investment of approximately $5.0 million in our Series C preferred unit financing. We do not expect any future payments under the Novartis Agreement unless we and Novartis negotiate a new agreement constructed around a higher-capacity payload system.

Takeda Evaluation Agreement

In November 2017, we entered into an Evaluation and First Rights Agreement, or the Takeda Agreement, with Shire International GmbH, which was subsequently acquired by Takeda Pharmaceutical Company Limited, or Takeda. Pursuant to the Takeda Agreement, which was amended in May 2019 and April 2020, we agreed to perform certain specified research for Takeda to evaluate our oral drug delivery technology with Takeda's recombinant Factor VIII therapeutic. We own all intellectual property generated under the Takeda Agreement and we granted Takeda a non-exclusive, fully paid-up license to exploit pharmaceutical products delivered via any delivery route other than through use of any microtablet. We also grant Takeda a right of first negotiation to obtain a worldwide, exclusive license under our intellectual property related to RT-108, which right Takeda may exercise at any time prior to 30 days after the date that we deliver Takeda a final report summarizing the results of our research activities. If we and Takeda do not reach an agreement in this period, for a period of another 6 months, Takeda will have the opportunity to make a topping bid on any third-party transaction proposal for the use of our delivery technology with a recombinant or plasma-derived Factor VIII therapeutic. Prior to these periods, Takeda may terminate for convenience upon 30 days' notice, and we and Takeda may terminate for the other party's material uncured breach. In addition, if we do not enter into an agreement with Takeda and we subsequently enter into an agreement with a third party for the use of our delivery technology with a recombinant or plasma-derived Factor VIII therapeutic, we will pay Takeda a portion of the consideration we receive from that third party. On May 21, 2021, Takeda gave written notice of their intention to terminate the agreement for convenience. We do not expect any future payments under the Takeda Agreement.

Changchun High & New Technology Industries Evaluation Agreement

In August 2017, we entered into an Evaluation and Right of First Refusal Agreement, or the CCHN Agreement, with CCHN in which we agreed to perform and share data from preclinical testing of RT-109. We will provide CCHN with reports and data resulting from our performance of our preclinical testing and CCHN will have a non-exclusive right to use this information in connection with specified activities. CCHN will own intellectual property generated under the CCHN Agreement that comprises of or relates to certain materials and assays provided by CCHN and we will own all other intellectual property generated under the CCHN Agreement. Following the completion of the evaluation program, we and CCHN will negotiate, for a period of 90 days, an agreement to provide CCHN with commercial rights for RT-109 in China. Additionally, we granted CCHN a right of first refusal with respect to commercial rights for RT-109 in China for a period of two years following the completion of our preclinical testing, pursuant to which CCHN will have a period of 90 days following our receipt of a third party proposal for commercial rights for RT-109 in China to make a competing offer for such rights. The CCHN Agreement will expire upon the expiration of CCHN's right of first refusal, or up to ninety days longer if CCHN makes a bid under its right of first refusal. Prior to these periods, CCHN may terminate for convenience upon 30 days' notice, and we and CCHN may terminate for the other party's material uncured breach.

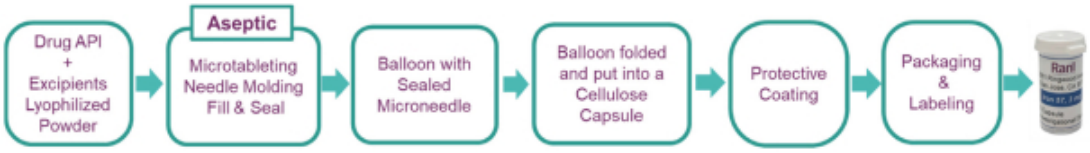
There are no payment obligations under the CCHN Agreement.

Manufacturing and Quality Assurance

We currently manufacture and assemble RaniPill capsules at our facility in San Jose, California. We also inspect, package and ship finished products to support our clinical trials from this facility. We are intentionally pursuing a vertically integrated manufacturing strategy, which we believe offers significant advantages, including rapid product iteration, control over our product quality and the ability to rapidly scale our manufacturing capacity. This capability allows us to develop future generations of products while maintaining the confidentiality of our intellectual property.

Each RaniPill capsule is assembled through a process which involves a series of integrated, well-developed and highly reproducible steps, as shown below, that have been optimized to consistently produce capsules of high reliability. A lyophilized drug substance, combined with excipients specific to the drug, is compressed into a solid microtablet form. The microtablet is sealed inside the microneedle and is then packaged in a tiny vial under aseptic conditions. The vial containing the microneedle is incorporated in the RaniPill capsule, which is given a protective coating. Each of these steps in the manufacturing process has been subjected to rigorous testing and process qualification procedures to ensure manufacturing consistency.

The RaniPill capsule manufacturing process



We rely on non-exclusive, third-party relationships with several cGMP manufacturers for the drug API. We maintain in-house capabilities related to the aseptic manufacturing of drug microtablets, filled inside sterile microneedles, following FDA cGMP guidelines. Our personnel have significant technical, manufacturing, analytical, quality, regulatory and project management experience to oversee our third-party manufacturers and to manage in-house manufacturing and quality operations in compliance with regulatory requirements.

The current semi-automated manufacturing process will be sufficient to support our currently planned clinical trials. In parallel, we are in the process of automating the entire manufacturing process, which we anticipate being complete by the time the RaniPill capsule is commercialized.

Commercialization Plan

Currently we do not have any approved products. We intend to either develop the commercialization infrastructure as our product candidates are approved, or partner with pharma companies for commercialization. The key markets for our products, once approved, are the United States, Europe and Asia.

Coverage and Reimbursement

Sales of our products in the United States will depend, in part, on the extent to which the costs of the products are covered by third-party payors, such as government health programs, commercial insurance and managed health care organizations. The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product is typically separate from the process for setting the price of such a product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that the reimbursement rate will be adequate.

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As such, one third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

Competition

Our industry is highly competitive and subject to rapid and significant technological changes as researchers learn more about diseases and develop new technologies and treatments. Key competitive factors affecting the commercial success of product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement.

Broadly speaking, we will face competition from current and future (generic or biosimilars) manufacturers of the branded injectable versions of our pipeline drugs, such as AbbVie Inc., Eli Lilly and Company, Novartis AG, Roche Holdings AG, etc. We believe that oral biologics have the potential to take significant market share from injectable therapies and expand existing markets by reaching new patient populations that are averse to taking injections.

We are aware of a few companies that are pursuing oral biologics through either device-based or chemistry-based technologies. Early stage device-based technologies such as the SOMA and LUMI from the Novo Nordisk-MIT collaboration were reported to be in preclinical stages several years ago. Chemistry-based oral delivery companies include Oramed Pharmaceuticals, Inc., Entera Bio Ltd., Applied Molecular Transport Inc., Protagonist Therapeutics, Inc., and two with recently approved oral peptide products – Chiasma, Inc. (*Mycappssa*) and Novo Nordisk A/S (*Rybelsus*). Chemistry-based approaches have limited applications because they work only for small peptides and, even then, with less than 1% bioavailability. In contrast, our versatile technology is designed to deliver biologics, from small peptides to large proteins, irrespective of molecular mass and with bioavailability similar to that of injections.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain protection for our current and future product candidates and the technologies used to develop and manufacture them. Our policy is to seek to protect our proprietary position through patents, trademarks, trade secrets, domain names, intellectual property assignment agreements, confidentiality agreements and facility and network security measures. Some of our intellectual property is in-licensed. We believe that our intellectual property portfolio provides good coverage for our current and pipeline product candidates.

Patents

We have built a patent portfolio globally around several aspects of the current and future generations of our technology. We file new patent applications as we conduct research and development, initiate new programs and monitor the activities of others. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date if all fees continue to be paid. In some cases, the term of a U.S. patent may be shortened by terminal disclaimer, such that its term is reduced to end with that of an earlier-expiring patent. In some cases, U.S. patent term can be adjusted to recapture a portion of delay by the U.S. Patent & Trademark Office (USPTO) in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both.

Foundational Patent Family

Our foundational patent family has a priority date in 2009, with patent term expected to extend into at least 2030 if all fees are paid. This patent family claims many device aspects of the RaniPill capsule, and the delivery of a wide variety of biologics using the RaniPill capsule. Patents and patent applications in this core family number more than 200. As of June 1, 2021, this patent family included 64 patents issued in the United States and 94 patents issued in other jurisdictions (in Australia, Austria, Belgium, Canada, China, Denmark, Finland, France, Germany, India, Ireland, Italy, Japan, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), with applications pending in the United States, Australia, Canada, China, Europe, India, and Japan.

Device aspects of the RaniPill capsule and methods of using the RaniPill capsule are claimed in U.S. Patents 8,721,620, 8,759,284, and 8,562,589, and in PCT/US2010/062070 and PCT/US2010/062073, and in their respective progeny. Devices containing specific biologics and methods of delivering them are claimed in U.S. Patents 8,764,733, 8,809,269, 8,809,271, 8,846,040, 8,969,293, 8,980,822, 9,259,386, 9,283,179, 9,284,367, 9,402,806, 9,402,807, 9,415,004, 9,629,799, 9,861,683, and in PCT/US2012/044441 and PCT/US2014/024385, and in their respective progeny.

Microtablet Patent Family

Our microtablet patent family includes claims covering the microtablets delivered by the RaniPill capsule. This patent family has a priority date in 2014, includes several dozen patents and patent applications and is expected to have patent terms extending into at least 2035 if all fees are paid. As of June 1, 2021, this patent family included 7 patents issued in the United States and 1 patent issued in Australia, with applications pending in the United States, Australia, Canada, China, Europe, India, and Japan.

Microtablets having various characteristics and containing various biologics are claimed in U.S. Patents 10,098,931, 10,058,595, 10,039,810, and 10,220,076, and in PCT/US2016/030480, PCT/US2016/031548, and PCT/US2016/050832, and in their respective progeny.

Additional Patent Families

We own numerous additional patents and patent applications outside of the foundational and microtablet patent families, with claims to additional biologics, pharmacologic properties of various biologics and various next generation devices, with applications pending in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, Mexico, and South Korea. Patents in these families are expected to expire between the late 2030s and early 2040s if all fees are paid.

Trademarks

We have several trademark registrations and applications in 10 jurisdictions.

Trade Secrets and Other Proprietary Information

We rely in part on keeping our trade secrets and other proprietary information confidential. We protect proprietary information by executing confidentiality agreements and intellectual property assignment agreements prior to commencement of our relationship with our employees, consultants, scientific advisors, sponsored researchers, contractors and other collaborators. Confidentiality agreements limit use and disclosure of our confidential information during and after the relationship. Intellectual property assignment agreements require that all inventions resulting from work performed for us or relating to our business and conceived during the period of the relationship are our exclusive property. We take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

For information regarding the risks related to our intellectual property, see the section titled “Risk Factors— Risks Related to Our Intellectual Property.”

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing.

U.S. Biologics Regulation

In the United States, the FDA regulates biological products under the FDCA and the PHSA and their implementing regulations. Biological products are also subject to other federal, state, local and foreign statutes and regulations. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may result in delays to the conduct of a study, regulatory review and approval or subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license suspension or revocation, refusal to allow an applicant to proceed with clinical trials, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations or penalties.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices, and other clinical trial-related regulations to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with cGCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to

humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns, non-compliance, or other issues affecting the integrity of the trial. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial and, once begun, issues may arise that could cause the trial to be suspended or terminated.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB or ethics committee for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined.

- Phase 1. The investigational product is typically introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, to identify possible side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2. The investigational product is typically administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- Phase 3. The investigational product is typically administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for physician approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and further document clinical benefit in the case of drugs approved under Accelerated Approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the biologic, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

The FDA, the sponsor or the IRB or may suspend a clinical study at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. Additionally, if the trial is being overseen by a data safety monitoring board or committee, this group may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as interim data suggesting a lack of efficacy.

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include

all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Under PDUFA, as amended, each BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies, which is adjusted on an annual basis. The FDA has 60 days from the applicant's submission of a BLA to either issue a refusal to file letter or accept the BLA for filing, indicating that it is sufficiently complete to permit substantive review. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval, and may require additional preclinical, clinical or other studies before it accepts the filing.

Once a BLA has been submitted, the FDA's goal is to review standard applications within 10 months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured to determine whether the facilities comply with cGMPs. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies and/or other significant and time-consuming requirements related to preclinical studies and manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. Even if such data and information is submitted, the FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. The FDA may also place other conditions on approvals, including the requirement of a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as

restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity on the basis of greater effectiveness or safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. For example, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development, and the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the

treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of a BLA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of standard review designation under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug or biologic products intended to treat serious or life threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs and biologics referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Post-approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to cGMPs, quality controls, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified

suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, potential civil and criminal penalties, government investigation, and/or debarment or exclusion from participation in federal health care programs. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the practice of medicine by physicians or their choice of treatments. The FDA does, however, regulate manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The ACA includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biologics that are biosimilar to or interchangeable with an FDA-approved reference biologic. This amendment to the PHSA attempts to minimize duplicative testing.

Biosimilarity, which requires that there be no clinically meaningful differences between the biologic and the reference product in terms of safety, purity, and potency and that the biologic is highly similar to the reference product notwithstanding minor differences in clinically inactive components, which can be demonstrated through comparative analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient or that it can be substituted for the reference product without the intervention of a health care provider who prescribed the reference product, and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biologics, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

U.S. Regulation of Combination Products

Certain products may be comprised of components, such as biologic components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biologic packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biologic packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a biologic-device combination product is attributable to the biologic, the FDA center responsible for premarket review of the biologic product, whether CBER or CDER, would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

Even when a single marketing application is required for a combination product, such as an BLA for a combination biologic and device product, both CBER or CDER and FDA's Center for Devices and Radiological Health may participate in the review. If a product candidate is considered a biologic-device combination product, an applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, including applicable portions of the FDA's Quality System regulation, to their combination product.

Some combination products feature a device constituent part that may be used as a platform across multiple products. Additionally, the same device information may be applicable to and used to support multiple submissions to FDA. For such combination products, a device master file may be submitted. A device master file is a submission that includes technical, manufacturing, preclinical, clinical and safety information about a medical device component or material that may be incorporated by reference into a sponsor's IDE, BLA or other submission to the FDA. A master file is not approved by FDA, but is a mechanism to provide information regarding the device constituent part when the same information is applicable to several other applications.

An investigational device exemption, or IDE, allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Although the FDA's Quality System Regulation does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that FDA may impose with respect to manufacturing.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute, the federal False Claims Act, the Sunshine Act, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar foreign, federal and state fraud and abuse, transparency, and health information privacy and security laws.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value, including stock options. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but they are drawn narrowly and require strict compliance in order to offer protection. Our activities, including our engagement of consultants, may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of an applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all relevant facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. 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. In addition, a claim including items or service resulting from a violation of the federal Anti-Kickback Statute, can result in a false or fraudulent claim for purposes of the federal False Claims Act.

Civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent. For example, the federal False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free products or other illegal kickbacks to customers to induce customers to refer or use the companies’ products over competitors’ products or alternative treatments that were billed to federal healthcare programs for reimbursement for the products.

The U.S. federal Physician Payments Sunshine Act requires applicable manufacturers of prescription drugs, devices, biologics or medical supplies subject to FDA approval or clearance for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare & Medicaid Services (CMS) information related to certain payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, including ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false

statements relating to healthcare matters. In addition, HIPAA, as amended the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, impose certain requirements on HIPAA covered entities, which include certain healthcare providers, healthcare clearinghouses, and health plans, and individuals and entities, known as business associates, that provide services for or on behalf of the covered entities that involve individually identifiable health information as well as their covered subcontractors, relating to the privacy, security, and transmission of individually identifiable health information.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, complicating compliance efforts. For example, we may be subject to state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; 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; state and local 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; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; 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, complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, government investigations, consent decrees, corporate integrity agreements, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and market share, and the curtailment or restructuring of our operations.

Privacy and Data Protection Requirements

In the ordinary course of our business, we collect, process and store proprietary, confidential and sensitive information, including personal information, intellectual property, trade secrets, and proprietary information owned or controlled by ourselves or other third parties. We, and third parties upon whom we rely, use information technology, software and services to process, store, use, generate, transfer, and disclose personal information and other sensitive information.

The legislative and regulatory framework related to the collection, use, retention, safeguarding, disclosure, sharing, transfer, security and other processing of personal data worldwide is rapidly evolving. The number and scope of data protection laws and regulations is changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions, or in conflict with other rules, laws or other data processing obligations. Efforts to ensure that our current and future business arrangements, including our relationship with our CROs or other vendors who process data on our behalf, comply with applicable data privacy and data security laws and regulations will involve substantial costs.

For example, the European General Data Protection Regulation, or GDPR, imposes several requirements relating to the consent of the individuals to whom personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. European data protection laws, such as the GDPR, also impose strict rules on the transfer of personal data out of the European Economic Area, Switzerland, and the United Kingdom. Further, the GDPR authorizes the imposition of penalties (such as restrictions or prohibitions on personal data processing) and large fines for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, or CCPA, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. In any event, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable information security or privacy laws in light of the lack of applicable precedent and regulations. Federal, state and foreign enforcement bodies have increased their scrutiny of biotechnology companies, which has led to a number of investigations, prosecutions, convictions, fines, penalties and settlements in the industry.

If we, or the third parties upon who we rely, fail, or are perceived to have failed, to address or comply with applicable data protection laws, privacy policies and data protection obligations, or if our privacy policies are, in whole or part, found to be inaccurate, incomplete, deceptive, unfair, or misrepresentative of our actual practices, it could: increase our operational costs, expose us to regulatory scrutiny, actions, fines and penalties; result in reputational harm; lead to a loss of customers; interrupt or stop clinical trials; result in an inability to process personal data or to operate in certain jurisdiction, or result in other material harm to our business.

Moreover, we use third-party service providers, including vendors and CROs, and subprocessors to help us operate our business and engage in processing on our behalf. If we, our service providers, partners, or other relevant third-parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, or an inability to process data in some jurisdictions. Furthermore, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customers, regulators and credit reporting agencies. Such disclosures are costly, and the disclosure or the failure to comply with such requirements, could result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage policy, formulary, and reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical, and/or cost-effectiveness support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures, and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, 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, a new licensure framework for follow on biologic products, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (Tax Act) was enacted, which, among other things, removed penalties for not complying with ACA's individual mandate to carry health insurance, effective January 1, 2019. On December 14, 2018, the Texas District Court Judge ruled that 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case but it is unknown when a decision will be reached. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, 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 on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs 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.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. These reductions 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, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Employees and Human Capital Resources

As of March 31, 2021, we had 71 full-time employees and no part-time employees. Of our full-time employees, 19 have advanced degrees, including but not limited to Ph.D.s in pharmacology, chemical engineering, and chemistry, 46 work in manufacturing and automation, 13 work in research and development, and 12 work in general and administrative functions. Our employees are primarily located in San Jose, California. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that we have good relations with our employees.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

The success of our business is fundamentally connected to the well-being of our employees. We provide market competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, broad-based equity awards, a 401(k) plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave and flexible work schedules, among others. These benefits provide our employees choices where possible so they can customize their benefits to meet their needs and the needs of their families, as well as access to tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors to improve their physical and mental health.

In response to the COVID-19 pandemic and “shelter in place” and similar orders issued by state and local governments, we have temporarily restricted access to our offices in California, as well as suspended any non-essential business travel. Our employees are conducting their work remotely, and they otherwise have minimal presence in our offices for essential activities. The safety, health and well-being of our employees is paramount. As such, we will consider ongoing government regulations and local health conditions before lifting any restrictions on travel or allowing any gatherings at our offices.

Consultants

We have established, and expect to continue to establish, consulting agreements with drug development professionals, clinicians, attorneys and regulatory experts with experience in numerous fields, including clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing and regulatory affairs. We retain each consultant according to the terms of a consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out of pocket expenses incurred in performing their services for us. In addition, we have in the past and may again in the future grant options to purchase our common stock to consultants, subject to the vesting requirements contained in the consulting agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer, or may have other consulting or advisory agreements that may limit their availability to us.

Facilities

Our corporate headquarters are currently located in San Jose, California, where we lease 22,000 square feet of office, research and development, production and manufacturing, and laboratory space pursuant to a service agreement with InCube Labs, LLC. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

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.

MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth the names, ages, and positions of our executive officers, directors and key employees, as of June 17, 2021:

Name	Age	Position
Executive Officers:		
Talat Imran	40	Chief Executive Officer and Director
Svai Sanford	51	Chief Financial Officer
Mir Hashim	62	Chief Scientific Officer
Non-Employee Directors:		
Mir Imran	65	Executive Chairman
Dennis Ausiello(3).	75	Director
Jean-Luc Butel(1)(2)	64	Director
Laureen DeBuono(1)(2)(3)	63	Director
Andrew Farquharson.	52	Director
Maulik Nanavaty(1)(2)(3)	59	Director

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee

Executive Officers

Talat Imran. Mr. Imran has served as a member of our board of directors and our Chief Executive Officer since June 2021. From January 2014 to June 2021, Mr. Imran served as our Vice President, Strategy. Previously, Mr. Imran served as a partner at InCube Ventures, LP, a venture capital company in the healthcare sector, from May 2007 to June 2021, as co-founder and Managing Director of VentureHealth, a healthcare investment company, from December 2012 to June 2021, and as chief executive officer of Venture Web Partners, a web design, development and hosting firm, from June 2006 to December 2016. He earned a B.A. in Computer Science from the University of California, Santa Cruz.

We believe Mr. Imran is qualified to serve on our board of directors because of his experience in the healthcare sector and his extensive knowledge of our company.

Svai Sanford. Mr. Sanford has served as our Chief Financial Officer since November 2018. Prior to joining us, from June 2017 to November 2018, Mr. Sanford served as an executive consultant and acting Chief Financial Officer for pH Pharma Inc., a consumer skin care company. From September 2015 to March 2017, he served as the Chief Financial Officer of SFJ Pharmaceuticals, Inc., a drug development company, and from July 2012 to September 2015, he served as the Chief Financial Officer and Chief Accounting Officer of VIVUS, Inc., a public biopharmaceutical company. Mr. Sanford was a member of the audit practice at KPMG LLP from 1996 to 2002. He earned a B.S. in Accounting from Kansas State University and is a Certified Public Accountant (inactive).

Mir Hashim. Dr. Hashim has served as our Chief Scientific Officer since June 2013 and was a member of our board of directors from June 2013 to June 2021. Dr. Hashim has served as Vice President, Research and Development, at InCube Labs, LLC, a medical device research company, since September 2008. Prior to this, he spent 18 years serving in multiple scientific roles at GlaxoSmithKline plc, a global pharmaceutical company, including as Head of Pharmacology. Dr. Hashim earned a B.S. in Biology and Chemistry from Osmania University, an M.S. in Life Sciences from the University of Hyderabad and a Ph.D. in Pharmacology from the School of Medicine, Memorial University of Newfoundland.

Non-Employee Directors

Mir Imran. Mr. Imran founded Rani Therapeutics, LLC and has served as a member of our board of directors since February 2012. From February 2012 to June 2021, he served as our President and Chief Executive Officer, and since June 2021, as our Executive Chairman. Since November 2012, Mr. Imran has served as a co-founder and a Managing Director of InCube Ventures, LP and InCube Crowdfunding, LLC, venture capital companies in the healthcare sector. Since 1995, Mr. Imran has also served as the Chairman of InCube Labs, LLC, a research company that he founded. Mr. Imran is a fellow of the American Institute of Medical and Biological Engineers, the National Academy of Engineering and the National Academy of Inventors. Mr. Imran earned a B.S. in Electrical Engineering from Rutgers University, and attended Rutgers Medical School.

We believe Mr. Imran is qualified to serve on our board of directors because of his experience in the healthcare sector and medical device research and his extensive knowledge of our company.

Dennis Ausiello. Dr. Ausiello has served as a member of our board of directors since September 2018. Dr. Ausiello serves as the Director of the Center for Assessment Technology and Continuous Health (CATCH), which he co-founded, Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School and Physician-in-Chief Emeritus at Massachusetts General Hospital. From 1996 to April 2013, Dr. Ausiello served as the Chief of Medicine at Massachusetts General Hospital. Dr. Ausiello is a member of the Institute of Medicine of the National Academy of Sciences and a fellow of the American Academy of Arts and Sciences. Dr. Ausiello has served on the board of directors of Alnylam Pharmaceuticals, Inc., an RNA interference company, since April 2012, the board of directors of Seres Therapeutics, Inc., a microbiome therapeutics company, since April 2015 and previously served on the board of directors of Pfizer Inc., a pharmaceuticals company. Dr. Ausiello received a B.A. in Biochemistry from Harvard College and an M.D. from the University of Pennsylvania.

We believe Dr. Ausiello is qualified to serve on our board of directors because of his leadership experience in the medical field, including in finance and research.

Jean-Luc Butel. Mr. Butel has served as a member of our board of directors since April 2021. Mr. Butel currently serves on the board of directors of multiple companies, including Takeda Pharmaceutical Company Limited, a global pharmaceuticals company, since June 2016, Novo Holdings A/S, a life science investment company, since June 2017, JanaCare, a digital health company, since March 2019, SGInnovate, a start-up investment company, since January 2017, and A*ccelerate Technologies Pte. Ltd., an entity responsible for the commercialization of A*STAR's IP portfolio, from September 2015 to December 2020. Since June 2015, he has also served as President and Global Healthcare Advisor at K8 Global Pte Ltd., a business consulting firm. Mr. Butel served on the board of directors of Varian Medical Systems Inc., a medical equipment manufacturer, from February 2017 to April 2021. From July 2015 to September 2019, Mr. Butel served on the board of directors of BioMers Pte Ltd., a dental product manufacturer. Mr. Butel served as a member of the Singapore Economic Development Board, from January 2012 to January 2018, and as the Chair of the Finance Committee from March 2017 to March 2018. Mr. Butel also served as a Senior Advisor for the Healthcare Systems and Services group at McKinsey & Company, a management consulting firm, from July 2015 to January 2017. Mr. Butel earned a B.A. from George Washington University and an M.B.A from Thunderbird School of Global Management.

We believe Mr. Butel is qualified to serve on our board of directors because of his leadership experience in healthcare companies.

Laureen DeBuono. Ms. DeBuono has served as a member of our board of directors since April 2021. Ms. DeBuono has served as a partner of FLG Partners, LLC, a financial consulting and advisory firm, since October 2011 and, since May 2020, she has served as the firm's Managing Partner. From August 2018 to December 2019, she also served as Chief Executive Officer and a member of the Board of Directors of Govino, LLC, a sustainable wine glass distributor. From February 2018 to April 2019, Ms. DeBuono served as the Interim Chief Financial Officer and Advisor to the Chief Executive Officer of HotelTonight, a mobile travel booking

company that was acquired in April 2019 by Airbnb, Inc. Prior to this, from May 2017 to February 2018, she served as the Chief Operating Officer for Circa of America, LLC, a private-label textiles company. From January 2014 to January 2017, Ms. DeBuono served as a member of the Board of Directors, member of the audit committee and chair of the governance committee of Turtle Beach, a gaming headset company. Prior to this, she served as an advisor to the Chief Executive Officer and Board of Directors of BuildDirect Technologies Inc., a Vancouver-based building goods company, from September 2016 to January 2017. From July 2014 to September 2016, she served as an Advisor to the Board of Directors and Interim Chief Financial Officer of Rodan & Fields, LLC, a premium skincare company. Ms. DeBuono earned a B.A. from Duke University, an M.A. from Stanford University and a J.D. from New York University School of Law.

We believe Ms. DeBuono is qualified to serve on our board of directors because of her financial management experience and experience in the healthcare and medical technology industries.

Andrew Farquharson. Mr. Farquharson has served as a member of our board of directors since June 2012. Since January 2008, he has served as a Managing Director of InCube Ventures, LP, a venture capital firm in the healthcare sector that he co-founded. Mr. Farquharson is also the co-founder of VentureHealth, and has been a Kauffman Fellow since 2006. Prior to entering venture capital, he served as Executive Vice President of Operon Technologies and held various roles within Genentech. Mr. Farquharson continues to serve on the boards of several private companies. Mr. Farquharson earned a B.A. from the University of California, Berkeley and an M.B.A. from Harvard Business School.

We believe Mr. Farquharson is qualified to serve on our board of directors because of his experience in the healthcare sector and extensive knowledge of our company.

Maulik Nanavaty. Dr. Nanavaty has served as a member of our board of directors since June 2016. Dr. Nanavaty has served as Senior Vice President and President, Neuromodulation, at Boston Scientific Corporation, a medical device company, since September 2011. Prior to this he served as President of Boston Scientific Japan and as Vice President and General Manager, Interventional Cardiology, Boston Scientific Japan. Dr. Nanavaty joined Boston Scientific in 2005 as Vice President, Corporate Strategy, Boston Scientific Japan. Prior to joining Boston Scientific, Dr. Nanavaty spent 16 years working in various executive positions at Baxter International, Inc., a healthcare products company. Dr. Nanavaty holds a Ph.D. in Pharmaceutical Sciences from the University of Illinois and an M.B.A. from the University of Chicago.

We believe Dr. Nanavaty is qualified to serve on our board of directors because of his extensive experience in the medical device industry.

Family Relationships Between Directors and Executive Officers

Mir Imran is the brother of Dr. Hashim and the father of Talat Imran.

Board Composition

Our board of directors currently consists of seven members. After the completion of this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Our amended and restated certificate of incorporation provides that, until the earlier to occur of (i) the date that is ten (10) years following the closing of this offering, (ii) a date fixed by the board of directors that is not less than sixty (60) days nor more than one hundred and eighty (180) days after the death or disability of the last to die or be the subject of a disability of Mir Imran the Executive Chairman of the Company, Talat Imran the Company’s Chief Executive Officer or Sanah Imran the Company’s Special Project Manager, and (iii) the

date on which the holders of at least two-thirds (2/3) of the voting power of the Class B common stock, voting as a single class, affirmatively vote to retire all outstanding shares of Class B common stock (the "Final Conversion Date"), our board of directors will be elected at each annual meeting of stockholders to hold office until the next annual meeting or until his or her successor is duly elected and qualified or his or her earlier death, resignation or removal. We will have a classified board with three (3) classes from and after the Final Conversion Date.

Controlled Company Status

Following the completion of this offering, we will be a "controlled" company within the meaning of the corporate governance rules of Nasdaq. Although we do not intend to rely on the exemptions from these corporate governance requirements, if we do rely on such exemptions in the future, you will not have the same protections afforded to stockholders of companies that are subject to these corporate governance requirements. In the event that we cease to be a "controlled company" and our shares continue to be listed on Nasdaq, we will be required to comply with these provisions within the applicable transition periods.

Director Independence

Our Class A common stock is listed on the Nasdaq Global Market. Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of the Nasdaq Stock Market require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance, and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the rules of the Nasdaq Stock Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of the Nasdaq Stock Market, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of the Nasdaq Stock Market, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of such director, including any consulting, advisory, or other compensatory fee paid by the company to such director and (2) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees, and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment, and affiliations, including family relationships, our board of directors has determined that Drs. Ausiello and Nanavaty, Mr. Butel and Ms. DeBuono, representing four of our seven directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the Nasdaq Stock Market.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Person Transactions."

Lead Independent Director

Our board of directors has appointed Laureen DeBuono as our lead independent director. As our lead independent director, Ms. DeBuono will preside over periodic meetings of our independent directors and coordinate certain activities of the independent directors.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks, and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and corporate governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected the board of directors' leadership structure.

Board Committees

Our board of directors has an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below.

Audit Committee

The members of our audit committee are Laureen DeBuono, Maulik Nanavaty and Jean-Luc Butel. Laureen DeBuono is the chair of our audit committee and also our audit committee financial expert, as that term is defined under the SEC rules implementing SOX Section 407, and possesses financial sophistication, as defined under the rules of the Nasdaq Stock Market. Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in monitoring our financial systems. Our audit committee will also:

- appoint, approve the compensation of, and assess the qualifications, performance and independence of our independent registered public accounting firm;
- pre-approve audit and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- discuss on a periodic basis, or as appropriate, with management, our policies, programs and controls with respect to risk assessment and risk management;
- review financial statements related disclosures as well as critical accounting policies and practices used by us and discuss with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- monitor the rotation of partners of the independent registered public accounting firm on our engagement team in accordance with requirements established by the SEC;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;

- recommend, based upon the audit committee's review and discussions with management and the independent registered public accounting firm, whether our audited consolidated financial statements shall be included in our Annual Report on Form 10-K;
- monitor our compliance with legal and regulatory requirements as they relate to our consolidated financial statements and accounting matters;
- review the audit committee charter and the audit committee's performance at least annually;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- review our policies on risk assessment and risk management;
- review all related party transactions for potential conflict of interest situations and approving all such transactions; and
- establish and oversee procedures for the receipt, retention, and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee will operate under a written charter, to be effective prior to the closing of this offering, which will satisfy the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

Compensation Committee

The members of our compensation committee are Maulik Nanavaty, Laureen DeBuono and Jean-Luc Butel. Maulik Nanavaty is the chair of our compensation committee. Our compensation committee oversees our compensation policies, plans, and benefits programs. The compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans, and benefit programs;
- review and approve or recommend to the board of directors for approval compensation for our executive officers and directors;
- prepare the compensation committee report that the SEC will require to be included in our annual proxy statement; and
- administer our equity compensation plans.

Our compensation committee will operate under a written charter, to be effective prior to the closing of this offering, which will satisfy the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Jean-Luc Butel, Dennis Ausiello and Laureen DeBuono. Jean-Luc Butel is the chair of our nominating and corporate governance committee. Our nominating and corporate governance committee oversees and assists our board of directors in reviewing and recommending nominees for election as directors. Specifically, the nominating and corporate governance committee will:

- identify, evaluate, and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;

- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the closing of this offering, which will satisfy the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

Non-Employee Director Compensation

On June 17, 2021, the board of directors approved grants of options to purchase common units of Rani LLC to each of Jean-Luc Butel, Laureen DeBuono, Maulik Nanavaty and Dennis Ausiello. Jean-Luc Butel and Laureen DeBuono were each granted an option to purchase 257,000 common units of Rani LLC (which will be automatically exchanged for an option to purchase Class A common stock of Rani Holdings in connection with the closing of this offering), with one-third of the units subject to the option vesting on the first anniversary of April 20, 2021, and one thirty-sixth of the units subject to the option vesting each month thereafter, subject to the non-employee director's continuous service with us through each vesting date. Maulik Nanavaty and Dennis Ausiello were each granted an option to purchase 150,000 common units of Rani LLC (which will be automatically exchanged for an option to purchase Class A common stock of Rani Holdings in connection with the closing of this offering), with one thirty-sixth of the units subject to the option vesting each month following June 14, 2021, subject to the non-employee director's continuous service with us through each vesting date.

Non-Employee Director Compensation Policy

In anticipation of this offering and the increased responsibilities of our directors as directors of a public company, our board of directors has adopted a non-employee director compensation policy, effective as of the effectiveness of the registration statement of which this prospectus forms a part, pursuant to which each of our directors who is not an employee or consultant of our company will be eligible to receive compensation for service on our board of directors and committees of our board of directors.

Each non-employee director will receive an annual cash retainer of $45,000 for serving on our board of directors, and the executive chairperson and/or lead independent director of our board of directors will each receive an additional annual cash retainer of $35,000. The chairperson of the audit committee of our board of directors will be entitled to an annual service retainer of $20,000, and each other member of the audit committee will be entitled to an annual service retainer of $7,500. The chairperson of the compensation committee of our board of directors will be entitled to an annual service retainer of $15,000, and each other member of the compensation committee will be entitled to an annual service retainer of $5,000. The chairperson of the nominating and corporate governance committee of our board of directors will be entitled to an annual service retainer of $10,000, and each other member of the nominating and corporate governance committee will be entitled to an annual service retainer of $4,000. All annual cash compensation amounts will be payable in equal quarterly installments in arrears, on the last day of each fiscal quarter for which the service occurred, pro-rated for any partial months of service.

On the date of each annual meeting of our stockholders following the closing of this offering, each continuing nonemployee director will receive an option to purchase a number of shares of Class A common stock of Rani Holdings under the 2021 Plan with a grant date fair value of $300,000. The grant date fair value of any annual option grant to a nonemployee director who is elected or appointed on a date other than the date of an

annual meeting of our stockholders will be prorated to reflect the time between the date of such director's election or appointment and the date of such first annual stockholder meeting. The shares subject to annual option grants will vest upon the earlier of the first anniversary of the grant date or the date of the next annual meeting of our stockholders, subject to the non-employee director's continuous service with us through the vesting date.

Each new non-employee director who joins our board of directors following the closing of this offering will be granted an option to purchase a number of shares of Class A common stock of Rani Holdings under the 2021 Plan with a grant date fair value of $600,000. The shares subject to this option will vest over a three-year period, with one-third of the shares subject to the option vesting on the first anniversary of the grant date and one thirty-sixth of the shares subject to the option vesting each month thereafter, subject to the non-employee director's continuous service with us through each vesting date.

All options granted under the non-employee director compensation policy will vest upon a change in control of us, subject to the non-employee director's continuous service with us through the date of our change in control. The exercise price per share of each option granted under the non-employee director compensation policy will be equal to the closing price of Rani Holding's Class A common stock on the Nasdaq Stock Market on the date of grant. Each option will have a term of ten years from the grant date, subject to earlier termination in connection with a termination of the non-employee director's continuous service with us.

In addition, we will reimburse non-employee directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in board and committee meetings.

The following table presents the total compensation each of our non-employee directors received during the year ended December 31, 2020. Other than as set forth in the table, we did not pay any compensation, make any equity awards or non-equity awards to or pay any other compensation to any of our non-employee directors in 2020.

Name	Fees Earned or Paid in Cash ($)	Total ($)
Dennis Ausiello(1)(3)(4)	30,000	30,000
Andrew Farquharson(2)(3)(5)	150,000	150,000
Maulik Nanavaty(3)(6)	—	—
Jean-Luc Butel(7)	—	—
Laureen DeBuono(8)	—	—

(1) Reflects a retainer fee of $2,500 per month paid to Dr. Ausiello subject to his continuous service through each such month and pursuant to a Board Service Letter Agreement by and between Rani Therapeutics, LLC and Dr. Ausiello, dated as of May 14, 2018.
(2) Reflects a discretionary bonus to reward active and longstanding board service.
(3) The table below sets forth the aggregate number of outstanding Profits Interests units beneficially owned by each of our non-employee directors as of December 31, 2020:

Name	Number of Profits Interests Units Outstanding as of December 31, 2020
Dennis Ausiello	150,000
Andrew Farquharson	500,000
Maulik Nanavaty	300,000

(4) We made the following Profits Interests grants to Dr. Ausiello: 50,000 common units granted in September 2018 with a participation threshold of $2.18 per unit that vest monthly over four years from the vesting commencement date of July 1, 2018; and 100,000 common units granted in September 2019 with a participation threshold of $2.29 per unit that vest monthly over four years from the vesting commencement date of September 17, 2019.

(5) We made the following Profits Interests grant to Mr. Farquharson: 500,000 common units granted in May 2016 with a participation threshold of $1.44 per unit of which 25% vest on the one-year anniversary of the vesting commencement date of February 21, 2012 and 1/48th of which vest on each monthly anniversary of the vesting commencement date thereafter.
(6) We made the following Profits Interests grants to Dr. Nanavaty: 100,000 common units granted in June 2016 with a participation threshold of $1.44 per unit of which 25% vest on the one-year anniversary of the vesting commencement date of June 1, 2016 and 1/48th of which vest on each monthly anniversary of the vesting commencement date thereafter; 100,000 common units granted in June 2016 with a participation threshold of $1.44 per unit of which 25% vest on the one-year anniversary of the vesting commencement date of July 1, 2014 and 1/48th of which vest on each monthly anniversary of the vesting commencement date thereafter; and 100,000 common units granted in September 2019 with a participation threshold of $2.29 per unit that vest monthly over four years from the vesting commencement date of September 17, 2019.
(7) Mr. Butel joined our board of directors in April 2021.
(8) Ms. DeBuono joined our board of directors in April 2021.

Directors who are also our employees receive no additional compensation for their service as directors. Mir Imran and Dr. Hashim were our only employee directors during fiscal 2020. See the section titled “Executive Compensation” for additional information about Dr. Hashim’s compensation. Mir Imran does not receive any compensation for his services as an officer or a director.

Compensation Committee Interlocks and Inside Participation

None of the members of our compensation committee is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or, persons performing similar functions. Following the completion of this offering, the code of business conduct and ethics will be available on our website at https://www.ranitherapeutics.com/. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, or our directors on our website identified above. Information contained on the website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus.

EXECUTIVE COMPENSATION

Unless we state otherwise or the context otherwise requires, in this Executive Compensation section the terms "Rani Therapeutics," "Rani," "we," "us," "our" and the "Company" refer to Rani LLC, for the period up to this offering, and for all periods following the completion of this offering, to Rani Therapeutics Holdings, Inc.

We are currently considered an "emerging growth company" within the meaning of the Securities Act for purposes of the SEC's executive compensation disclosure rules. Accordingly, we are required to provide a Summary Compensation Table and an Outstanding Equity Awards at Fiscal Year-End Table, as well as limited narrative disclosures regarding executive compensation for our last completed fiscal year. Further, our reporting obligations extend only to the following "named executive officers," who are the individuals who served as our principal executive officer during and the next two most highly compensated executive officers at the end of the fiscal year ended December 31, 2020. For the fiscal year ended December 31, 2020, our named executive officers and their principal positions were as follows:

- Mir Imran, our Executive Chairman and former President and Chief Executive Officer;
- Mir Hashim, our Chief Scientific Officer; and
- Svai Sanford, our Chief Financial Officer.

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)	Option Awards ($)(2)	Total ($)
Mir Imran(3)	2020	—	—	—	—
Executive Chairman and former President and Chief Executive Officer					
Mir Hashim	2020	$ 325,532	$ 160,000	$ 144,750	$ 630,282
Chief Scientific Officer					
Svai Sanford	2020	$ 302,564	$ 140,000	$ 77,200	$ 519,764
Chief Financial Officer					

(1) Amounts reflect annual salary, as adjusted on November 15, 2020.
(2) Amounts reflect the aggregate grant date fair value of Profits Interests granted to our named executive officers during 2020 under our 2016 Plan (as defined below), computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation – Stock Compensation*. The assumptions used in calculating the grant date fair value of the award disclosed in this column are set forth in the notes to our audited financial consolidated statements included elsewhere in this prospectus. These amounts do not correspond to the actual value that may be recognized by the named executive officers. See the subsection titled "—Outstanding Equity Awards at Fiscal Year-End" for additional information.
(3) Mir Imran resigned from his position as President and Chief Executive Officer in June 2021.

Mir Imran did not receive compensation for his services as our President and Chief Executive Officer, *provided that*, ICL, of which Mir Imran is the sole Managing Member, has entered into certain transactional agreements with the Company, as described in the section titled "Certain Relationships and Related Person Transactions."

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Below are descriptions of the offer letters with each of our named executive officers setting forth the terms and conditions of such executive's employment with RMS, a wholly owned subsidiary of the Company.

Mir Imran did not have a formal offer letter or employment agreement with RMS that was in effect during fiscal year 2020, while serving as our President and Chief Executive Officer.

Mir Hashim

In December 2019, we signed an offer letter with Dr. Hashim, our Chief Scientific Officer, effective January 1, 2020. The offer letter provides for an annual salary of $315,000, that was increased to $400,000, effective as of November 15, 2020.

Svai Sanford

In December 2019, we signed an offer letter with Mr. Sanford, our Chief Financial Officer, effective January 1, 2020. The offer letter provides for an annual salary of $300,000, that was increased to $350,000, effective as of November 15, 2020.

Equity Incentives

We have historically offered equity incentives to our named executive officers through grants of Profits Interests in the Company. Certain of these incentive unit awards are subject to time-based vesting requirements and are subject to accelerated vesting upon the occurrence of certain change-in-control events, including the closing of this offering. See below under " —Actions Taken in Connection with this Offering—Acceleration of Profits Interests Grants" for additional information regarding the expected acceleration of certain of the Profits Interests.

Annual Bonus

In December 2020, our compensation committee approved discretionary annual bonuses for Dr. Hashim and Mr. Sanford for 2020 in the amount equal to 40% of their then-current annual salary, equal to $160,000 and $140,000, respectively, which were paid in December 2020, as reflected in the "Bonus" column of the Summary Compensation Table above.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of Profits Interests outstanding for our named executive officers as of December 31, 2020 that were issued by the Company under the 2016 Equity Incentive Plan, or the 2016 Plan. For more information about the outstanding equity awards granted to our named executive officers, please see the section titled "Narrative Disclosure to Summary Compensation Table—Equity Incentives" above:

		Option Awards(1)				
Name	Grant Date	Vesting Commencement Date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options(#) unexercisable	Option exercise price(2) ($)	Option expiration date
Mir Imran(3)	—	—	—	—	—	—
Mir Hashim	05/09/2016(4)	02/21/2012	750,000	—	$ 1.44	05/09/2026
	06/05/2020(5)	06/05/2020	9,375	65,625	$ 1.87	06/05/2030
Svai Sanford	01/08/2019(4)	11/05/2018	117,187	107,813	$ 2.18	01/08/2029
	09/17/2019(5)	09/17/2019	23,437	51,563	$ 2.29	09/17/2029
	06/05/2020(5)	06/05/2020	5,000	35,000	$ 1.87	06/05/2030

(1) Represent Profits Interests that vest based on satisfaction of a service-based vesting condition, which will accelerate and vest concurrently with the effectiveness of this offering as described below in the subsection "Actions Taken in Connection with This Offering—Acceleration of Profits Interests Grants."

(2) Reflects the Profits Interests threshold amount.
(3) Mir Imran resigned from his position as President and Chief Executive Officer in June 2021.
(4) 25% of the Profits Interests vest on the one-year anniversary of the vesting commencement date and 1/48th of the Profits Interests vest on each monthly anniversary of the vesting commencement date thereafter, provided the holder remains a service provider to the Company on each applicable vesting date.
(5) 1/48th of the Profits Interests vest on each monthly anniversary of the vesting commencement date over four years, provided the holder remains a service provider to the Company on each applicable vesting date.

Actions Taken in Connection with This Offering

Acceleration of Profits Interests

In connection with this offering, we expect the vesting of Profits Interests granted prior to December 31, 2020 and granted in February 2021 to existing service providers, including those held by our named executive officers, to be accelerated in full concurrent with the effectiveness of this offering, subject to the holder's continued status as a service provider through the date of effectiveness of this offering. See the "Outstanding Equity Awards at Fiscal Year-End" table above for additional details regarding the Profits Interests subject to vesting that are held by our Named Executive Officers.

New Employment Agreements

In June 2021, and in connection with this offering, our affiliate, Rani Management Services, Inc. (RMS), entered into new employment agreements with each of Mr. Imran, Dr. Hashim and Mr. Sanford. The agreements generally provide for at-will employment and set forth the executive officer's base salary, target bonus, and eligibility for employee benefits. Under the new agreements, effective as of June 17, 2021, each of Mr. Imran's and Mr. Sanford's annual base salary was increased to $500,000 and $400,000, respectively. Dr. Hashim's annual base salary remained $400,000. In addition, the target bonus for each of Mr. Imran, Dr. Hashim and Mr. Sanford will be up to 75% of their respective base salaries. Mr. Sanford's agreement also provides that if his employment terminates without cause (as defined in his agreement) prior to the closing of this offering and the effectiveness of the Severance Plan (as described below), and if he executes a severance agreement and release satisfactory to RMS, he is entitled to receive (i) continued payment of his base salary for six months after such termination, (ii) reimbursement for the cost of acquiring group health insurance for six months after such termination and (iii) continued vesting the Profits Interests granted to him through February 2021 for six months after such termination.

Severance and Change in Control Plan

Effective in connection with this offering, each of our executive officers will become eligible to receive benefits under the terms of our Severance and Change in Control Plan adopted by the board of directors on June 17, 2021, or the Severance Plan. Mir Imran will not participate in the Severance Plan.

The Severance Plan provides for severance and change in control benefits to the executive officers upon (i) a "change in control termination" or (ii) a "regular termination" (each as described below). Upon a change in control termination, each of our executive officers is entitled to a lump sum payment equal to a portion of his base salary (18 months for Mr. Imran and 12 months for each of Dr. Hashim and Mr. Sanford), a lump sum payment equal to 150% (for Mr. Imran) or 100% (for each of Dr. Hashim and Mr. Sanford) of his annual target cash bonus, payment of group health insurance premiums for a period of 18 months (for Mr. Imran) and 12 months (for each of Dr. Hashim and Mr. Sanford) and accelerated vesting of outstanding time-vesting equity awards. Upon a regular termination, each of our executive officers is entitled to continued payment of his base salary for a period 12 months (for Mr. Imran) and nine months (for each of Dr. Hashim and Mr. Sanford) and payment of group health insurance premiums for a period of 12 months (for Mr. Imran) and nine months (for each of Dr. Hashim and Mr. Sanford). All severance benefits under the Severance Plan are subject to the executive officer's execution of an effective release of claims against us.

For purposes of the Severance Plan, a "regular termination" is an involuntary termination (i.e., a termination without "cause" (and not as a result of death or disability) or a resignation for "good reason," each as defined in the Severance Plan) that does not occur during the period of time beginning three months prior to, and ending 12 months following, a "change in control" (as defined in the 2021 Plan), or the "change in control period." A "change in control termination" is a regular termination that occurs during the change in control period.

Option Awards

On June 17, 2021, and in connection with this offering, each of our executive officers was granted an option to purchase common units under the 2016 Plan. Each option has an exercise price per unit equal to $4.99, which was the per-unit fair market value of the underlying common units on the date of grant. Mr. Imran, Dr. Hashim and Mr. Sanford were granted options to purchase 149,309, 400,000 and 400,000 of our common units, respectively, with one-forty-eighth of the common units subject to each option vesting on a monthly basis over four years from the date of grant, subject to the executive officer's continuous service with us on each applicable vesting date. Mir Imran did not receive an option award.

Employee Benefit and Stock Plans

2021 Equity Incentive Plan

Our board of directors adopted the Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan, or the 2021 Plan, in July 2021, and our stockholders approved the 2021 Plan in July 2021. The 2021 Plan became effective upon the execution of the underwriting agreement for this offering. After the 2021 Plan became effective, no further grants will be made under the 2016 Plan.

Types of Awards. Our 2021 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based awards and other awards for shares of Rani Holdings Class A common stock, or collectively, awards. ISOs may be granted only to employees, of Rani Holdings, employees of a "parent corporation" of Rani Holdings or employees of a "subsidiary corporation" of Rani Holdings (as such terms are defined in Sections 424 of the Code). Because of our organizational structure, we currently do not anticipate that any ISOs will be granted under the 2021 Plan. All other awards may be granted to our employees, including our officers, our non-employee directors and consultants and the employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of Class A common stock that may be issued under our 2021 Plan is 5,500,000 shares. The number of shares of Class A common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each year, beginning on January 1, 2022, and continuing through and including January 1, 2031, by 5% of the aggregate number of shares of common stock of all classes issued and outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares that may be issued upon the exercise of ISOs under our 2021 Plan is 16,500,000 shares.

Shares issued under our 2021 Plan will be authorized but unissued or reacquired shares of Class A common stock. Shares subject to awards granted under our 2021 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2021 Plan. Additionally, shares issued pursuant to awards under our 2021 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of an award or to satisfy the tax withholding obligations to an award, will become available for future grant under our 2021 Plan.

The maximum number of shares of Class A common stock subject to stock awards granted under the 2021 Plan or otherwise during any calendar year beginning in 2022 to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such calendar year for service on the board

of directors, will not exceed $750,000 in total value (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes), or, with respect to the calendar year in which a non-employee director is first appointed or elected to our board of directors, $1,000,000.

Plan Administration. Our board of directors, or a duly authorized committee of our board, may administer our 2021 Plan. Our board of directors has delegated concurrent authority to administer our 2021 Plan to the compensation committee under the terms of the compensation committee's charter. We sometimes refer to the board of directors, or the applicable committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified awards, and (2) determine the number of shares subject to such awards.

The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2021 Plan.

In addition, subject to the terms of the 2021 Plan, the administrator also has the power to modify outstanding awards under our 2021 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the administrator. The administrator determines the exercise price for a stock option, within the terms and conditions of the 2021 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our Class A common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified in the stock option agreement as specified in the stock option agreement by the administrator.

The administrator determines the term of stock options granted under the 2021 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of Class A common stock issued upon the exercise of a stock option will be determined by the administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO and (5) other legal consideration approved by the administrator.

Options may not be transferred to third-party financial institutions for value. Unless the administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISOs may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations, unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the administrator. Restricted stock awards may be granted in consideration for cash, check, bank draft or money order, services rendered to us or our affiliates or any other form of legal consideration. Class A common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation right grant agreements adopted by the administrator. The administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of Class A common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of Class A common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2021 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator.

The administrator determines the term of stock appreciation rights granted under the 2021 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provide otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2021 Plan permits the grant of performance-based stock and cash awards. The compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the Class A common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, the compensation committee will appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of Class A common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Awards. The administrator may grant other awards based in whole or in part by reference to common stock. The administrator will set the number of shares under the award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2021 Plan; (2) the class and maximum number of shares by which the share reserve may increase automatically each year; (3) the class and maximum number of shares that may be issued upon the exercise of ISOs and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards.

Corporate Transactions. The following applies to stock awards under the 2021 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant. Under the 2021 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

In the event of a corporate transaction, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock

awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction. In addition, the plan administrator may also provide, in its sole discretion, that the holder of a stock award that will terminate upon the occurrence of a corporate transaction if not previously exercised will receive a payment, if any, equal to the excess of the value of the property the participant would have received upon exercise of the stock award over the exercise price otherwise payable in connection with the stock award.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur.

Transferability. A participant may not transfer awards under our 2021 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2021 Plan.

Plan Amendment or Termination. Our board has the authority to amend, suspend or terminate our 2021 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board adopted our 2021 Plan. No awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2016 Equity Incentive Plan

Our board adopted the Rani Therapeutics, LLC 2016 Plan in May 2016, or 2016 Plan, and our members adopted the 2016 Plan in March 2016. The 2016 Plan provides for the grant of options to purchase common units, Profits Interests awards, and restricted common units to our managers, consultants and other individuals who provides services to or for the benefit of the Company. The 2016 Plan terminated on the date the 2021 Plan became effective. However, any outstanding awards granted under the 2016 Plan remain outstanding, subject to the terms of our 2016 Plan and award agreements.

Authorized Units. Upon the effective date of the 2021 Plan, we no longer grant awards under our 2016 Plan. As of June 17, 2021, 8,726,483 Profits Interests were outstanding, and 2,123,517 common units remained available for future issuance under our 2016 Plan. As of June 17, 2021, 2,292,309 options to purchase common units or restricted common units were outstanding under our 2016 Plan.

Plan Administration. Our board or a duly authorized committee of our board administers our 2016 Plan. The administrator has the power to modify or amend outstanding awards under our 2016 Plan, to prescribe, amend and rescind rules and regulations relating to the 2016 Plan, to construe and interpret the terms of the 2016 Plan and awards granted thereunder and to make all other determinations deemed necessary or advisable for administering the 2016 Plan. The administrator's powers include the power to institute an exchange program (without the approval of our members) under which (i) outstanding awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type and/or cash, (ii) participants would have the opportunity to transfer any outstanding awards to a financial institution or other person or entity selected by the administrator and/or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's decisions are final and binding on all participants and any other persons holding awards.

Profits Interests Awards. We have granted Profits Interests to our service providers under our 2016 Plan. Subject to the provisions of our 2016 Plan, the administrator determines the vesting terms of the Profits Interests, the number of common units subject to the award, and Profits Interests threshold amount. The common units underlying each Profits Interests award entitles the holder, upon a sale or other specified capital transaction (in each case as set forth in our Amended and Restated 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. The Profits Interests are intended to qualify as partnership Profits Interests for U.S. federal income tax purposes.

Option Awards. The administrator determines the term of option to purchase common units granted under our 2016 Plan, up to a maximum of ten years. The administrator also determines the vesting schedule and the exercise price for an option, within the terms and conditions of our 2016 Plan, provided that the exercise price of an option cannot be less than 100% of the fair market value of a common unit on the date of grant. Unless the terms of an optionholder's option agreement provide otherwise, if an optionholder's service relationship with us, ceases for any reason other than death or disability, the optionholder may generally exercise any vested options for a period of 30 days following the cessation of service. If an optionholder's service relationship with us ceases due to death or disability, the optionholder or a beneficiary may generally exercise any vested options for a period of six months following the cessation of service. In no event may an option be exercised beyond the expiration of its term.

Transferability. Unless determined otherwise by the administrator, awards may not be sold, transferred, pledged, assigned, hypothecated or otherwise transferred in any manner other than by will or by the laws of descent and distribution. In addition, during an applicable participant's lifetime, only that participant may exercise their award. If the administrator makes an award transferable, such award may only be transferred (i) by will, (ii) by the laws of descent and distribution, or (iii) as permitted by Rule 701 of the Securities Act.

Trigger Event. Subject to the provisions of the merger, reorganization or other agreement setting forth the terms of a direct exchange, merger or other reorganization transaction, upon a trigger event, as defined in our 2016 Plan, all awards granted under the 2016 Plan will be exchanged for or converted into, in such transaction, options to acquire shares of the resulting corporation's common stock of which the base amount on which compensation is measured is determined by reference to the value of the resulting corporation's common stock with terms substantially equivalent to the terms of the options, as the case may be, they are intended to replace.

Certain adjustments. In the event of any split, reverse split, dividend, recapitalization, combination, reclassification, reorganization, merger, consolidation, split-up, spin-off, repurchase, exchange of common units or other securities of the Company, other distribution of common units or other securities of the Company without the receipt of consideration by the Company, or other change in the corporate structure of the Company affecting the common units occurs, the administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2016 Plan, will adjust the number and class of common units that may be delivered under the 2016 Plan and/or the number, class, and price of common units covered by each outstanding award.

Merger or Liquidation Event. Our 2016 Plan provides that in the event of a merger or liquidation event, as defined under our 2016 Plan, awards shall be subject to the agreement governing the merger or liquidation event, which shall provide for one or more of the following: (1) the continuation of such outstanding awards by the Company (if the Company is the surviving entity); (2) the assumption or substitution of substantially equivalent awards by the acquiring or succeeding corporation with appropriate adjustments to the number and kind of equity interests and prices; (3) the full or partial vesting of unvested awards, or the full or partial cancellation of unvested awards without consideration, in each case upon the closing of the merger or liquidation event; (4) the cancellation or redemption of outstanding awards in exchange for a payment, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant rights as of the date of the occurrence of the transaction (such payment may be made in the form of cash, cash equivalents, or securities of the surviving entity and may be subject to vesting based on the participant's continuing service, provided that the vesting schedule shall not be less favorable to the participant than the schedule under which such award would have otherwise vested); or (5) amounts of cash or other consideration from a sale of assets of the Company constituting a liquidity event otherwise distributable to a common unit holder shall be reduced by the Profits Interests threshold amount attributable to each Profits Interests receiving such distribution.

Plan Amendment or Termination. Our board has the authority to amend, suspend or terminate our 2016 Plan at any time. No amendment, alteration, suspension or termination of our 2016 Plan will impair the rights of a participant, unless mutually agreed otherwise between the participant and the administrator in writing. As noted above, our 2016 Plan has terminated, and we will not grant any additional awards under our 2016 Plan.

2021 Employee Stock Purchase Plan

Our board of directors adopted the ESPP in July 2021, and our stockholders adopted the ESPP in July 2021. The ESPP became effective upon the execution of the underwriting agreement for this offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is designed to allow our eligible employees to purchase Class A common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Internal Revenue Code, or the 423 component. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment, or the non-423 component. Because of our organizational structure, we currently anticipate that any benefits offered to eligible employees would be offered under the non-423 component of the ESPP.

Authorized Shares. The maximum aggregate number of shares of Class A common stock that may be issued under our ESPP is 500,000 shares. The number of shares of Class A common stock reserved for issuance under our ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by the lesser of (1) 1% of the aggregate number of shares of common stock of all classes issued and outstanding on December 31 of the preceding calendar year, (2) 100,000 shares and (3) a number of shares determined by our board. Shares subject to purchase rights granted under our ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our ESPP.

Plan Administration. Our board, or a duly authorized committee thereof, will administer our ESPP. Our board has delegated concurrent authority to administer our ESPP to the compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings with specific terms approved by the administrator and under which eligible employees are granted purchase rights to purchase shares of Class A common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for our eligible employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, with a maximum dollar amount as designated by the board. Unless otherwise determined by the administrator, Class A common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of Class A common stock on the first date of an offering or (b) 85% of the fair market value of a share of Class A common stock on the date of purchase. For the initial offering, which we expect will commence upon the execution and delivery of the underwriting agreement relating to this offering, the fair market value on the first day of the initial offering will be the price at which shares are first sold to the public.

Limitations. Our employees, including executive officers, or any of our designated affiliates may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (1) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year, or (2) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. Under the 423 component,

an employee may not be granted rights to purchase stock under our ESPP if such employee (1) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of Class A common stock, or (2) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain corporate transactions, including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of 50% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transaction, and (4) the consummation of a merger or consolidation where we do survive the transaction but the shares of our Class A common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of Class A common stock within 10 business days (or such other period specified by the board) prior to such corporate transaction, and such purchase rights will terminate immediately.

Under the ESPP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, and (4) a merger or consolidation where we do survive the transaction but the shares of our Class A common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

ESPP Amendment or Termination. The administrator has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

401(k) Plan

Our eligible employees are permitted to participate in the ICL 401(k) Plan, or the 401(k) Plan, and we will continue to offer a 401(k) plan after the closing of this offering. Participation in the 401(k) Plan is offered for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Under the 401(k) Plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) Plan. The 401(k) Plan authorizes discretionary matching employer contributions. The 401(k) Plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) Plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) Plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) Plan if certain conditions are satisfied.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Class A common stock on a periodic basis. Under a

Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without further direction from them. The director or executive officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Without the prior written consent of the representatives of the underwriters, prior to the day following the 180th day after the date of this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or executive officer has entered into with the underwriters.

Limitation of Liability and Indemnification of Directors and Officers

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by Delaware law. Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we are also empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a summary of transactions since January 1, 2018, to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2019 and 2020, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation arrangements which are described in the sections titled “Executive Compensation” and “Management—Non-Employee Director Compensation.”

Promissory Notes between Rani and InCube Labs, LLC

ICL holds more than 5% of our capital stock and is wholly-owned by Mir Imran and his family. Mir Imran is our Executive Chairman and former President and Chief Executive Officer, and is a Managing Member of ICL. From inception to December 31, 2017, we advanced funds to ICL for ICL to make payments directly to certain vendors on behalf of us and we have reimbursed ICL for all such payments at cost. During the year ended December 31, 2017, we converted the outstanding advances of approximately $6.6 million to ICL into notes receivable, or the ICL Notes. The ICL Notes accrued interest at a rate of 1.97% compounded annually, loan fees of 2.75%, and principal and accrued interest were due and payable on demand by us at any time after January 1, 2024. During 2019 and 2020, we received $1.0 million and $0.2 million, respectively, in payments for interest and repayment of principal on the ICL Notes. At December 31, 2019 and 2020, approximately $1.9 million and $1.7 million, respectively, of the ICL Notes were outstanding. In March 2021, the outstanding balance, including all accrued interest, was fully repaid by ICL.

Service Agreement between Rani and InCube Labs, LLC

We and ICL entered into a Service Agreement effective as of January 2019 whereby we agreed to pay fees in exchange for services provided by ICL. The services are related to occupancy, research and technology development, administrative services and other services including but not limited to intellectual property diligence and maintenance, general legal support, product and business development support services, public relations support, customer relations support and financing and investor relations.

In January 2020, the parties entered into Amendment No. 1 to Service Agreement whereby they amended the service rates for 2020. Effective January 2020, the ICL personnel that were substantially dedicated to providing services to the Company were hired by our wholly owned subsidiary RMS as full-time employees. The Service Agreement was again amended in June 2021, effective January 2021, to extend the term for an additional year and automatically renew annually for an additional year, unless terminated by ICL or us, While substantially all of our service providers are currently employed by RMS, we continuously evaluate the efficiency and efficacy of our employment strategy, whether it be to employ personnel through us, RMS or otherwise.

All of our facilities are owned by an entity affiliated with our Executive Chairman, who is also the owner of ICL. We pay for the use of these facilities through the Service Agreement.

The table below details the amounts charged by ICL for services and rent (in thousands):

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Research and development	$17,129	$ 535	$184	$ 33
General and administrative	3,308	1,826	244	182
Total	**$20,437**	**$2,361**	**$428**	**$215**

Intellectual Property Agreement and Exclusive License Agreement with InCube Labs, LLC

In June 2012, we entered into an Intellectual Property Agreement and an Exclusive License Agreement with ICL, which were each amended on June 2013, pursuant to which ICL assigned to us certain intellectual property made by ICL during the course of providing services to us that relates primarily to, or has application primarily within, the field of oral delivery of biotherapeutic agents such as peptides, proteins and antibodies and excluding swallowable devices that do not deliver such drugs, or the Field of Use. ICL also granted to us a fully-paid, royalty-free, sublicensable, exclusive license under the intellectual property made by ICL during the course of providing services to us that is useful in the Field of Use but does not relate primarily to, or have application primarily within, the Field of Use to make, have made, use, offer to sell, sell and import products and services that are covered by such intellectual property within the Field of Use.

In June 2021, we and ICL entered into an Amended and Restated Exclusive License Agreement, which replaced the 2012 Exclusive License Agreement as amended in 2013 and terminated the 2012 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 to exploit products 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 InCube Labs, LLC

In June 2021, we entered into a Non-Exclusive License Agreement with ICL, pursuant to which we granted ICL a non-exclusive, fully-paid license under specified patents that were assigned from ICL to us to exploit products covered by such patents for all fields of use other than the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. 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 which will not be unreasonably denied, conditioned or delayed. ICL may enforce the patents licensed under the Non-Exclusive License Agreement only with our consent which will not be unreasonably conditioned, delayed or denied.

The Non-Exclusive License Agreement will continue in perpetuity unless earlier terminated. The Non-Exclusive License Agreement will terminate when there are no remaining valid claims of the patents licensed under the Non-Exclusive License Agreement. Additionally, ICL may terminate the Non-Exclusive License Agreement in its entirety or as to any particular licensed patent upon notification to us of such intent to terminate.

Intellectual Property Agreement between Mir Imran and Rani

In June 2021, we entered into an Intellectual Property Agreement with Mir Imran, or the Mir Agreement, pursuant to which we and Mir Imran agreed that we 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 (3) 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 (3) year term upon providing three (3) months' notice to the other party.

Service Agreement between Rani Management Services, Inc. and InCube Labs, LLC

In June 2021, our affiliate, RMS, entered into a Service Agreement, effective as of January 2021, with ICL, or the RMS-ICL Service Agreement, pursuant to which ICL agreed to rent a specified portion of its facility to RMS for a monthly rent in the mid five figures. Additionally, RMS agreed to provide personnel services to ICL upon ICL's request and each party agreed to provide other specified services to the other upon request. Such services will be invoiced based on RMS's or ICL's hourly billing rate, as applicable. Except for intellectual property created by Mir Imran which will be owned pursuant to the Mir Agreement, each party will assign all intellectual property that it creates directly from performing services to the other party. Neither us nor ICL may assign the RMS-ICL Service Agreement without the other party's consent. The RMS-ICL Service Agreement will have a 12-month term and will automatically renew for successive 12-month periods unless terminated. Either we or ICL may terminate the RMS-ICL Service Agreement for convenience upon 6 months' notice to the other party or on 30 days' notice for the other party's material breach.

Warrants

In December 2020, we amended the terms of certain warrants to purchase Series B units, issued to InCube Ventures II, LP, or 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 we issued 51,341 Series B units. There were no Series B Warrants outstanding as of March 31, 2021.

Tax Receivable Agreement

We expect to obtain an increase in our share of the tax basis of the assets of Rani LLC when (as described below under " —Rani LLC Agreement—LLC Interest Redemption Right") the Continuing LLC Owners (a) redeem or exchange their LLC Interests for newly issued shares of our Class A common stock on a one-for-one basis (or, at our option, for cash) and (b) receive payments under the Tax Receivable Agreement (such basis increase, a " Basis Adjustment"). We intend to treat such redemptions or exchanges of LLC Interests as the direct purchase of LLC Interests by Rani Holdings from such Continuing LLC Owners for U.S. federal income and other applicable tax purposes, regardless of whether such LLC Interests are surrendered by such Continuing LLC Owners to Rani LLC for redemption or sold to Rani Holdings upon the exercise of our election to acquire such LLC Interests directly. A Basis Adjustment may have the effect of reducing the amounts that we would otherwise pay in the future to various tax authorities to the extent that we have positive taxable income in a future tax period that is offset by tax depreciation or amortization deductions arising from such Basis Adjustment. The Basis Adjustments may also decrease gains (or increase losses) on future dispositions of certain capital assets to the extent tax basis is allocated to those capital assets, which could also generate tax savings for us.

In connection with the Organizational Transactions described above, we will enter into the Tax Receivable Agreement with certain of the Continuing LLC Owners. The Tax Receivable Agreement will provide 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 (calculated using certain assumptions) as a result of any Basis Adjustments and certain other tax benefits arising from payments under the Tax Receivable Agreement. Rani LLC 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 LLC 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. Actual tax benefits realized by us may differ from tax benefits calculated under the Tax Receivable Agreement as a result of the use of certain assumptions in the Tax Receivable Agreement, including the use of an assumed weighted-average state and local income tax rate to calculate tax benefits.

The Basis Adjustments, as well as any amounts paid to certain of the Continuing LLC Owners under the Tax Receivable Agreement, will vary depending on a number of factors, including:

- the timing of any subsequent redemptions or exchanges—for instance, the increase in any tax deductions will vary depending on the fair value, which may fluctuate over time, of the depreciable or amortizable assets of Rani LLC at the time of each redemption or exchange;

- the price of shares of our Class A common stock at the time of redemptions or exchanges—the Basis Adjustments, as well as any related increase in any tax deductions, are directly related to the price of shares of our Class A common stock at the time of each redemption or exchange;

- the extent to which such redemptions or exchanges are taxable—if a redemption or exchange is not taxable for any reason, increased tax deductions will not be available; 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) —the Tax Receivable Agreement generally will require Rani Holdings to pay 85% of the tax benefits as and when those benefits are treated as realized under the terms of the Tax Receivable Agreement. Except as discussed below in cases of (i) a material breach of a material obligation under the Tax Receivable Agreement, (ii) a change of control or (iii) an early termination of the Tax Receivable Agreement, if Rani Holdings does not have taxable income, it will generally not be required to make payments under the Tax Receivable Agreement for that taxable year because no tax benefits will have been realized. However, any tax benefits that do not result in realized tax benefits in a given taxable year may generate tax attributes that may be utilized to generate tax benefits in future taxable years. The utilization of any such tax attributes will result in payments under the Tax Receivable Agreement.

For purposes of the Tax Receivable Agreement, cash savings in income tax will be computed by comparing Rani Holdings' actual income tax liability to the amount of such taxes that it would have been required to pay had there been no Basis Adjustments and had the Tax Receivable Agreement not been entered into. The Tax Receivable Agreement will generally apply to each of our taxable years, beginning with the first taxable year ending after the consummation of the offering. The actual and hypothetical tax liabilities determined in the Tax Receivable Agreement will be calculated using the actual U.S. federal income tax rate in effect for the applicable period and an assumed, weighted-average state and local income tax rate based on apportionment factors for the applicable period (along with the use of certain other assumptions). There is no maximum term for the Tax Receivable Agreement; however, the Tax Receivable Agreement may be terminated by us pursuant to an early termination procedure that requires us to pay certain of the Continuing LLC Owners an agreed upon amount equal to the estimated present value of the remaining payments to be made under the agreement (calculated based on certain assumptions, including regarding tax rates and utilization of the Basis Adjustments).

The payment obligations under the Tax Receivable Agreement are obligations of Rani Holdings and not of Rani LLC. Although the actual timing and amount of any payments that may be made under the Tax Receivable Agreement will vary, we expect that the payments that we may be required to make to certain of the Continuing LLC Owners could be significant. For example, if we acquired all of the LLC Interests of certain of the Continuing LLC Owners in taxable transactions as of this offering, based on the initial public offering price of $11.00 per share and on certain assumptions, including that (i) there are no material changes in relevant tax law and (ii) we earn sufficient taxable income in each year to realize on a current basis all tax benefits that are subject to the Tax Receivable Agreement, we expect that the resulting reduction in tax payments for us, as determined for purposes of the Tax Receivable Agreement, would aggregate to approximately $120.7 million, substantially all of which would be realized over the next 15 years, and we would be required to pay certain of the Continuing LLC Owners 85% of such amount, or $102.6 million, over the same period. The actual increases in tax basis with respect to future taxable redemptions, exchanges or purchases of LLC Interests, as well as the

amount and timing of any payments we are required to make under the Tax Receivable Agreement in respect of the acquisition of LLC Interests from certain of Continuing LLC Owners in connection with this offering or future taxable redemptions, exchanges or purchases of LLC Interests, may differ materially from the amounts set forth above because the potential future reductions in our tax payments, as determined for purposes of the Tax Receivable Agreement, and the payments we will be required to make under the Tax Receivable Agreement, will each depend on a number of factors, including the market value of our Class A common stock at the time of redemption or exchange, the prevailing federal tax rates applicable to us over the life of the Tax Receivable Agreement (as well as the assumed combined state and local tax rate), the amount and timing of the taxable income that we generate in the future and the extent to which future redemptions, exchanges or purchases of LLC Interests are taxable transactions. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Source of Liquidity" for more information about expected payments under the Tax Receivable Agreement.

There may be a material negative effect on our liquidity if, as described below, the payments made by us to certain of the Continuing LLC Owners under the Tax Receivable Agreement exceed the actual benefits we receive in respect of the tax attributes subject to the Tax Receivable Agreement and/or distributions to us by Rani LLC are not sufficient to permit us to make payments under the Tax Receivable Agreement. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, the unpaid amounts generally will be deferred and will accrue interest until paid by us. Decisions made by us in the course of running our business, such as with respect to mergers, asset sales, other forms of business combinations or other changes in control, may influence the timing and amount of payments that are received by certain of the Continuing LLC Owners under the Tax Receivable Agreement. For example, the earlier disposition of assets following a transaction that results in a Basis Adjustment will generally accelerate payments under the Tax Receivable Agreement and increase the present value of such payments.

In addition, although we are not aware of any issue that would cause the IRS to challenge the tax basis increases or other benefits arising under the Tax Receivable Agreement, the Continuing LLC Owners who are parties to the Tax Receivable Agreement will not reimburse us for any payments previously made if such tax basis increases or other tax benefits are subsequently disallowed, except that any excess payments made to the Continuing LLC Owners who are parties to the Tax Receivable Agreement will be netted against future payments otherwise to be made under the Tax Receivable Agreement, if any, after our determination of such excess. As a result, in such circumstances we could make payments to certain of the Continuing LLC Owners under the Tax Receivable Agreement that are greater than our actual cash tax savings and may not be able to recoup those payments, which could negatively impact our liquidity.

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 fully utilize the benefits arising from the increased tax deductions and tax basis and other benefits covered by the Tax Receivable Agreement. As a result, upon a change of control, we could be required to make payments under the Tax Receivable Agreement that are greater than or less than the specified percentage of our actual cash tax savings, which could negatively impact our liquidity.

This provision of the Tax Receivable Agreement may result in situations where certain of the Continuing LLC Owners have interests that differ from or are in addition to those of our other stockholders. In addition, we could be required to make payments under the Tax Receivable Agreement that are substantial and in excess of our, or a potential acquirer's, actual cash savings in income tax.

Finally, because we are a holding company with no operations of our own, our ability to make payments under the Tax Receivable Agreement is dependent on the ability of Rani LLC to make distributions to us. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid.

Rani LLC Agreement

We will operate our business through Rani LLC and its subsidiary. In connection with the completion of this offering, we and the Continuing LLC Owners will enter into Rani LLC's fifth amended and restated limited liability company agreement, which we refer to as the "Rani LLC Agreement." The operations of Rani LLC, and the rights and obligations of the holders of LLC Interests, will be set forth in the Rani LLC Agreement.

Appointment as Manager

Under the Rani LLC Agreement, we will become a member and the sole manager of Rani LLC. As the sole manager, we will be able to control all of the day-to-day business affairs and decision-making of Rani LLC. As such, we, through our officers and directors, will be responsible for all operational and administrative decisions of Rani LLC and the day-to-day management of Rani LLC's business. Pursuant to the terms of the Rani LLC Agreement, we cannot, under any circumstances, be removed as the sole manager of Rani LLC except by our election.

Compensation

We will not be entitled to compensation for our services as manager. We will be entitled to reimbursement or capital contribution credit by Rani LLC for fees and expenses incurred on behalf of Rani LLC, including all expenses associated with this offering and maintaining our corporate existence.

Distributions

The Rani LLC Agreement will require "tax distributions" to be made by Rani LLC to its members, as that term is defined in the agreement. Tax distributions will be made to members on a pro rata basis, including us, in amounts intended to be sufficient to allow the members, including us, to pay taxes owed in respect of income allocated by Rani LLC and to allow us to meet our obligations under the Tax Receivable Agreement (as described above under " —Tax Receivable Agreement"). The Rani LLC Agreement will also allow for distributions to be made by Rani LLC to its members on a pro rata basis out of "distributable cash," as that term is defined in the agreement. We expect Rani LLC may make distributions out of distributable cash periodically to the extent permitted by our agreements governing our indebtedness and necessary to enable us to cover our operating expenses and other obligations, including our tax liability and obligations under the Tax Receivable Agreement, as well as to make dividend payments, if any, to the holders of our Class A common stock.

LLC Interest Redemption Right

The Rani LLC Agreement will provide a redemption right to the Continuing LLC Owners which will entitle them to have their LLC Interests redeemed, at their election (subject to the terms of the Rani LLC Agreement), for newly issued shares of our Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications). Upon the exercise of the redemption right, the redeeming member will surrender its LLC Interests to Rani LLC for cancellation. The Rani LLC Agreement will require that we contribute shares of our Class A common stock to Rani LLC in exchange for an amount of newly issued LLC Interests in Rani LLC that will be issued to us equal to the number of LLC Interests redeemed from the Continuing LLC Owners. Rani LLC will then distribute the shares of our Class A common stock to the Continuing LLC Owners to complete the redemption. In the event of such a redemption election by Continuing LLC Owners, Rani Holdings may effect a direct exchange of Class A common stock or a cash payment equal to a volume weighted average market price of one share of Class A common stock for each such LLC Interest in lieu of such a redemption. Whether by redemption or exchange, we will be obligated to ensure that at all times the number of LLC Interests that we own equals the number of shares of Class A common stock issued by us (subject to certain exceptions for treasury shares and shares underlying certain convertible or exchangeable securities).

Indemnification

The Rani LLC Agreement will provide for indemnification of the manager, members and officers of Rani LLC and their respective subsidiaries or affiliates.

Investors' Rights Agreement

We are party to an investors' rights agreement, as amended, with certain holders of our units, including Rani Investment Corp., InCube Ventures II, L.P., VH Rani, LP and Biologix Partners, LP. 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. This agreement will terminate upon the closing of this offering.

Registration Rights Agreement

In connection with this offering, we intend to enter into a Registration Rights Agreement with the Continuing LLC Owners. The Registration Rights Agreement will provide the Continuing LLC Owners certain registration rights whereby, at any time following our initial public offering and the expiration of any related lock-up period, the Continuing LLC Owners can require us to register under the Securities Act shares of Class A common stock issuable to them upon, at our election, redemption or exchange of their LLC Interests, and the Former LLC Owners can require us to register under the Securities Act the shares of Class A common stock issued to them in connection with the Organizational Transactions. The Registration Rights Agreement will also provide for piggyback registration rights for the Continuing LLC Owners.

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of the members of our board of directors, and our amended and restated bylaws provides that we will indemnify each of our officers and the members of our board of directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide our board of directors with discretion to indemnify our employees and other agents when it determines to be appropriate. In addition, we have entered into or will enter into an indemnification agreement with each of our executive officers and the members of our board of directors requiring us to indemnify them. See the section titled "Executive Compensation—Limitation of Liability and Indemnification of Directors and Officers."

Reserved Share Program

At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors and officers and certain other related parties to us.

Related Person Transaction Policy

Our board of directors has adopted a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets as of the end of our last two completed fiscal years, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will

consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction, management's recommendation with respect to the proposed related person transaction, and the extent of the related person's interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information about the beneficial ownership of our Class A common stock and Class B common stock as of June 30, 2021 after giving effect to the organizational transactions as described in the section titled "Organizational Transactions":

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our Class A common stock or Class B common stock immediately prior to this offering;
- each of the named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

As described in the sections titled "Organizational Transactions" and "Certain Relationships and Related Person Transactions," the Continuing LLC Owners will be entitled to have their LLC Interests redeemed or exchanged for shares of Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications) in accordance with the terms of the Rani LLC Agreement; provided that, at Rani Holdings' election, Rani Holdings may effect a direct exchange of such Class A common stock or a cash payment equal to a volume weighted average market price of one share of Class A common stock for each LLC Interest redeemed in accordance with the terms of the Rani LLC Agreement. In connection with this offering, we will issue to the Continuing LLC Owners one share of Class B common stock for each LLC Interest they own. As a result, the number of shares of Class B common stock listed in the table below correlates to the number of LLC Interests the Continuing LLC Owners will own immediately prior to and after this offering (but after giving effect to the Organizational Transactions other than this offering). See the section titled "Organizational Transactions."

The percentage of beneficial ownership of shares of our Class A common stock and our Class B common stock outstanding before the offering set forth below is based on the number of shares of our common stock to be issued and outstanding immediately following the Organizational Transactions without giving effect to this offering. The percentage of beneficial ownership of our Class A common stock and our Class B common stock after the offering set forth below is based on shares of our common stock to be issued and outstanding immediately after the offering.

Immediately following the consummation of this offering, certain of the Continuing LLC Owners will hold all of the issued and outstanding shares of our Class B common stock. The shares of Class B common stock will have no economic rights, but each share will entitle the holder to 10 votes on all matters on which stockholders of Rani Holdings are entitled to vote generally. The voting power afforded to certain of the Continuing LLC Owners by their shares of Class B common stock will be automatically and correspondingly reduced as they exchange shares of Class B common stock, together with a corresponding number of LLC Interests, as applicable, for shares of Class A common stock of Rani Holdings. See the sections titled "Certain Relationships and Related Person Transactions—Rani LLC Agreement," and "Description of Capital Stock."

The number of shares beneficially owned by each stockholder as described in this prospectus is determined under rules issued by the SEC and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared

voting power or investment power. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights, including the redemption right described above, held by such person that are currently exercisable or will become exercisable within 60 days of June 30, 2021, are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable. The following table does not reflect any potential purchases pursuant to the reserved share program. If any shares are purchased pursuant to the reserved share program, the number and percentage of shares of our Class A common stock beneficially owned by them after this offering will differ from the amounts set forth in the following table. Beneficial ownership of Rani LLC Class A units held by the Continuing LLC Owners listed below has not been reflected as beneficial ownership of shares of our Class A common stock for which such units may be exchanged.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Rani Therapeutics Holdings, Inc. 2051 Ringwood Avenue, San Jose, California 95131.

	Shares of Class A Common Stock Beneficially Owned			Shares of Class B Common Stock Beneficially Owned			Total Common Stock Beneficially Owned		
Name of Beneficial Owner	Number	% After Giving Effect to the Organizational Transactions and Before the Offering	% After Giving Effect to the Organizational Transactions and After the Offering	Number	% After Giving Effect to the Organizational Transactions and Before the Offering	% After Giving Effect to the Organizational Transactions and After the Offering	% After Giving Effect to the Organizational Transactions and Before the Offering	% After Giving Effect to the Organizational Transactions and After the Offering	Voting Power After Giving Effect to the Organizational Transactions and After the Offering
5% Stockholders									
InCube Labs, LLC(1)	—	—	—	22,389,982	76.5%	76.5%	47.0%	46.6%	71.9%
InCube Ventures II, L.P. and Affiliates(2)	829,435	4.5%	4.4%	2,564,861	8.8%	8.8%	7.1%	7.1%	8.5%
South Lake One LLC and Affiliates(3)	11,572,750	63.0%	61.8%	—	—	—	24.3%	24.1%	3.7%
Named Executive Officers and Directors									
Dennis Ausiello(4)	4,402	*	*	—	—	—	*	*	*
Jean-Luc Butel	—	—	—	—	—	—	—	—	—
Laureen DeBuono	—	—	—	—	—	—	—	—	—
Andrew Farquharson(2)	829,435	4.5%	4.4%	2,752,255	9.4%	9.4%	7.5%	7.5%	9.1%
Mir Hashim(5)	8,804	*	*	171,985	*	*	*	*	*
Mir Imran(1)(2)	829,435	4.5%	4.4%	24,954,843	85.3%	85.3%	54.1%	53.7%	80.4%
Talat Imran(6)	832,721	4.5%	4.4%	—	—	—	1.7%	1.7%	*
Maulik Nanavaty(7)	4,402	*	*	52,828	*	*	*	*	*
Svai Sanford(4)	8,804	*	*	—	—	—	*	*	*
All directors and executive officers as a group (9 persons)(8)	859,133	4.7%	4.6%	25,367,050	86.7%	86.7%	55.0%	54.6%	81.72%

* Represents beneficial ownership of less than 1% of the outstanding shares of our Class A common stock or Class B Common Stock.

(1) Represents shares held by ICL. Mir Imran is the sole managing member of ICL, which is wholly owned by Mir Imran and his family. The address of this entity is 2051 Ringwood Avenue, San Jose, California 95131.

(2) Represents shares held by InCube Ventures II, L.P., or InCube Ventures II, Rani Investment Corporation, or RIC, VH Rani, LP, or VH, and Biologix Partners, LP, or Biologix. InCube Ventures II is a limited partnership and its general partners are Mir Imran, Andrew Farquharson and Wayne Roe. RIC is wholly

owned by InCube Ventures II which is owned 99% by its limited partner Raffles Fund I, Ltd., a Cayman Island company, and 1% by its general partner InCube Venture Associates II, LLC, a Delaware LLC. InCube Venture Associates II, LLC is owned by Mir Imran, Andrew Farquharson and Wayne Roe. VH and Biologix are both limited partnerships and each have a general partner, InCube Crowdfunding LLC, in which Mir Imran, Talat Imran and Andrew Farquharson are each Managing Members. The address of these entities is 2051 Ringwood Avenue, San Jose, California 95131.

(3) Represents shares held by Aequanimitas Limited Partnership and South Lake One LLC. Isidoro Quiroga Moreno is the President of South Lake One LLC and Isidoro Quiroga Cortés is the authorized representative of Aequanimitas Limited Partnership. The address of these entities is c/o Vcorp Services LLC, 21013 Centre Road, Suite 403-B, Wilmington, Delaware 19805. Furthermore, South Lake One LLC and its affiliates have indicated an interest in purchasing approximately $69.3 million of shares (or 6,300,000 shares) in the aggregate of our Class A common stock in this offering at the initial public offering price. Immediately following the closing of this offering, South Lake One LLC and its affiliates will beneficially own approximately 24.1% of our stock, representing approximately 3.7% of our voting power (or approximately 23.6% of our stock, representing approximately 3.7% of our voting power if the underwriters exercise in full their option to purchase additional shares of Class A common stock). However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

(4) Consists of shares issuable pursuant to options exercisable within 60 days of June 30, 2021.

(5) Includes 8,804 shares issuable pursuant to options exercisable within 60 days of June 30, 2021.

(6) Represents shares held by VH and Biologix. VH and Biologix are both limited partnerships and each have a general partner, InCube Crowdfunding LLC, in which Mir Imran, Talat Imran and Andrew Farquharson are each Managing Members, and includes 3,286 shares issuable pursuant to options exercisable within 60 days of June 30, 2021. The address of these entities is 2051 Ringwood Avenue, San Jose, California 95131.

(7) Includes 4,402 shares issuable pursuant to options exercisable within 60 days of June 30, 2021.

(8) Includes 29,698 shares issuable pursuant to options exercisable within 60 days of June 30, 2021.

DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part.

Our current authorized capital stock consists of 1,000 shares of Common Stock, par value $0.0001 per share. As of the consummation of this offering, our authorized capital stock will consist of 800,000,000 shares of Class A common stock, par value $0.0001, 40,000,000 shares of Class B common stock, par value $0.0001 per share, 20,000,000 shares of Class C common stock, par value $0.0001 per share and 20,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

As of the consummation of this offering, there will be 18,738,682 shares of our Class A common stock issued and outstanding, 29,269,540 shares of our Class B common stock issued and outstanding and no shares of our Class C common stock issued and outstanding.

Class A Common Stock

Voting Rights

Holders of our Class A common stock will be entitled to cast one vote per share. Holders of our Class A common stock will not be entitled to cumulate their votes in the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all holders of Class A common stock and Class B common stock present in person or represented by proxy, voting together as a single class. Except as otherwise provided by law, amendments to the amended and restated certificate of incorporation must be approved by a majority or, in some cases, a super-majority of the combined voting power of all shares of Class A common stock and Class B common stock, voting together as a single class.

Dividend Rights

Any dividend or distribution paid or payable to the holders of shares of Class A common stock shall be paid pro rata, on an equal priority, pari passu basis; provided, however, that if a dividend or distribution is paid in the form of Class A common stock (or rights to acquire shares of Class A common stock), then the holders of the Class A common stock shall receive Class A common stock (or rights to acquire shares of Class A common stock).

Liquidation Rights

In the event of our liquidation, dissolution or winding-up, upon the completion of the distributions required with respect to any series of redeemable convertible preferred stock that may then be outstanding, our remaining assets legally available for distribution to stockholders shall be distributed on an equal priority, pro rata basis to the holders of Class A common stock and Class C common stock, unless different treatment is approved by the majority of the voting power of the outstanding shares of Class A common stock and Class B common stock.

Other Matters

No shares of Class A common stock will be subject to redemption or have preemptive rights to purchase additional shares of Class A common stock. Holders of shares of our Class A common stock do not have

subscription, redemption or conversion rights. There will be no redemption or sinking fund provisions applicable to the Class A common stock. Upon consummation of this offering, all the outstanding shares of Class A common stock will be validly issued, fully paid and non-assessable.

Class B Common Stock

Issuance of Class B Common Stock with LLC Interests

Shares of Class B common stock will only be issued in the future to the extent necessary to maintain a one-to-one ratio between the number of LLC Interests held by the Continuing LLC Owners and the number of shares of Class B common stock issued to the Continuing LLC Owners. Shares of Class B common stock are transferable only together with LLC Interests. Shares of Class B common stock will be cancelled on a one-for-one basis if we, at the election of the Continuing LLC Owners, redeem or exchange their LLC Interests pursuant to the terms of the Rani LLC Agreement.

Voting Rights

Holders of Class B common stock will be entitled to cast 10 votes per share until the Final Conversion Date and thereafter, one vote per share), with the number of shares of Class B common stock held by each Continuing LLC Owner being equivalent to the number of LLC Interests held by such Continuing LLC Owner. Holders of our Class B common stock will not be entitled to cumulate their votes in the election of directors. The voting power afforded to Continuing LLC Owners by their shares of Class B common stock will be automatically and correspondingly reduced as they redeem their LLC Interests because an equal number of their shares of Class B common stock will be cancelled.

Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all Class A and Class B stockholders present in person or represented by proxy, voting together as a single class. Except as otherwise provided by law, amendments to the amended and restated certificate of incorporation must be approved by a majority or, in some cases, a super-majority of the combined voting power of all shares of Class A common stock and Class B common stock, voting together as a single class. There will be a separate vote of the Class B common stock in the following circumstances:

- If we amend, alter or repeal any provision of the amended and restated certificate of incorporation or the amended and restated bylaws in a manner that modifies the voting, conversion or other powers, preferences, or other special rights or privileges, or restrictions of the Class B common stock; or

- If we reclassify any of outstanding shares of Class A common stock or Class C common stock into shares having rights as to dividends or liquidation that are senior to the Class B common stock or, in the case of Class A common stock, the right to more than one vote for each share thereof and, in the case of Class C common stock, the right to have any vote for any share thereof, except as required by law.

- If we authorize any shares of preferred stock with rights as to dividends or liquidation that are senior to the Class B common stock or the right to more than one vote for each share thereof.

Dividend Rights

The shares of Class B common stock have no economic rights. Holders of shares of our Class B common stock do not have any rights to receive dividends.

Retirement

Pursuant to the amended and restated certificate of incorporation, each share of Class B common stock will be retired, and all rights with respect to such shares shall cease and terminate, automatically upon the earlier to occur of (a) the occurrence of a Transfer (as defined therein), other than a Permitted Transfer (as defined therein) of such share of Class B common stock and (b) on the Final Conversion Date.

Liquidation Rights

On our liquidation, dissolution or winding up, holders of Class B common stock will not be entitled to receive any distribution of our assets.

Transfers

Pursuant to the Rani LLC Agreement, each holder of Class B common stock agrees that:

- the holder will not transfer any shares of Class B common stock to any person unless the holder transfers an equal number of LLC Interests to the same person; and
- in the event the holder transfers any LLC Interests to any person, the holder will transfer an equal number of shares of Class B common stock to the same person.

Other Matters

No shares of Class B common stock will have preemptive rights to purchase additional shares of Class B common stock. Holders of shares of our Class B common stock do not have subscription, redemption or conversion rights. There will be no redemption or sinking fund provisions applicable to the Class B common stock. Upon consummation of this offering, all outstanding shares of Class B common stock will be validly issued, fully paid and nonassessable.

Class C Common Stock

Voting Rights

Holders of our Class C common stock are not entitled to vote on any matter that is submitted to a vote of the stockholders, except as otherwise required by law. No shares of Class C common stock will be issued and outstanding in connection with of this offering.

Dividend Rights

Any dividend or distribution paid or payable to the holders of shares of Class C common stock shall be paid pro rata, on an equal priority, pari passu basis; provided, however, that if a dividend or distribution is paid in the form of Class C common stock (or rights to acquire shares of Class C common stock), then the holders of the Class C common stock shall receive Class C common stock (or rights to acquire shares of Class C common stock).

Liquidation Rights

In the event of our liquidation, dissolution or winding-up, upon the completion of the distributions required with respect to any series of redeemable convertible preferred stock that may then be outstanding, our remaining assets legally available for distribution to stockholders shall be distributed on an equal priority, pro

rata basis to the holders of Class A common stock and Class C common stock, unless different treatment is approved by the majority of the voting power of the outstanding shares of Class A common stock and Class B common stock.

Preferred Stock

Our amended and restated certificate of incorporation provides that our board of directors has the authority, without action by the stockholders, to designate and issue up to 20,000,000 shares of preferred stock in one or more classes or series and to fix the powers, rights, preferences, privileges and restrictions of each class or series of preferred stock, including dividend rights, conversion rights, voting rights, redemption privileges, liquidation preferences and the number of shares constituting any class or series, which may be greater than the rights of the holders of the common stock. There will be no shares of preferred stock outstanding immediately after this offering.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Additionally, the issuance of preferred stock may adversely affect the holders of our Class A common stock by restricting dividends on the Class A common stock, diluting the voting power of the Class A common stock or subordinating the liquidation rights of the Class A common stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our Class A common stock.

Renouncement of Corporate Opportunity

Our amended and restated certificate of incorporation provides that, to the extent permitted by law, we renounce any expectancy that a "covered person" offer us an opportunity to participate in a "specified opportunity" and waives any claim that the specified opportunity constitutes a corporate opportunity that should have been presented by the covered person to us; provided, however, that the covered person acts in good faith. A "covered person" is any officer, member of the board of directors or stockholder (or affiliate thereof) who is not an employee of ours or any of our subsidiaries. A "specified opportunity" is any transaction or other business opportunity that is not presented to the covered person solely in his or her capacity as an officer, member of the board of directors or stockholder (or affiliate thereof).

Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws

Certain provisions of Delaware law and certain provisions that are included in our amended and restated certificate of incorporation and amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay, deter, or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

Preferred Stock

Our amended and restated certificate of incorporation contains provisions that permit our board of directors to issue, without any further vote or action by the stockholders, shares of preferred stock in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting rights (if any) of the shares of the series and the powers, preferences, or relative, participation, optional, and other special rights, if any, and any qualifications, limitations, or restrictions, of the shares of such series.

Classified Board

Our amended and restated certificate of incorporation provides that from and after the Final Conversion Date our board of directors will be divided into three classes, designated Class I, Class II and Class III. Each class will be an equal number of directors, as nearly as possible, consisting of one-third of the total number of directors constituting the entire board of directors. The term of initial Class I directors shall terminate on the first annual meeting of the stockholders after the Final Conversion Date, the term of the initial Class II directors shall terminate on the second annual meeting of the stockholders after the Final Conversion Date, and the term of the initial Class III directors shall terminate on the third annual meeting of the stockholders after the Final Conversion Date. At each annual meeting of stockholders beginning after the Final Conversion Date, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term.

Removal of Directors

Our amended and restated certificate of incorporation provides that stockholders may only remove a director for cause by a vote of no less than a majority of the total voting power of the shares present in person or by proxy at the meeting and entitled to vote.

Director Vacancies

Our amended and restated certificate of incorporation authorizes only our board of directors to fill vacant directorships.

No Cumulative Voting

Our amended and restated certificate of incorporation provides that stockholders do not have the right to cumulate votes in the election of directors.

Special Meetings of Stockholders

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, except as otherwise required by law, special meetings of the stockholders may be called only (i) prior to the Final Conversion Date, by the 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; (ii) by a resolution adopted by a majority of our board of directors; (iii) by the chairperson of our board of directors; or (iv) by our Chief Executive Officer.

Advance Notice Procedures for Director Nominations

Our amended and restated bylaws provides that stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders must provide timely notice thereof in writing. To be timely, a stockholder’s notice generally will have to be delivered to and received at our principal executive offices before notice of the meeting is issued by the secretary of the Company, with such notice being served not later than the close of business on the ninetieth (90th) day nor earlier than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the preceding year’s annual meeting. Although the amended and restated bylaws does not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, the amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.

Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, after the Final Conversion Date, any action to be taken by the stockholders must be affected at a duly called annual or special meeting of stockholders and may not be affected by written consent.

Amending our Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the DGCL. Our amended and restated bylaws may be adopted, amended, altered, or repealed by stockholders only upon approval of at least majority of the voting power of all the then outstanding shares of the Class A common stock and Class B common stock, voting together as a single class. Furthermore our amended and restated certificate of incorporation provides Class B common stock protective provisions that require approval of a majority of the voting power of the Class B common stock then outstanding to amend, alter or repeal the amended and restated certificate of incorporation and the amended and restated bylaws. Additionally, our amended and restated certificate of incorporation and amended and restated bylaws provide that our bylaws may be amended, altered, or repealed by the board of directors.

Authorized but Unissued Shares

Our authorized but unissued shares of Class A common stock and preferred stock will be available for future issuances without stockholder approval, except as required by the listing standards of the Nasdaq Stock Market, and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Class A common stock and preferred stock could render more difficult or discourage an attempt to obtain control of the Company by means of a proxy contest, tender offer, merger, or otherwise.

Choice of Forum

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: (i) any derivative action or proceeding brought on our behalf; (ii) 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; (iii) 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 DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) 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; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) 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 further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to 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.

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.

Business Combinations with Interested Stockholders

We have elected not be subject to or governed by Section 203 of the DGCL. Subject to certain exceptions, Section 203 of the DGCL prohibits a public Delaware corporation from engaging in a business combination (as defined in such section) with an "interested stockholder" (defined generally as any person who beneficially owns 15% or more of the outstanding voting stock of such corporation or any person affiliated with such person) for a period of three years following the time that such stockholder became an interested stockholder, unless (i) prior to such time the board of directors of such corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) upon the closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of such corporation at the time the transaction commenced (excluding for purposes of determining the voting stock of such corporation outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (A) by persons who are directors and also officers of such corporation and (B) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or (iii) at or subsequent to such time the business combination is approved by the board of directors of such corporation and authorized at a meeting of stockholders (and not by written consent) by the affirmative vote of at least 66 2/3% of the outstanding voting stock of such corporation not owned by the interested stockholder.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL. We are expressly authorized to, and do, carry directors' and officers' insurance providing coverage for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive directors.

The limitation on liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Listing

Our Class A common stock has been approved for listing on the Nasdaq Global Market under the symbol "RANI."

Transfer Agent and Registrar

The transfer agent and registrar for our Class A common stock immediately prior to the closing of this offering will be American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219 and the telephone number is (800) 937-5449.

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our Class A common stock. Future sales of substantial amounts of Class A common stock in the public market (including shares of Class A common stock issuable upon redemption or exchange of LLC Interests), or the perception that such sales may occur, could adversely affect the market price of our Class A common stock. Although our Class A common stock is listed on Nasdaq, we cannot assure you that there will be an active public market for our Class A common stock.

Upon the closing of this offering, we will have outstanding an aggregate of 18,738,682 shares of Class A common stock, assuming the issuance of 6,666,667 shares of Class A common stock offered by us in this offering and the issuance of 12,072,015 shares of Class A common stock to the Former LLC Owners. In addition, 30,813,262 LLC Interests, following the completion of this offering, will be redeemable, at the Continuing LLC Owners' election (subject to the terms of the Rani LLC Agreement), for newly issued shares of Class A common stock on a one-for-one basis (subject to customary adjustments, including for stock splits, stock dividends and reclassifications) in accordance with the terms of the Rani LLC Agreement; 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 Class A common stock for each LLC Interest redeemed. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement. The remaining outstanding shares of our common stock will be "restricted securities" as that term is defined under Rule 144 of the Securities Act.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities (including shares of Class A common stock issuable upon redemption or exchange of LLC Interests) will be available for sale in the public market as follows:

- no shares will be available for sale until 180 days after the date of this prospectus, subject to certain limited exceptions provided for in the lock-up agreements; and

- all shares of Class A common stock (without giving effect to any redemptions or exchanges of LLC Interests for shares of Class A common stock), plus any shares purchased by our affiliates in this offering, will be eligible for sale beginning more than 180 days after the date of this prospectus, subject, in the case of shares held by our affiliates, to the volume limitations under Rule 144.

Lock-up Agreements

In connection with this offering, our officers and directors, and certain of our stockholders, have each entered into a lock-up agreement with the underwriters of this offering that restricts the sale of shares of our common stock by those parties for a period of 180 days after the date of this prospectus without the prior written consent of the representatives. However, the representatives, on behalf of the underwriters, may, in their discretion, choose to release any or all of the shares of our common stock subject to these lock-up agreements at any time prior to the expiration of the lock-up period without notice. For more information, see the section titled "Underwriting." Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days

before a sale, who has beneficially owned shares of our Class A common stock for at least 180 days would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our Class A common stock then outstanding; and
- the average weekly trading volume in our Class A common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the 90 days preceding a sale, and who has beneficially owned shares of our Class A common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register the offer and sale of all shares of Class A common stock issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the closing of this offering, Continuing LLC Owners will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section titled "Certain Relationships and Related Person Transactions—Registration Rights Agreement" for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement described in "—Lock-up Agreements."

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the ownership and disposition of our Class A common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax consequences. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, or the Treasury Regulations, judicial decisions, and published rulings and administrative pronouncements of the IRS, in each case as in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our Class A common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to those discussed below regarding the tax consequences of the purchase, ownership and disposition of our Class A common stock.

This discussion is limited to Non-U.S. Holders that hold our Class A common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare tax on net investment income or the alternative minimum tax, or the consequences to persons subject to special tax accounting rules as a result of any item of gross income with respect to our Class A common stock being taken into account in an applicable financial statement. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our Class A common stock as part of a straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or certain electing traders in securities that mark their securities positions to market for tax purposes;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our Class A common stock under the constructive sale provisions of the Code;
- "qualified foreign pension funds" (within the meaning of Section 897(I)(2) of the Code and entities, all of the interests of which are held by qualified foreign pension funds); and
- tax-qualified retirement plans.

If any partnership or arrangement classified as a partnership for U.S. federal income tax purposes holds our Class A common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our Class A common stock and partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE OWNERSHIP AND DISPOSITION OF OUR CLASS A COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our Class A common stock that is neither a "United States person" nor an entity treated as a partnership for U.S. federal income tax purposes. A United States person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the U.S.;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our Class A common stock in the foreseeable future. However, if we do make distributions of cash or property on our Class A common stock (other than certain pro rata distributions of our stock), such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Any portion of a distribution that exceeds our current and accumulated earnings and profits generally will be treated first as a tax-free return of capital, causing a reduction in the adjusted tax basis of a Non-U.S. holder's Class A common stock, and to the extent the amount of the distribution exceeds a Non-U.S. holder's adjusted tax basis in our Class A common stock, the excess will be treated as gain from the disposition of our Class A common stock (the tax treatment of which is discussed below under " —Sale or Other Taxable Disposition").

Subject to the discussion below on effectively connected income, backup withholding, and the Foreign Account Tax Compliance Act, dividends paid to a Non-U.S. Holder of our Class A common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty), provided that the Non-U.S. Holder will be required to furnish to the applicable withholding agent prior to the payment of dividends a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate in order to avoid withholding with respect to such tax). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net-income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits (as adjusted for certain items), which will include such effectively connected dividends. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below on backup withholding and the Foreign Account Tax Compliance Act, a Non-U.S. Holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our Class A common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);

- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

- our Class A common stock constitutes a U.S. real property interest (a "USRPI"), by reason of our status as a U.S. real property holding corporation (a "USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits (as adjusted for certain items), which will include such effectively connected gain.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may generally be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our Class A common stock will not be subject to U.S. federal income tax if our Class A common stock is "regularly traded" on an established securities market (as defined by applicable Treasury Regulations), and such Non-U.S. Holder has not owned, actually or constructively, more than five percent of our Class A common stock throughout the shorter of (1) the five-year period ending on the date of the sale or other taxable disposition and (2) the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our Class A common stock generally will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns generally will be filed with the IRS in connection with any distributions on our Class A common stock paid to a Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our Class A common stock within the U.S. or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our Class A common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred to as the "Foreign Account Tax Compliance Act" or "FATCA") generally impose withholding at a rate of 30% in certain circumstances on certain payments in respect of securities which are held by or through certain foreign financial institutions (including investment funds), unless any such institution (i) enters into, and complies with, an agreement with the IRS to report, on an annual basis, information with respect to interests in, and accounts maintained by, the institution that are owned by certain U.S. persons and by certain non-U.S. entities that are wholly or partially owned by U.S. persons and to withhold on certain payments, or (ii) if required under an intergovernmental agreement between the United States and an applicable foreign country, reports such information to its local tax authority, which will exchange such information with the U.S. authorities. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Accordingly, the entity through which shares of our Class A common stock are held will affect the determination of whether such withholding is required. Similarly, certain payments in respect of our Class A common stock held by an investor that is a non-financial non-U.S. entity that does not qualify under certain exceptions will generally be subject to withholding at a rate of 30%, unless such entity either (i) certifies to the applicable withholding agent that such entity does not have any "substantial United States owners" or (ii) provides certain information regarding the entity's "substantial United States owners," which will in turn be provided to the U.S. Department of Treasury. FATCA currently applies to dividends paid on our Class A common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our Class A common stock. The U.S. Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of our Class A common stock. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our Class A common stock. Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our Class A common stock.

UNDERWRITING

BofA Securities, Inc., Stifel, Nicolaus & Company, Incorporated, Cantor Fitzgerald & Co. and Canaccord Genuity LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us, Rani LLC and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of Class A common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	2,666,668
Stifel, Nicolaus & Company, Incorporated	1,666,666
Cantor Fitzgerald & Co.	1,000,000
Canaccord Genuity LLC	800,000
BTIG LLC	533,333
Total	6,666,667

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We and Rani LLC have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $0.462 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$ 11.00	$ 73,333,337	$84,333,337
Less: Underwriting discount	(0.77)	(5,133,334)	(5,903,334)
Proceeds, before expenses, to us	$ 10.23	$ 68,200,003	$78,430,003

The expenses of the offering, not including the underwriting discounts and commissions, payable by us are estimated to be approximately $4.1 million. We have also agreed to reimburse the underwriters for certain of their expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to $30,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,000,000 additional shares at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, Rani LLC, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any Class A common stock or Class B common stock or securities convertible into, exchangeable for, exercisable for, or repayable with Class A common stock or Class B common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Stifel, Nicolaus & Company, Incorporated. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any Class A common stock or Class B common stock,
- sell any option or contract to purchase any Class A common stock or Class B common stock,
- purchase any option or contract to sell any Class A common stock or Class B common stock,
- grant any option, right or warrant to purchase any Class A common stock or Class B common stock,
- otherwise dispose of or transfer any Class A common stock or Class B common stock,
- exercise any right with respect to the registration of any Class A common stock or Class B common stock or file, cause to be filed or cause to be confidentially submitted any registration statement under the Securities Act related to the Class A common stock or Class B common stock, or
- enter into any swap or other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of any Class A common stock or Class B common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to Class A common stock and Class B common stock and to securities convertible into or exchangeable or exercisable for or repayable with Class A common stock or Class B common stock. It also applies to Class A common stock or Class B common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Listing

Our Class A common stock has been approved for listing on the Nasdaq Global Market under the symbol "RANI."

Determination of Offering Price

Before this offering, there has been no public market for our Class A common stock. The initial public offering price was determined through negotiations between us, Rani LLC and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,

- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our Class A common stock. However, the representatives may engage in transactions that stabilize the price of the Class A common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our Class A common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our Class A common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of Class A common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our Class A common stock or preventing or retarding a decline in the market price of our Class A common stock. As a result, the price of our Class A common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our Class A common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates, including Rani LLC. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Reserved Share Program

At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors and officers and certain other related parties to us. If these persons purchase reserved shares, it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

European Economic Area

In relation to each Member State of the European Economic Area (each a “Relevant State”), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus

Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a "qualified investor" within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(l) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom (U.K.), no shares have been offered or will be offered pursuant to the offering to the public in the U.K. prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority in the U.K. in accordance with the U.K. Prospectus Regulation and the FSMA, except that offers of shares may be made to the public in the U.K. at any time under the following exemptions under the U.K. Prospectus Regulation and the FSMA:

a. to any legal entity which is a qualified investor as defined under the U.K. Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the U.K. Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer;

c. at any time in other circumstances falling within section 86 of the FSMA; or

d. provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the U.K. Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the U.K. Prospectus Regulation.

Each person in the U.K. who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the U.K. Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the U.K. Prospectus Regulation, each such financial intermediary will be deemed to have represented,

acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the U.K. to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any Shares in the U.K. means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, the expression "U.K. Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression "FSMA" means the Financial Services and Markets Act 2000.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the Financial Promotion Order), (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, FINMA, and the offer of shares has not been and will not be authorized under CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities

Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the ASIC in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (ii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in

Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA,

- where no consideration is or will be given for the transfer,

- where the transfer is by operation of law, or

- as specified in Section 276(7) of the SFA.

In connection with Section 309B of the SFA and the Capital Markets Products (CMP) Regulations 2018, the shares are prescribed capital markets products (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in Monetary Authority of Singapore Notice SFA 04-N12: Notice on the Sale of Investment Products and Monetary Authority of Singapore Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of

the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

LEGAL MATTERS

The validity of the issuance of our Class A common stock offered in this prospectus will be passed upon for us by Cooley LLP, Palo Alto, California. Goodwin Procter LLP, Redwood City, California is acting as counsel for the underwriters.

EXPERTS

The financial statements of Rani Therapeutics Holdings, Inc. at April 19, 2021 appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Rani Therapeutics, LLC as of December 31, 2019 and 2020, and for each of the two years in the period ended December 31, 2020, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our Class A common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our Class A common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements, and other information about us, are available at the SEC's website, www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act, and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at https://www.ranitherapeutics.com/ where these materials are available. Upon the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

GLOSSARY

ACA	Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act
API	Active Pharmaceutical Ingredient
ASIC	Australian Securities and Investments Commission
AUC	Area Under Curve
BLA	Biologics License Application
BPCIA	Biologics Price Competition and Innovation Act (2009)
CBER	The FDA Center for Biologics Evaluation and Research
CCPA	California Consumer Privacy Act of 2018
CDC	U.S. Centers for Disease Control and Prevention
CDER	The FDA Center for Drug Evaluation and Research
CDRH	The FDA Center for Device and Radiological Health
cGCP	Current Good Clinical Practice
cGMP	Current Good Manufacturing Practice
CISA	Swiss Federal Act on Collective Investment Schemes
Cmax	Maximal Concentration
CMS	Center for Medicare & Medicaid Services
COVID-19	COVID-19 Pandemic
CRO	Contract Research Organizations
DFSA	Dubai Financial Services Authority
DGCL	Delaware General Corporation Law
EMA	European Medicines Agency
EPO	European Patent Office
FATCA	Foreign Account Tax Compliance Act
FCPA	U.S. Foreign Corrupt Practices Act
FDA	United States Food and Drug Administration
FDCA	Federal Food, Drug and Cosmetic Act
FINMA	Swiss Financial Market Supervisory Authority
FSMA	Financial Services and Markets Act 2000
GAAP	Generally Accepted Accounting Principles
GCP	Good Clinical Practice
GDPR	European General Data Protection Regulation
GI	Gastrointestinal
GLP	Glucagon-like Peptide
GRAS	Generally Regarded as Safe
hGH	Human Growth Hormone
HHS	The Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act of 2009

ICA	Investment Company Act of 1940, as amended—1940 Act
ICL	InCube Labs, LLC
IDE	Investigational Device Exemption
IDT	Intestinal Deployment Time
IJ	Intrajejunal
IND	Investigational New Drug Application
IRB	Institutional Review Board
IRS	Internal Revenue Service
IV	Intravenous
JOBS Act	Jumpstart our Business Startups Act of 2021
JW	Jejunal Wall
MFN	Most-Favored Nation
Nasdaq	Nasdaq Stock Market
NDA	New Drug Application
NET	Neuroendocrine Tumors
OCP	Office of Combination Products
OIG	Office of Inspector General
OP	Osteoporosis
PD	Pharmacodynamic
PHSA	Public Health Service Act
PK	Pharmacokinetic
PTH	Parathyroid Hormone
PTH-Hypo	Parathyroid Hormone for the Treatment of Hypoparathyroidism
PTH-OP	Parathyroid Hormone for the Treatment of Osteoporosis
QSRs	Quality System Regulations
RA	Rheumatoid Arthritis
REMS	Risk Evaluation and Mitigation Strategy
SC	Subcutaneous
SEC	Securities and Exchange Commission
SFA	U.S. Securities and Futures Act
SIX	SIX Swiss Exchange
Tmax	Time To Maximum Concentration
USPTO	U.S. Patent Trademark Office
USRPHC	U.S. Real Property Holding Corporation
USRPI	U.S. Real Property Interest

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholder of Rani Therapeutics Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Rani Therapeutics Holdings, Inc. (the Company) as of April 19, 2021 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at April 19, 2021 in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

Redwood City, California
April 26, 2021

RANI THERAPEUTICS HOLDINGS, INC.
BALANCE SHEET
As of April 19, 2021

Assets:	
Cash	$10
Total assets	$ 10
Commitments and contingencies	
Stockholder's Equity:	
Common stock, $0.0001 par value per share, 1,000 shares authorized, issued and outstanding	$ –
Additional paid-in-capital	10
Total stockholder's equity	$ 10

The accompanying notes are an integral part of the financial statements.

RANI THERAPEUTICS HOLDINGS, INC.
NOTES TO FINANCIAL STATEMENT

1. Organization

Rani Therapeutics Holdings, Inc. (the "Company") was formed as a Delaware corporation on April 6, 2021. The Company was formed for the purpose of completing a public offering and related transactions in order to carry on the business of Rani Therapeutics, LLC and its subsidiary ("Rani LLC"). As the manager of Rani LLC, the Company 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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Accounting

The financial statement has been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Separate statements of operations, comprehensive income, changes in stockholder's equity, and cash flows have not been presented because there have been no activities in this entity as of April 19, 2021.

These financial statements have been prepared assuming the Company 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 U.S. generally accepted accounting principles 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. Common Stock

On April 6, 2021, the Company was authorized to issue 1,000 shares of common stock, par value $0.0001 per share, all of which have been issued or are outstanding. On the balance sheet date, the Company 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, the Company had outstanding 1,000 shares all of which were owned by Rani LLC.

4. Subsequent Events

The Company has evaluated subsequent events through April 26, 2021, the date these financial statements were available to be issued. The Company has concluded that no subsequent event has occurred that requires disclosure.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Managers of Rani Therapeutics, LLC

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rani Therapeutics, LLC (the Company) as of December 31, 2019 and 2020, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred units and member's deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Redwood City, California
April 26, 2021

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

	December 31, 2019	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 16,536	$ 73,058
Current portion of related party notes receivable	250	1,720
Prepaid expenses	158	167
Total current assets	16,944	74,945
Related party notes receivable, less current portion	1,625	—
Property and equipment, net	4,453	4,470
Total assets	$ 23,022	$ 79,415
Liabilities, Convertible Preferred Units and Members' Deficit		
Current liabilities:		
Accounts payable	$ 198	$ 537
Related party payable	1,926	145
Accrued expenses	1,195	550
Deferred revenue	179	2,717
Current portion of long-term debt	—	1,359
Total current liabilities	3,498	5,308
Preferred unit warrant liability	655	320
Long-term debt, less current portion	—	2,412
Total liabilities	$ 4,153	$ 8,040
Commitments and contingencies (Note 11)		
Convertible preferred units, 21,605,000 and 32,620,000 units authorized, and 17,084,696 and 26,745,528 units issued and outstanding at December 31, 2019 and 2020, respectively	$115,505	$ 184,714
Members' deficit:		
Common units, 90,000,000 and 101,000,000 units authorized, and 46,890,280 units issued and outstanding at December 31, 2019 and 2020, respectively	664	664
Accumulated deficit	(97,300)	(114,003)
Total members' deficit	(96,636)	(113,339)
Total liabilities, convertible preferred units and members' deficit	$ 23,022	$ 79,415

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

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

	Years Ended December 31,	
	2019	2020
Contract revenue	$ 979	$ 462
Operating expenses		
Research and development	24,579	12,044
General and administrative	3,465	4,962
Total operating expenses	28,044	17,006
Loss from operations	$ (27,065)	$ (16,544)
Other income (expense), net		
Interest income	$ 423	$ 63
Interest expense and other, net	(10)	(124)
Change in estimated fair value of preferred unit warrant liability	65	(63)
Loss before income taxes	(26,587)	(16,668)
Income tax expense	—	(35)
Net loss and comprehensive loss	$ (26,587)	$ (16,703)
Net loss per unit—basic and diluted	$ (0.57)	$ (0.36)
Weighted-average common units outstanding—basic and diluted	46,890,280	46,890,280

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

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

	Convertible Preferred		Common		Accumulated Deficit	Total Members' Deficit
	Units	Amount	Units	Amount		
Balance at December 31, 2018	17,084,696	$115,505	46,890,280	$ 664	$ (70,713)	$ (70,049)
Net loss	—	—	—	—	(26,587)	(26,587)
Balance at December 31, 2019	17,084,696	$115,505	46,890,280	$ 664	$ (97,300)	$ (96,636)
Cashless exercise of warrant for Series B preferred units	51,341	718	—	—	—	—
Issuance of Series E preferred units, net of issuance costs of $190	9,609,491	68,491	—	—	—	—
Net loss	—	—	—	—	(16,703)	(16,703)
Balance at December 31, 2020	26,745,528	$184,714	46,890,280	$ 664	$ (114,003)	$ (113,339)

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

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

	Years Ended December 31,	
	2019	2020
Cash flows from operating activities		
Net loss	$(26,587)	$(16,703)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	564	589
Change in estimated fair value of preferred unit warrant liability	(65)	63
Other	(16)	47
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(86)	(9)
Accounts payable	(271)	933
Accrued expenses	103	(636)
Related party payable	270	(1,782)
Deferred revenue	(179)	2,538
Net cash used in operating activities	$(26,267)	$(14,960)
Cash flows from investing activities		
Purchases of property and equipment	$ (1,581)	$ (1,200)
Proceeds from disposal of property and equipment	49	—
Net cash used in investing activities	$ (1,532)	$ (1,200)
Cash flows from financing activities		
Proceeds from issuance of preferred units, net of issuance costs	$ —	$ 68,491
Proceeds from issuance of convertible note, net of issuance costs	—	2,781
Proceeds from the Paycheck Protection Program Loan	—	1,254
Principal repayments from related party for notes receivable	852	156
Net cash provided by financing activities	852	72,682
Net (decrease) increase in cash and cash equivalents	(26,947)	56,522
Cash and cash equivalents, beginning of year	43,483	16,536
Cash and cash equivalents, end of year	$ 16,536	$ 73,058
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ 57
Supplemental disclosures of non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued liabilities	$ 594	$ —
Reissuance of previously expired warrant for Series B preferred units	$ —	$ 718
Cashless exercise of warrant for Series B preferred units	$ —	$ 718

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

RANI THERAPEUTICS LLC
NOTES TO 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.

Since its inception, Rani has devoted substantially all of its resources to research and development activities, including drug formulation, preclinical studies, clinical trials, manufacturing automation and scale-up, building its intellectual property portfolio, establishing strategic relationships with pharmaceutical companies that may benefit from the RaniPill capsule as well as administrative activities such as business planning, raising capital, and providing general and administrative support for these operations.

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 7).

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $26.6 million and $16.7 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, the Company had an accumulated deficit of $114.0 million and negative cash flows from operations of $15.0 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. As of December 31, 2020, the Company expects that its cash and cash equivalents of $73.1 million will be sufficient to fund its operations through at least one year from April 2021, the date the consolidated financial statements are available to be 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, an initial public offering ("IPO") of common stock, 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 investors. 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

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.

Operating Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. The Company operates and manages its business as one operating segment.

Revenue Recognition

The Company enters into evaluation and first rights 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 contract receivable when it has an unconditional right to consideration. No contract assets balance was recorded as of December 31, 2019 and 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, 2019, and 2020, the Company had deferred revenue of $0.2 million and $2.7 million, respectively.

Cash and Cash Equivalents

The Company considers all cash held on deposit and highly liquid investments purchased with original or remaining maturities of less than three months at the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value. The Company's cash and cash equivalents consist of balances held in demand depositary accounts and money market funds. The Company limits its credit risk associated with cash and cash equivalents by maintaining its bank accounts at major financial institutions.

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 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 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.

Property and Equipment, Net

Property and equipment, net are recorded at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method based on the estimated useful lives of the depreciable property. Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or their estimated useful lives. The Company's estimated useful lives of its property and equipment are as follows:

	Estimated Useful Lives (in years)
Laboratory equipment	3 years
Office and computer equipment	3 years
Leasehold improvements	Estimated useful life

Upon sale or retirement of the assets, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is recognized in the consolidated statement of operations and comprehensive loss. Expenditures for maintenance and repairs are expensed as incurred.

Impairment of Long-Lived Assets

The Company reviews the carrying amounts of its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (or asset group) may not be recoverable. If indicators of impairment exist, an impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment charge is determined based upon the excess of the carrying value of the asset over its estimated fair value, with estimated fair value determined based upon an estimate of discounted future cash flows or other appropriate measures of estimated fair value. Management believes that no revision to the remaining useful lives or write-down of long-lived assets is required as of and for the year ended December 31, 2020.

Notes Receivable from Related Party

The principal balance on the notes receivable from related party is recorded on the consolidated balance sheet along with earned and not yet received interest income. The principal balance is classified on the consolidated balance sheet based upon the expected timing of the repayments by the related party. Interest income received and receivable on the related party notes receivable is recorded as a component of interest income in the consolidated statement of operations and comprehensive loss. Associated interest earned is recognized using the effective interest method. The estimated fair value of the Company's related party notes receivable at December 31, 2019 and 2020 approximated their carrying value due to their short-term nature.

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 the Company and consultants in the form of non-vested incentive units ("Profits Interests"). All awards of Profits Interests 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 Company utilizes estimates and assumptions in determining the fair value of its Profits Interests on the date of grant. 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 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.

Income Taxes

The Company's wholly-owned subsidiary, RMS, is a taxpaying entity in the United States. Accordingly, the Company provides current and deferred income taxes for this entity. The Company is treated as a pass through entity for federal and state income tax purposes and is not subject to income tax as the limited liability company ("LLC") members are responsible for the tax consequences of their proportionate share of the pass through income or loss. As such, the Company's tax provision consists solely of the activities of RMS, which is taxed as a corporation for federal and state income tax purposes.

The Company's taxable subsidiary accounts for income taxes using the asset and liability method, under which deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are classified as noncurrent on the consolidated balance sheet. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not to be realized. The Company uses a recognition threshold and measurement attribute for the consolidated financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. A tax position is recognized when it is more likely than not that the tax position will be sustained upon examination, including the resolution of any related appeals or litigation. A tax position that meets the more-likely-than-not recognition threshold is measured at the largest amount of benefit that is greater than a 50% likelihood of being realized upon ultimate settlement with a taxing authority. Interest and penalties related to unrecognized tax benefits are recognized in benefit from income taxes in the accompanying consolidated statements of operations and comprehensive loss. No such interest and penalties were recognized for any period presented.

In March 2020, the Families First Coronavirus Response Act ("FFCR Act") and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

In June 2020, Assembly Bill 85 ("A.B. 85") was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

Other than the Company's receipt of a Paycheck Protection Program Loan during 2020 (see Note 12), the FFCR Act, CARES Act and A.B. 85 did not have a material impact on the Company's consolidated financial statements as of December 31, 2020; however, the Company continues to examine the impacts the FFCR Act, CARES Act and A.B. 85 may have on its business, consolidated results of operations, financial condition, liquidity and related disclosures.

Convertible Preferred Units

The Company records convertible preferred units at fair value on the dates of issuance, net of issuance costs. The Company has classified convertible preferred units as temporary equity in the accompanying consolidated balance sheets due to terms that allow for redemption of the units in cash upon certain change in control events that are not within the Company's control, including the sale or transfer of the Company.

The carrying values of the convertible preferred units are adjusted to their liquidation preferences if and when it becomes probable that such a liquidation even will occur. The Company did not accrete the value of the convertible preferred units to their redemption values since a liquidation event was not considered probable as of December 31, 2019 and 2020. Subsequent adjustments of the carrying values to the ultimate redemption values will only be made when it becomes probable that such liquidation events will occur, causing the units to become redeemable.

The Company also evaluates the features of its convertible preferred units to determine if the features require bifurcation from the underlying units, by evaluating if they are clearly and closely related to the underlying units and if they do, or do not, meet the definition of a derivative.

Preferred Unit Warrant Liability

Outstanding warrants to purchase preferred units of the Company are classified as liabilities in the accompanying consolidated balance sheets due to a contingent redemption right of the holder of the preferred unit warrants that is outside of the control of the Company that precludes equity classification. Such preferred unit warrants are subject to re-measurement at the end of each reporting period. The Company estimates the fair value of preferred unit warrants at each reporting period, using a hybrid between the probability weighted expected return and option pricing methods, estimating the probability weighted value across multiple scenarios, but using the option pricing method to estimate the allocation of value within one or more of those scenarios, until the earlier of the exercise of the preferred unit warrants, at which time the liability will be revalued and reclassified to members' deficit, the expiration of the preferred unit warrants, or the completion of a liquidation event, including the completion of an IPO. The determination of fair value of these preferred unit warrants requires management to make certain assumptions regarding subjective input variables such as estimated fair value of the underlying convertible preferred units at the measurement date, timing and likelihood of achieving a

liquidity event, risk free interest rates, expected volatility, and a discount for lack of marketability reflective of the different rights of the preferred unit warrant holders. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease other income (expense), net, which could be material to the Company's consolidated results of operations.

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 contains 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 years ended December 31, 2019 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.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

New Accounting Pronouncements

Recently Adopted Accounting Standards

In June 2018, the Financial Accounting Standards Board (the "FASB") issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). This ASU expanded the scope of Topic 718, *Compensation—Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. The ASU was effective for the Company on January 1, 2020. The Company's adoption of this standard did not have a material impact on the consolidated financial statements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). This ASU eliminated certain disclosure requirements for fair value measurements for all entities and modified some disclosure requirements and added enhanced disclosures for Level 3 inputs. This ASU was effective for the Company on January 1, 2020. The Company's adoption of ASU 2018-13 resulted in new disclosures regarding the Company's Level 3 fair value measurements, see Note 3.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02, *Leases* ("Topic 842"), as subsequently amended, to improve financial reporting and disclosures about leasing transactions. This ASU requires companies that lease assets to recognize on the 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 consolidated balance sheet. This ASU 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 consolidated financial statements but does expect that it will 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 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 December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$15,912	$ —	$ —	$15,912
Total assets	**$15,912**	**$ —**	**$ —**	**$15,912**
Liabilities:				
Preferred unit warrant liability	$ —	$ —	$ 655	$ 655
Total liabilities	**$ —**	**$ —**	**$ 655**	**$ 655**

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

During the years ended December 31, 2019 and 2020, there were no transfers between Level 1, Level 2 and Level 3 of the fair value hierarchy.

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 warrants are accounted for as liabilities.

The following table summarizes the significant unobservable inputs used in the fair value measurement of the preferred unit warrant liability as of December 31, 2020:

Fair Value (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average
$320	Hybrid between the probability weighted expected return and option pricing methods	Time to exit	1 - 3 years	2 years
		Probability of exit events	25% - 75%	50%
		Discount for lack of marketability	20% - 35%	31%
		Volatility	66%	66%

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 December 31, 2020.

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):

	December 31,	
	2019	2020
Balance at beginning of period	$720	$ 655
Change in fair value	(65)	63
Settlement of Series B preferred unit warrant	—	(718)
Issuance of Series E preferred unit warrant	—	320
Balance at end of period	**$655**	**$ 320**

4. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2019	2020
Laboratory equipment	$ 1,399	$ 1,612
Leasehold improvements	1,018	1,120
Office equipment	5	28
Software	57	60
Total	2,479	2,820
Less: Accumulated depreciation	(1,245)	(1,834)
Total	1,234	986
Construction-in-progress	3,219	3,484
Property and equipment, net	**$ 4,453**	**$ 4,470**

Construction-in-progress consists of production equipment that will be used to scale-up the manufacturing of RaniPill capsules for clinical trials and that has been determined to have an alternative future use. Construction-in-progress is stated at cost and does not begin to depreciate until it is put into production.

Depreciation expense for each of the years ended December 31, 2019 and 2020 was $0.6 million. As of December 31, 2019 and 2020, all of the Company's property and equipment was located in the United States, with the exception of $3.2 million and $3.5 million, respectively, of construction-in-progress that is located in Germany at a third-party manufacturing facility.

5. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2019	2020
Accrued laboratory equipment costs	$ 594	$—
Payroll and related	—	136
Other	601	414
Total accrued expenses	**$1,195**	**$550**

6. Evaluation Agreements

Takeda

In November 2017, the Company entered into an evaluation agreement with Shire International GmbH ("Shire"), a subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") post acquisition of Shire by Takeda in 2019, hereafter referred to as Takeda as the party to the agreement. Takeda is 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 grants Takeda a right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to FVIII-RaniPill therapeutic. Takeda paid the Company an up-front payment of $2.1 million upon execution of the agreement. Upon the initial evaluation services being completed, Takeda may pay the Company $3.0 million to perform later stage evaluation services. Takeda may 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 ends upon the expiration of the right of first negotiation period which is 120 days after the completion of the evaluation services. The Takeda agreement may 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 will terminate.

In addition to the non-refundable upfront payment, Takeda also concurrently acquired 593,120 units of the Company's Series D convertible preferred units for $10.0 million at $16.86 per unit.

In May 2019, the Company entered into the first amendment to the Takeda agreement, which increased the scope of the agreement, and received an additional upfront payment of $0.8 million for the additional services to be performed. The first amendment to the Takeda agreement also provided Takeda an option to acquire later stage evaluation services for additional consideration. In April 2020, the Company entered into the second amendment to the Takeda agreement to perform additional in vivo studies, and received an additional upfront payment of $3.0 million. Both amendments were evaluated and concluded to be modifications of the Takeda agreement. The Company updated the transaction price and measure of progress for its single performance obligation. The cumulative catch-up related to the modifications was not material for any periods presented.

The Company concluded that Takeda is a customer, and the contract is not subject to guidance on collaborative arrangements, because the Company is providing research and development services, all of which are current outputs of the Company's ongoing activities, in exchange for consideration.

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. The options to acquire later stage evaluation services were not determined to be material rights because they did not provide an incremental discount to Takeda for these futures services. The options were instead considered to be marketing offers and will be accounted for as separate contracts if exercised. The Company's participation on a Joint Oversight Committee was determined to be immaterial in the context of the agreement. The Company provided to Takeda standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services. The right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to FVIII-RaniPill capsule was not considered to be a performance obligation because it does not require any specific action by the Company.

The transaction price at the inception of the Takeda agreement consisted of the upfront payment of $2.1 million and the $10.0 million received from Takeda for the purchase of the Company's Series D convertible preferred units. The sale of the Series D convertible preferred units was not considered to be a performance obligation as it was a separate financing component of the transaction participated in by other independent

investors. Accordingly, $10.0 million of the transaction price was allocated to the issuance of 593,120 shares of Series D convertible preferred units at a fair value of $16.86 per unit and was recorded in members' deficit.

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.

For the year ended December 31, 2019 and 2020, the Company recognized contract revenue related to the Takeda agreement of $0.8 million and $0.5 million, respectively. As of December 31, 2019 and 2020, deferred revenue related to the remaining identified performance obligation for the Takeda agreement of $0.2 million and $2.7 million was recorded on the consolidated balance sheets. The Company expects the performance obligation to be completed by the end of 2021, and therefore all deferred revenue was recorded as a current liability. Upon completion of the Research and Development Services, the Company will provide Takeda with a final report summarizing the outcome of the in vivo testing services. Once this report has been made available, Takeda will have the right to enter into an exclusive negotiation with the Company, for a period of 120 days, for an exclusive licensing and commercialization arrangement.

Novartis

In May 2015, the Company entered into an Evaluation and First Rights Agreement (the "Novartis Agreement") with Novartis Pharmaceuticals Corporation ("Novartis") in which the Company agreed to perform certain specified research for Novartis to evaluate two specified Novartis compounds with the Company's oral drug delivery technology. The Novartis Agreement grants Novartis a right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to a Novartis compound-RaniPill therapeutic. Novartis paid the Company an up-front payment of $7.0 million. Unless terminated early, the agreement term ends upon the expiration of the right of first negotiation period. Novartis also concurrently acquired 593,120 units of the Company's Series C convertible preferred units for $5.0 million.

In August 2019 and July 2020, the Company amended the Novartis Agreement to focus on one compound and extend the term of the right of first negotiation periods. Both amendments were entered into for administrative purposes, and the Company determined the amendments were not a modification of contract under the contracts with customers guidance.

The transaction price at the inception of the Novartis Agreement consisted of the upfront payment of $7.0 million and the $5.0 million received from Novartis for the purchase of the Company's Series C convertible preferred units. The sale of the Series C convertible preferred units was not considered to be a performance obligation as it was a separate financing component of the transaction participated in by other independent investors. Accordingly, $5.0 million of the transaction price was allocated to the issuance of shares of Series C convertible preferred units and recorded in members' deficit.

The Company concluded that Novartis is a customer, and the contract is not subject to guidance on collaborative arrangements. The Company identified one material promise under the Novartis Agreement, the obligation to perform research and development, which was concluded to be a single performance obligation. The Company determined that the cost-based input method most faithfully depicted the transfer of its performance obligation. The research and development services were completed in 2019.

For the year ended December 31, 2019, the Company recognized contract revenue related to the Novartis Agreement of $0.2 million. There was no revenue recognized during the year ended December 31, 2020.

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

	December 31,	
	2019	2020
Balance at beginning of period	$ 358	$ 179
Additions	800	3,000
Deductions	(979)	(462)
Balance at end of period	**$ 179**	**$2,717**

There were no receivables or net contract assets recorded as of December 31, 2019 or 2020 associated with the Takeda agreement.

The Company expensed all incremental costs of obtaining the Takeda and Novartis agreements, as such amounts were insignificant.

7. Related Party Transactions

ICL is wholly-owned by the Company's President, Chief Executive Officer and Chairman of the Board of Managers ("the Company's CEO") and his family. The Company's Chief Scientific Officer and Manager is also the brother of the Company's CEO. The Company's CEO is also the father of the Company's Vice President, Strategy.

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. Since January 2021, the Company has been operating on a month-to-month basis with ICL for such services under the legacy terms of this agreement. The Company or ICL may terminate 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 years ended December 31, 2019 and 2020. 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. Effective January 1, 2020, the ICL personnel that were substantially dedicated to Rani were hired by RMS as full-time employees.

In addition, under the service agreement, RMS bills ICL on the same cost basis described above for certain hours incurred by RMS employees performing services on behalf of ICL. For the year ended December 31, 2020, RMS charged ICL $0.4 million for services performed, and such amounts charged were recorded as a reduction to research and development expense in the consolidated statement of operations and comprehensive loss.

The table below details the amounts charged by ICL for services and rent included in the consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2019	2020
Research and development	$ 17,129	$ 535
General and administrative	3,308	1,826
Total	**$ 20,437**	**$ 2,361**

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 LLC's facilities are owned by an entity affiliated with the Company's CEO. Rani LLC 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 2019 and 2020, the Company received $1.0 million and $0.2 million, respectively, in payments for interest and repayment of principal on the remaining notes receivable.

As of December 31, 2019 and 2020, $1.9 million and $1.7 million, respectively, 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 8). This same entity also acquired 59,312 Series D units for $1.0 million in 2019.

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 consolidated balance sheet as the transaction was considered a common control transaction.

The Company is obligated to develop and commercialize such products and services and to pay for costs to prosecute and maintain the patents ICL licensed to the Company.

The intellectual property agreement will terminate upon sale, merger or liquidation of the Company and the exclusive license agreement will terminate on the date of the expiration or abandonment of the last-to-expire patent that is licensed to the Company. The Company may terminate the exclusive license agreement in its entirety or with respect to any licensed patent by giving prior written notice to ICL.

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.

8. Warrants

Preferred unit warrants

In May 2013, in conjunction with the Series B convertible preferred unit (the "Series B" or "Series B units") financing, the Company issued warrants to InCube Ventures II, LP ("ICV II"), an entity affiliated with

ICL, to purchase 107,357 Series B units. The Series B warrants were exercisable for a period of five years from the grant date at an exercise price of $3.73 per unit. During 2018, the Company amended the terms of the Series B warrants, extending the exercise period for an additional two years. These Series B warrants expired unexercised in May 2020 resulting in a $0.6 million decrease in fair value. In December 2020, the Company amended the terms of these expired Series B warrants, extending the exercise period for an additional two years resulting in a $0.7 million increase in fair value. At December 31, 2019, all of the Series B warrants were outstanding. In December 2020, ICV II elected to cashless exercise all of their Series B warrants and the Company issued 51,341 Series B units. There were no Series B warrants outstanding at December 31, 2020.

In September 2020, in conjunction with a loan and security Agreement (see Note 12), 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 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 will 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.

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. At December 31, 2019 and 2020, all of the 229,315 common warrants were outstanding.

9. 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 November 2020, the Company sold a total of 9,609,491 units of its Series E units at a purchase price of $7.1471 per unit, for total net proceeds of $68.5 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):

December 31, 2019	Units Authorized	Units Outstanding	Carrying Value	Liquidation Preference	Units issuable upon conversion
Series A units	4,000,000	4,000,000	$ 3,974	$ 8,000	4,000,000
Series B units	2,600,000	2,458,905	9,362	18,937	2,458,905
Series C units	5,000,000	4,972,115	32,348	32,488	4,972,115
Series C-1 units	2,505,000	2,504,099	17,607	18,325	2,504,099
Series D units	7,500,000	3,149,577	52,214	53,102	3,149,577
	21,605,000	**17,084,696**	**$ 115,505**	**$ 130,852**	**17,084,696**

December 31, 2020	Units Authorized	Units Outstanding	Carrying Value	Liquidation Preference	Units issuable 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:

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 December 31, 2020, 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 the years ended December 31, 2019 and 2020.

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 under of common units held. Common units reserved for future issuance, consisted of the following as of:

	December 31,	
	2019	2020
Series A units	4,000,000	4,000,000
Series B units	2,458,905	2,510,246
Series C units	4,972,115	4,972,115
Series C-1 units	2,504,099	2,511,058
Series D units	3,149,577	3,380,906
Series E units	—	9,609,491
Units reserved for Profits Interests, issued and outstanding	6,616,350	6,926,358
Units reserved for Profits Interests, authorized for future issuance	2,233,650	3,923,642
	25,934,696	**37,833,816**

10. Equity-Based Compensation

In 2016, the Company adopted the 2016 Equity Incentive Plan (the "Plan") under which the Board of Managers may issue options, 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 and Profits Interests to be reserved under the Plan. At December 31, 2020, a total of 10,850,000 common units and Profits Interests are reserved under the Plan.

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:

	Profits Interests Available for Grant	Number of Profits Interests	Weighted Average Grant Date Fair Value Per Unit	Profits Interests Threshold Per Unit
Balance at December 31, 2019	2,233,650	6,616,350	$ 1.67	$ 1.44 - $2.29
Additional reserved	2,000,000	—		
Forfeitures	182,942	(182,942)	1.94	1.44 - $2.29
Grants	(492,950)	492,950	1.88	1.87 - $2.29
Balance at December 31, 2020	3,923,642	6,926,358	$ 1.63	$ 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.

The fair value of the incentive units underlying the Profits Interests was estimated by taking the aggregate implied equity value of Rani and a hybrid between the probability weighted expected return and option pricing ("OPM") methods, estimating the probability weighted value across multiple scenarios. An OPM was then used to allocate the total equity value of Rani to the different classes of equity according to their rights and preferences. To apply the OPM, volatility was estimated based on the historical volatility of similar public companies' stock price over a preceding period commensurate with the expected term of the Profits Interests awards. The Company estimated the expected term of the Profits Interests awards by considering the timing and probabilities of a liquidity event. The risk-free interest rate for the expected term of the Profits Interests awards was based on the U.S. Treasury yield curve in effect at the time of grant.

The following table summarizes the Company's Profits Interests assumptions that the Company used to determine the grant date fair value of the Profits Interests:

	Year Ended December 31,	
	2019	2020
Expected term (in years)	2	1 - 3
Expected volatility	80%	66%
Risk-free interest rate	1.18%	0.19%

As of December 31, 2020, there was $11.6 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.

11. Commitments and Contingencies

Leases

Rani LLC 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 7) which is accounted for as an operating lease with an implied renewal option into 2025. Rent expense incurred with ICL was $1.1 million and $0.8 million for the years ended December 31, 2019 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.

Indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, customers and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The Company's operating agreement requires that it indemnifies its managers, officers and members against expenses, judgments, fines, settlements and other losses and damages arising out of their services to the Company. The indemnification obligations are more fully described in the Company's operating agreement. Since a maximum obligation is not explicitly stated in the Company's operating agreement and will depend on the facts and circumstances that arise out of any future claims, the overall maximum amount of the obligations cannot be reasonably estimated. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

12. 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 as of December 31, 2020, 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 8). The Company recorded the issuance-date fair value of the Series E warrants of $0.3 million as a warrant liability, and is amortizing the associated debt discount of $0.3 million as interest expense over the expected term of the Loan. In the year ended December 31, 2020, the Company recorded less than $0.1 million of related interest expense.

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 share 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 equal to the sum of (i) the greater of (A) the Prime Rate and (B) three and one-quarters percent (3.25%), plus (ii) eight percent (8.00%), 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. Debt issuance costs of $0.5 million, including the estimated fair value of the Series E warrant of $0.3 million described above, are being accreted to interest expense over the life of the Loan. In addition to the final payment, the Company will pay an amount equal to 4.25% of the original commitment, this is being accrued over the life of the Loan through interest expense. Upon issuance, the Loan had an effective interest rate of 20.56% per year.

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 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 December 31, 2020 and there were no events of default during the year ended December 31, 2020.

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.

All or a portion of the PPP Loan may be forgiven by the U.S. Small Business Administration (“SBA”) upon the application and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act and Payroll Protection Program Flexibility Act, loan forgiveness is available for the sum of documented payroll costs, covered mortgage interest, covered rent payments and covered utilities during the 24 week period beginning on the date of loan disbursement. For purposes of the PPP Loan, payroll costs exclude compensation of an individual employee in excess of $100,000, annualized and prorated for the covered period. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines during the covered period as compared to specified reference periods, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%, unless certain safe harbors are satisfied. In the event the PPP Loan, or any portion thereof, is forgiven pursuant to the PPP Loan, the amount forgiven is applied to outstanding principal and includes accrued interest.

As the legal form of the PPP Loan is a debt obligation, the Company has accounted for this loan as long-term debt.

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. If the Company completes its IPO, it plans to repay the loan in full with proceeds raised from the IPO. The Company was in compliance with all of the debt covenants under the PPP Loan and there were no events of default during the year ended December 31, 2020.

As of December 31, 2020, future principal payments for the Company's long term debt are as follows (in thousands):

Years Ending December 31,	
2021	$ 1,350
2022	1,779
2023	1,125
Total principal payments	4,254
Less: amount representing debt discount	(492)
Add: amount representing interest	9
Present value of remaining debt payments	3,771
Less: current portion	(1,359)
Total long-term debt, less current portion	$ 2,412

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):

	Years Ended December 31,	
	2019	2020
Numerator:		
Net loss	$ (26,587)	$ (16,703)
Denominator:		
Weighted average common units outstanding—basic and diluted	46,890,280	46,890,280
Net loss per unit—basic and diluted	$ (0.57)	$ (0.36)

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

	Years Ended December 31,	
	2019	2020
Preferred units	17,084,696	26,983,816
Units reserved for Profits Interests	6,616,350	6,926,358
Common unit warrants	229,315	229,315
Preferred unit warrants	107,357	118,929
Total	24,037,718	34,258,418

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

14. 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.

Income tax expense consisted of the following for the years ended (in thousands):

	December 31, 2019	December 31, 2020
Current		
Federal	$ —	$ 34
State	—	1
Total current	—	35
Deferred		
Federal	—	—
State	—	—
Total deferred	—	—
Income tax expense	$ —	$ 35

The effective tax rate for the years ended December 31, 2019 and 2020 is different from the federal statutory rate primarily due to the valuation allowance against deferred tax assets as a result of insufficient sources of income and pass-through income not subject to income tax. A reconciliation between the Company's effective tax rate and the applicable U.S. federal statutory income tax rate is summarized as follows:

	December 31, 2019	December 31, 2020
Federal statutory rate	21.0%	21.0%
State tax, net of federal tax benefit	— %	(0.3)%
Pass-through income not subject to tax	(21.0)%	(21.9)%
Research and development credits	— %	3.8%
Uncertain tax position	— %	(0.6)%
Change in valuation allowance	— %	(2.2)%
Effective tax rate	— %	(0.2)%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes. The components that comprise the Company's net deferred taxes consist of the following (in thousands):

	December 31, 2019	December 31, 2020
Deferred tax assets		
Accruals	$ —	$ 32
Research and development credits	—	350
Total gross deferred tax assets	—	382
Valuation allowance	—	(369)
Net deferred tax asset	—	13
Deferred tax liability		
Prepaid insurance	—	(13)
Net deferred tax asset	$ —	$ —

The Company determines its valuation allowance on deferred tax assets by considering both positive and negative evidence in order to ascertain whether it is more likely than not that deferred tax assets will be realized. Realization of deferred tax assets is dependent upon the generation of future taxable income, if any, the

timing and amount of which are uncertain. Because of the Company's recent history of operating losses, the Company believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and accordingly, has provided a valuation allowance on its deferred tax assets. The valuation allowance increased by $0.4 million for the year ended December 31, 2020, primarily due to the increase in the Company's research and development tax credits.

As of December 31, 2020, the Company had federal and California research tax credits of approximately $0.2 million and $0.3 million, respectively. The federal research credits begin to expire in 2040, and the California research tax credits do not expire and can be carried forward indefinitely.

Pursuant of Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's research and development credit carryforwards may be limited in the event accumulative change in ownership of more than 50% occurs within a three-year period. As of December 31, 2020, the Company has not performed an IRC Section 382 or 383 analysis. If a change in ownership were to have occurred, additional tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

The Company is subject to U.S. federal and California income taxes and is not currently under examination by any federal or state taxing authorities. The federal and California returns for tax years 2016 through 2020 remain open to examination.

The following table summarizes the changes in the amount of the unrecognized tax benefits (in thousands):

	December 31,	
	2019	2020
Balance at the beginning of the year	$ —	$ —
Increase related to current year positions	—	104
Balance at the end of the year	$ —	$ 104

Included in the balance of unrecognized tax benefits at December 31, 2020 is $0.1 million that if recognized would impact the Company's income tax benefit and effective tax rate. The Company does not expect any significant increases or decreases in its unrecognized tax benefits within the next twelve months.

15. Subsequent events

The Company has evaluated subsequent events through April 26, 2021, the date these consolidated financial statements were available to be issued.

In January 2021 the Company issued 884,276 units of Series E preferred units for gross proceeds of $6.3 million.

In April 2021, Rani Therapeutic Holdings, Inc. ("Rani Holdings") was incorporated and issued common stock to Rani LLC, making Rani Holdings a wholly owned subsidiary of the Company.

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

	December 31, 2020	March 31, 2021 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 73,058	$ 76,662
Related party note receivable	1,720	—
Prepaid expenses	167	140
Total current assets	74,945	76,802
Deferred financing costs	—	785
Property and equipment, net	4,470	4,490
Total assets	$ 79,415	$ 82,077
Liabilities, Convertible Preferred Units and Members' Deficit		
Current liabilities:		
Accounts payable	$ 537	$ 943
Related party payable	145	346
Accrued expenses	550	1,890
Deferred revenue	2,717	1,961
Current portion of long-term debt	1,359	1,946
Total current liabilities	5,308	7,086
Preferred unit warrant liability	320	536
Long-term debt, less current portion	2,412	1,892
Total liabilities	8,040	9,514
Commitments and contingencies (Note 10)		
Convertible preferred units, 32,620,000 units authorized, and 26,745,528 and 27,629,804 units issued and outstanding at December 31, 2020 and March 31, 2021, respectively	184,714	191,034
Members' deficit:		
Common units, 101,000,000 units authorized, and 46,890,280 and 46,896,280 units issued and outstanding at December 31, 2020 and March 31, 2021, respectively	664	1,130
Accumulated deficit	(114,003)	(119,601)
Total members' deficit	(113,339)	(118,471)
Total liabilities, convertible preferred units and members' deficit	$ 79,415	$ 82,077

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 March 31,	
	2020	2021
Contract revenue	$ 83	$ 756
Operating expenses		
Research and development	4,060	3,347
General and administrative	1,407	2,607
Total operating expenses	$ 5,467	$ 5,954
Loss from operations	(5,384)	(5,198)
Other income (expense), net		
Interest income	62	47
Interest expense and other, net	—	(188)
Change in estimated fair value of preferred unit warrant	(17)	(216)
Loss before income taxes	(5,339)	(5,555)
Income tax expense	(11)	(43)
Net loss and comprehensive net loss	$ (5,350)	$ (5,598)
Net loss per unit, basic and diluted	$ (0.11)	$ (0.12)
Weighted-average common units outstanding—basic and diluted	46,890,280	46,895,880

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 Three Months Ended March 31, 2020 (unaudited)	Convertible Preferred		Common		Accumulated Deficit	Total Members' Deficit
	Units	Amount	Units	Amount		
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)

For the Three Months Ended March 31, 2021 (unaudited)	Convertible Preferred		Common		Accumulated Deficit	Total Members' Deficit
	Units	Amount	Units	Amount		
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	—	—	—	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)

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)

	Three Months Ended March 31,	
	2020	2021
Cash flows from operating activities		
Net loss	$ (5,350)	$ (5,598)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	153	136
Equity-based compensation expense	—	453
Change in fair value of preferred unit warrant liability	17	216
Other	—	67
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(10)	27
Related party receivable	(51)	—
Accounts payable	778	385
Accrued expenses	(113)	821
Related party payable	(1,463)	201
Deferred revenue	(83)	(756)
Net cash used in operating activities	(6,122)	(4,048)
Cash flows from investing activities		
Purchases of property and equipment	(900)	(99)
Net cash used in investing activities	(900)	(99)
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
Payment of deferred offering costs	—	(302)
Principal and interest repayments from related party for note receivable	—	1,720
Net cash provided by financing activities	—	7,751
Net (decrease) increase in cash and cash equivalents	(7,022)	3,604
Cash and cash equivalents, beginning of year	16,536	73,058
Cash and cash equivalents, end of year	$ 9,514	$ 76,662
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ 84
Supplemental disclosures of non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued expenses	$ 137	$ 58
Deferred financing costs included in accrued expenses	$ —	$ 483

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

RANI THERAPEUTICS LLC
NOTES TO THE 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).

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $5.6 million for the three months ended March 31, 2021. As of March 31, 2021, the Company had an accumulated deficit of $119.6 million and for the three months ended March 31, 2021 had negative cash flows from operations of $4.0 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 $76.7 million as of March 31, 2021 will be sufficient to fund its operations through at least one year from the date the condensed consolidated financial statements are available to be 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, an initial public offering ("IPO") of common stock, 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 investors. 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 Condensed Financial Statements

The accompanying condensed consolidated balance sheet as March 31, 2021, condensed consolidated statements of operations and comprehensive loss and cash flows for the three months ended March 31, 2020 and 2021, condensed consolidated statement of changes in convertible preferred units and members' deficit for the three months ended March 31, 2020 and 2021, and related interim condensed consolidated notes 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 March 31, 2021 results of operations and cash flows for the three months ended March 31, 2020 and 2021; and the condensed consolidated statement of changes in convertible preferred units and members' deficit for the three months ended March 31, 2020 and 2021. The consolidated balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. The results for the three months ended March 31, 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 financial statements included elsewhere in this prospectus.

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 and first rights 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 contract receivable when it has an unconditional right to consideration. No contract assets balance was recorded as of December 31, 2020 and March 31, 2021.

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, and March 31, 2021 the Company had deferred revenue of $2.7 million and $2.0 million, respectively.

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 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 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.

Notes Receivable from Related Party

The principal balance on the notes receivable from related party is recorded on the condensed consolidated balance sheet along with earned and not yet received interest income. The principal balance is classified on the consolidated balance sheet based upon the expected timing of the repayments by the related party. Interest income received and receivable on the related party notes receivable is recorded as a component of interest income in the condensed consolidated statement of operations and comprehensive loss. Associated interest earned is recognized using the effective interest method. The estimated fair value of the Company's related party notes receivable at December 31, 2019 2020 approximated its carrying value due to their short-term nature. The principal balance and interest income was fully repaid in the three months ended March 31, 2021.

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 the Company and consultants in the form of non-vested incentive units ("Profits Interests"). All awards of Profits Interests 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 Company utilizes estimates and assumptions in determining the fair value of its Profits Interests on the date of grant. 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 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.

Convertible Preferred Units

The Company records convertible preferred units at fair value on the dates of issuance, net of issuance costs. The Company has classified convertible preferred units as temporary equity in the accompanying condensed consolidated balance sheets due to terms that allow for redemption of the units in cash upon certain change in control events that are not within the Company's control, including the sale or transfer of the Company.

The carrying values of the convertible preferred units are adjusted to their liquidation preferences if and when it becomes probable that such a liquidation even will occur. The Company did not accrete the value of the convertible preferred units to their redemption values since a liquidation event was not considered probable as of December 31, 2020 or March 31, 2021. Subsequent adjustments of the carrying values to the ultimate redemption values will only be made when it becomes probable that such liquidation events will occur, causing the units to become redeemable.

The Company also evaluates the features of its convertible preferred units to determine if the features require bifurcation from the underlying units, by evaluating if they are clearly and closely related to the underlying units and if they do, or do not, meet the definition of a derivative.

Preferred Unit Warrant Liability

Outstanding warrants to purchase preferred units of the Company are classified as liabilities in the accompanying condensed consolidated balance sheets due to a contingent redemption right of the holder of the preferred unit warrants that is outside of the control of the Company that precludes equity classification. Such preferred unit warrants are subject to re-measurement at the end of each reporting period. The Company estimates the fair value of preferred unit warrants at each reporting period, using a hybrid between the probability weighted expected return and option pricing methods, estimating the probability weighted value across multiple scenarios, but using the option pricing method to estimate the allocation of value within one or more of those scenarios, until the earlier of the exercise of the preferred unit warrants, at which time the liability will be revalued and reclassified to members' deficit, the expiration of the preferred unit warrants, or the completion of a liquidation event, including the completion of an IPO. The determination of fair value of these preferred unit warrants requires management to make certain assumptions regarding subjective input variables such as estimated fair value of the underlying convertible preferred units at the measurement date, timing and likelihood of achieving a liquidity event, risk free interest rates, expected volatility, and a discount for lack of marketability reflective of the different rights of the preferred unit warrant holders. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease other income (expense), net, which could be material to the Company's condensed consolidated results of operations.

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 contains 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 three months ended March 31, 2020 and 2021, 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 initial public offering costs

Deferred offering costs, which consist of direct incremental legal, consulting, banking and accounting fees primarily relating to the Company's contemplated IPO, are capitalized and will be offset against proceeds upon the consummation of the offering within members' deficit. In the event an anticipated offering is terminated, deferred IPO offering costs will be expensed. As of December 31, 2020, there were no capitalized deferred IPO offering costs on the condensed consolidated balance sheet. As of March 31, 2021, there were $0.8 million of deferred IPO offering costs recorded as a long term asset on the condensed consolidated balance sheet.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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 that it will 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 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**

	As of March 31, 2021		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$74,527	$ —	$ —
Total assets	**$74,527**	**$ —**	**$ —**
Liabilities:			
Preferred unit warrant liability	$ —	$ —	$ 536
Total liabilities	**$ —**	**$ —**	**$ 536**

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 warrants are accounted for as liabilities.

The following table summarizes the significant unobservable inputs used in the fair value measurement of the preferred unit warrant liability as of March 31, 2021:

Fair Value (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average
$536	Hybrid between the probability weighted expected return and option pricing methods	Time to exit	0.4 - 2.5 years	0.4 years
		Probability of exit events	50%	50%
		Discount for lack of marketability	10% - 31%	10%
		Volatility	75%	75%

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 March 31, 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 March 31,	
	2020	2021
Balance at beginning of period	$ 655	$ 320
Change in fair value	17	216
Balance at end of period	**$ 672**	**$ 536**

4. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2020	March 31, 2021
Accrued professional fees	$ —	$ 528
Payroll and related	136	509
Deferred financing costs	—	483
Other	414	370
Total accrued expenses	**$ 550**	**$ 1,890**

5. Evaluation Agreements

Takeda

In November 2017, the Company entered into an evaluation agreement with Shire International GmbH ("Shire"), a subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") post acquisition of Shire by

Takeda in 2019, hereafter referred to as Takeda as the party to the agreement. Takeda is 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 grants Takeda a right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to FVIII-RaniPill therapeutic. Takeda paid the Company an up-front payment of $2.1 million upon execution of the agreement. Upon the initial evaluation services being completed, Takeda may pay the Company $3.0 million to perform later stage evaluation services. Takeda may 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 ends upon the expiration of the right of first negotiation period which is 120 days after the completion of the evaluation services. The Takeda agreement may 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 will terminate.

In addition to the non-refundable upfront payment, Takeda also concurrently acquired 593,120 units of the Company's Series D convertible preferred units for $10.0 million at $16.86 per unit.

In May 2019, the Company entered into the first amendment to the Takeda agreement, which increased the scope of the agreement, and received an additional upfront payment of $0.8 million for the additional services to be performed. The first amendment to the Takeda agreement also provided Takeda an option to acquire later stage evaluation services for additional consideration. In April 2020, the Company entered into the second amendment to the Takeda agreement to perform additional in vivo studies, and received an additional upfront payment of $3.0 million. Both amendments were evaluated and concluded to be modifications of the Takeda agreement. The Company updated the transaction price and measure of progress for its single performance obligation. The cumulative catch-up related to the modifications was not material for any periods presented.

The Company concluded that Takeda is a customer, and the contract is not subject to guidance on collaborative arrangements, because the Company is providing research and development services, all of which are current outputs of the Company's ongoing activities, in exchange for consideration.

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. The options to acquire later stage evaluation services were not determined to be material rights because they did not provide an incremental discount to Takeda for these futures services. The options were instead considered to be marketing offers and will be accounted for as separate contracts if exercised. The Company's participation on a Joint Oversight Committee was determined to be immaterial in the context of the agreement. The Company provided to Takeda standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services. The right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to FVIII-RaniPill capsule was not considered to be a performance obligation because it does not require any specific action by the Company.

The transaction price at the inception of the Takeda agreement consisted of the upfront payment of $2.1 million and the $10.0 million received from Takeda for the purchase of the Company's Series D convertible preferred units. The sale of the Series D convertible preferred units was not considered to be a performance obligation as it was a separate financing component of the transaction participated in by other independent investors. Accordingly, $10.0 million of the transaction price was allocated to the issuance of 593,120 shares of Series D convertible preferred units at a fair value of $16.86 per unit and was recorded in members' deficit.

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.

For three months ended March 31, 2020 and 2021, the Company recognized contract revenue related to the Takeda agreement of $0.1 million and $0.8 million, respectively. As of December 31, 2020 and March 31, 2021, deferred revenue related to the remaining identified performance obligation for the Takeda agreement of $2.7 million and $2.0 million was recorded on the condensed consolidated balance sheets.

In May 2021, the Company received notice from Takeda as to their intent to terminate the contract for convenience. The termination of the contract is considered a modification of an arrangement and will be accounted for when it occurs.

Novartis

In May 2015, the Company entered into an Evaluation and First Rights Agreement (the "Novartis Agreement") with Novartis Pharmaceuticals Corporation ("Novartis") in which the Company agreed to perform certain specified research for Novartis to evaluate two specified Novartis compounds with the Company's oral drug delivery technology. The Novartis Agreement grants Novartis a right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to a Novartis compound-RaniPill therapeutic. Novartis paid the Company an up-front payment of $7.0 million. Unless terminated early, the agreement term ends upon the expiration of the right of first negotiation period. Novartis also concurrently acquired 593,120 units of the Company's Series C convertible preferred units for $5.0 million.

In August 2019 and July 2020, the Company amended the Novartis Agreement to focus on one compound and extend the term of the right of first negotiation periods. Both amendments were entered into for administrative purposes, and the Company determined the amendments were not a modification of contract under the contracts with customers guidance.

The transaction price at the inception of the Novartis Agreement consisted of the upfront payment of $7.0 million and the $5.0 million received from Novartis for the purchase of the Company's Series C convertible preferred units. The sale of the Series C convertible preferred units was not considered to be a performance obligation as it was a separate financing component of the transaction participated in by other independent investors. Accordingly, $5.0 million of the transaction price was allocated to the issuance of shares of Series C convertible preferred units and recorded in members' deficit.

The Company concluded that Novartis is a customer, and the contract is not subject to guidance on collaborative arrangements. The Company identified one material promise under the Novartis Agreement, the obligation to perform research and development, which was concluded to be a single performance obligation. The Company determined that the cost-based input method most faithfully depicted the transfer of its performance obligation. The research and development services were completed in 2019.

There was no revenue recognized for either of the three months ended March 31, 2020 or 2021.

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

	December 31, 2020	March 31, 2021
Balance at beginning of period	$ 179	$ 2,717
Additions	3,000	—
Deductions	(462)	(756)
Balance at end of period	**$ 2,717**	**$ 1,961**

There were no receivables or net contract assets recorded as of December 31, 2020 or March 31, 2021 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 Executive Chairman and his family. The Company's Chief Scientific Officer is the brother of the Executive Chairman and uncle of the Company's Chief Executive Officer and the Company's Special Projects Manager. The Executive Chairman of the Company, is also the father of the Company's Chief Executive Officer and the Company's Special Projects Manager.

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, effective January 1, 2021 (see Note 14). 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. Effective January 1, 2020, the ICL personnel that were substantially dedicated to Rani were hired by RMS as full-time employees.

In addition, under a separate service agreement, RMS and ICL bill each other on the same cost basis described above for certain hours incurred by RMS employees performing services on behalf of ICL or for certain hours incurred by ICL employees performing services for RMS, as the case may be. For the three months ended March 31, 2020 and 2021, RMS charged ICL $0.1 million and $0.2 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 included in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2020	2021
Research and development	$ 184	$ 33
General and administrative	244	182
Total	**$ 428**	**$ 215**

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 LLC's facilities are owned by an entity affiliated with the Company's CEO. Rani LLC 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 2019.

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.

The Company is obligated to develop and commercialize such products and services and to pay for costs to prosecute and maintain the patents ICL licensed to the Company. The agreement was replaced in June 2021 (see Note 14).

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, our Chief Scientific Officer and member of the Board of Managers and a 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 $0.2 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 May 2013, in conjunction with the Series B convertible preferred unit (the "Series B" or "Series B units") financing, the Company issued warrants to InCube Ventures II, LP ("ICV II"), an entity affiliated with ICL, to purchase 107,357 Series B units. The Series B warrants were exercisable for a period of five years from the grant date at an exercise price of $3.73 per unit. During 2018, the Company amended the terms of the Series B warrants, extending the exercise period for an additional two years. These Series B warrants expired unexercised in May 2020 resulting in a $0.6 million decrease in fair value. In December 2020, the Company amended the terms of these expired Series B warrants, extending the exercise period for an additional two years resulting in a $0.7 million increase in fair value. In December 2020, ICV II elected to cashless exercise all of their Series B warrants and the Company issued 51,341 Series B units. There were no Series B warrants outstanding at December 31, 2020.

In September 2020, in conjunction with a loan and security Agreement (see Note 12), 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 December 31, 2020 and March 31, 2021, all of these Series E warrants were outstanding. In the event of a change of control or IPO, the Series E warrants will 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.

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 December 31, 2020 and March 31, 2021, 229,315 common unit warrants and 223,315 common unit warrants were outstanding, respectively.

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 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 Value	Liquidation Preference	Units issuable upon conversion
December 31, 2020	**Authorized**	**Outstanding**			
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**

	Units		Carrying Value	Liquidation Preference	Units issuable upon conversion
March 31, 2021	**Authorized**	**Outstanding**			
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**

The following provides a summary of the rights of the holders of convertible preferred and common units:

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 March 31, 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 under of common units held. Common units reserved for future issuance, consisted of the following as of:

Class of Units	December 31, 2020	March 31, 2021
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	2,511,058	2,511,608
Units reserved for conversion of outstanding Series D	3,380,906	3,400,875
Units reserved for conversion of outstanding Series E	9,609,491	10,493,767
Units reserved for Profit Interests, issued and outstanding	6,926,358	8,726,483
Units reserved for Profit Interests, authorized for future issuance	3,923,642	2,123,517
	37,833,816	**38,738,611**

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, 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. At December 31, 2020 and March 31, 2021, a total of 10,850,000 common units are reserved under the Plan.

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:

	Profits Interests Available for Grant	Number of Profits Interests	Weighted Average Grant Date Fair Value	Profits Interests Threshold
Balance at December 31, 2020	3,923,642	6,926,358	$ 1.63	$ 1.44 - $2.29
Forfeitures	56,875	(56,875)	$ 1.96	$1.44 - $2.29
Grants	(1,857,000)	1,857,000	$ 2.00	$1.99 - $2.13
Balance at March 31, 2021	2,123,517	8,726,483	$ 1.71	$ 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.

The fair value of the incentive units underlying the Profits Interests was estimated by taking the aggregate implied equity value of Rani and a hybrid between the probability weighted expected return and option pricing ("OPM") methods, estimating the probability weighted value across multiple scenarios. An OPM was then used to allocate the total equity value of Rani to the different classes of equity according to their rights and preferences. To apply the OPM, volatility was estimated based on the historical volatility of similar public companies' stock price over a preceding period commensurate with the expected term of the Profits Interests awards. The Company estimated the expected term of the Profits Interests awards by considering the timing and probabilities of a liquidity event. The risk-free interest rate for the expected term of the Profits Interests awards was based on the U.S. Treasury yield curve in effect at the time of grant.

The following table summarizes the Company's Profits Interests assumptions that the Company used to determine the grant date fair value of the Profits Interests:

	December 31, 2020	March 31, 2021
Expected term (in years)	1 - 3	2.5
Expected volatility	66%	79%
Risk-free interest rate	0.19%	0.26%

As of March 31, 2021, there was $14.9 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.

10. Commitments and Contingencies

Leases

Rani LLC 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 $0.2 million and $0.2 million for three months ended March 31, 2020 and 2021, 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.

Indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, customers and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The Company's operating agreement requires that it indemnifies its managers, officers and members against expenses, judgments, fines, settlements and other losses and damages arising out of their services to the Company. The indemnification obligations are more fully described in the Company's operating agreement. Since a maximum obligation is not explicitly stated in the Company's operating agreement and will depend on the facts and circumstances that arise out of any future claims, the overall maximum amount of the obligations cannot be reasonably estimated. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

11. 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 (0.12)% and (0.21)% for the three months ended March 31, 2020 and 2021, respectively. The change in the Company's effective income tax rate for the three months ended March 31, 2020 compared to the three months ended March 31, 2021 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 months ended March 31, 2020 and 2021, and the Company does not anticipate material changes within the next 12 months.

12. 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 share 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 December 31, 2020 and March 31, 2021 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 December 31, 2020 and March 31, 2021.

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 March 31, 2021 and there were no events of default during the three months ended March 31, 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.

As the legal form of the PPP Loan is a debt obligation, the Company has accounted for this loan as long-term debt.

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. If the Company completes its IPO, it plans to repay the loan in full with proceeds raised from the IPO. The Company was in compliance with all of the debt covenants under the PPP Loan and there were no events of default as of March 31, 2021.

As of March 31, 2021, future principal payments for the Company's long term debt are as follows (in thousands):

2021 (remaining nine months)	$1,350
2022	1,779
2023	1,125
Total principal payments	4,254
Less: amount representing debt discount	(428)
Add: amount representing interest	12
Present value of remaining debt payments	3,838
Less: current portion	1,946
Total long-term debt, less current portion	$1,892

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 March 31,	
	2020	2021
Numerator:		
Net loss	$ (5,350)	$ (5,598)
Denominator:		
Weighted average common units outstanding—basic and diluted	46,890,280	46,895,880
Net loss per unit—basic and diluted	$ (0.11)	$ (0.12)

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

	Three Months Ended March 31,	
	2020	2021
Preferred units	17,084,696	27,888,611
Units reserved for Profits Interests	6,580,957	8,726,483
Common unit warrants	229,315	223,315
Preferred unit warrants	107,357	118,929
Total	24,002,325	36,957,338

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

14. Subsequent events

The Company has evaluated subsequent events through June 22, 2021, the date these condensed consolidated financial statements were available to be issued.

Amended and Restated Exclusive License Agreement between Rani and ICL ("Amended and Restated License Agreement")

In June 2021, the Company and ICL entered into an Amended and Restated Exclusive License Agreement, which replaced the 2012 Exclusive License Agreement as amended in 2013 and terminated the 2012 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 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.

Service Agreement between RMS and ICL (the "RMS-ICL Services Agreement")

In June 2021, RMS entered into the RMS-ICL Service Agreement effective January 1, 2021, pursuant to which ICL, a related party, 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 will have a 12-month term and will automatically renew for successive 12-month periods unless terminated.

Unit Option Grants

In June 2021, the Company granted options to acquire 2.3 million of the Company's common units to certain of its employees, executive officers and managers under the 2016 Equity Incentive Plan, at an exercise price of $4.99 per unit. The options vest over four years subject to individuals continuous service to the Company.

Through and including August 24, 2021 (the 25th day after the date of this prospectus) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

6,666,667 Shares

Class A common stock

PROSPECTUS

Book-Running Managers

BofA Securities **Stifel** **Cantor** **Canaccord Genuity**

Lead Manager

BTIG

July 30, 2021