UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission File Number: 001-40672

RANI THERAPEUTICS HOLDINGS, INC.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $54.1 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $4.12 per share.

As of March 14, 2024, the registrant had 26,040,848 shares of Class A common stock, $0.0001 par value per share, outstanding, 24,116,444 shares of Class B common stock, $0.0001 par value per share, outstanding and no shares of Class C common stock, $0.0001 par value per share, outstanding. Certain holders of units of the registrant's consolidated subsidiary, Rani Therapeutics, LLC, who do not hold shares of the registrant's Class B common stock can exchange their units of Rani Therapeutics, LLC for 1,345,067 shares of the registrant's Class A common stock.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report on Form 10-K, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2024, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2023.

Table of Contents

Unless otherwise stated or the context otherwise requires, throughout this Annual Report on Form 10-K, the terms "we," "us," and "our," and similar references refer to Rani Therapeutics Holdings, Inc. ("Rani Holdings") and its consolidated subsidiary, Rani Therapeutics, LLC ("Rani LLC") and, prior to December 15, 2022, Rani Management Services, Inc. ("RMS"). RMS was dissolved as of December 15, 2022.

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 Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and consolidated financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, manufacturing costs, regulatory approvals, development and advancement of our oral delivery technology, timing and likelihood of success, potential partnering activities as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

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

- the progress and focus of our current and future clinical trials in the United States and abroad, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our ability to complete development of the RaniPill HC or any redesign and conduct additional preclinical and clinical studies of the RaniPill HC or any future design of the RaniPill capsule to accommodate target payloads that are larger than the payload capacity of the RaniPill GO capsule used to date for clinical studies of our product candidates;
- our ability to further develop and expand our platform technology;
- our ability to utilize our technology platform to generate and advance additional product candidates;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our financial performance;
- our ability to continue as a going concern;
- our plans relating to commercializing our product candidates, if approved;
- our ability to selectively enter into strategic partnership and the expected potential benefits thereof;

•the implementation of our strategic plans for our business and product candidates;

•our ability to continue to scale and optimize our manufacturing processes by expanding our use of automation;

•our estimates of the number of patients in the United States who suffer from the indications we target and the number of patients that will enroll in our clinical trials;

•the size of the market opportunity for our product candidates in each of the indications we target;

•our ability to continue to innovate and expand our intellectual property by developing novel formulations and new applications of the RaniPill capsule;

•our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;

•the scope of protection we are able to establish and maintain for intellectual property rights, including our technology platform and product candidates;

•the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;

•our ability to realize savings from any restructuring plans or cost-containment measures we propose to implement;

•developments relating to our competitors and our industry, including competing product candidates and therapies;

•our realization of any benefit from our organizational structure, taking into account our obligations under the Tax Receivable Agreement (defined herein) and the impact of any payments required to be made thereunder on our liquidity and financial condition; and

•our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions described in the section titled *"Risk Factors"* and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, 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.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission ("SEC"), before making investment decisions regarding our Class A common stock. See "Special Note Regarding Forward-Looking Statements."

•There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms. If we are unable to raise additional capital when needed, we may be forced to delay, limit, reduce or terminate our product development programs or other operations.

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

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

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

•Any restructuring actions that we previously undertook or may undertake in the future may not deliver the expected results and these actions may adversely affect our business operations.

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

•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.

•As an organization, we have conducted limited early clinical development, have not submitted an investigational new drug application, ("IND"), to the U.S. Food and Drug Administration ("FDA"), and we have never conducted later-stage clinical trials or submitted a Biologics License Application ("BLA") or New Drug Application ("NDA"), and may be unable to do so for any of our product candidates.

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

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

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

•We depend on third-party suppliers for key materials used in our manufacturing processes as well as for the manufacturing of active pharmaceutical ingredients ("APIs") and drug substances. We do not have long-term supply arrangements in place for APIs and drug substances. The loss of third-party suppliers or their inability to supply us with adequate materials and APIs or drug substances could prevent or delay the conduct of our clinical trials and the commercialization of our products, if approved, and could harm our business.

•Our high-capacity oral delivery device, RaniPill HC, is in early stages of development, and it is subject to the inherent risks and uncertainties of developing a novel, innovative technology. Our efforts to develop RaniPill HC may not be successful.

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

•We 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 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 depends in part on our ability to build and maintain our intellectual property portfolio.

•We are a holding company and our principal asset is our interest in Rani LLC. 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 holders of units of Rani LLC 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 units of Rani LLC.

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

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

PART I

Item 1. Business

Overview

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

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

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

Data Overview

We have completed three Phase 1 clinical trials with the RaniPill capsule technology. In February 2024, we announced completion of a Phase 1 clinical trial with RT-111, a RaniPill GO capsule containing our proprietary formulation of an ustekinumab biosimilar supplied by Celltrion, Inc. (“Celltrion”), in Australia. The study evaluated the safety and tolerability of a single administration of RT-111 in healthy adult volunteers. The study met all its endpoints, RT-111 was well tolerated and delivered ustekinumab biosimilar with high bioavailability. No serious adverse events were reported in the study.

In 2022, we completed a Phase 1 clinical trial with RT-102, a RaniPill GO capsule containing our proprietary formulation of parathyroid hormone (1-34) (“PTH”), in Australia. The study involved a single-ascending dose portion and a seven-day repeat-dose portion. The Phase 1 study met all of its endpoints, RT-102 was well tolerated and delivered PTH with high bioavailability (more than 300% greater bioavailability than subcutaneous injection of Forteo (teriparatide)). No serious adverse events were reported in the study. In 2019, we completed a Phase 1 study with RT-101, a RaniPill GO capsule containing our proprietary formulation of octreotide, in Australia. The Phase 1 study met all of its endpoints, RT-101 was well tolerated and delivered octreotide with high bioavailability (comparable to subcutaneous injection of octreotide). No serious adverse events were reported in the study.

As of December 31, 2023, we have administered the RaniPill capsule 233 times to 146 human subjects in clinical trials, including seven-day repeat-dosing in ten subjects in our Phase 1 study of RT-102. This is in addition to oral administrations of the RaniPill capsule, without a drug or needle, in non-significant risk studies. In our clinical studies, our product candidates were generally well tolerated and no serious adverse events were observed.

Preclinically, we have tested 15 molecules in the RaniPill capsule, including eight antibodies, six peptides and one large protein. We have conducted preclinical testing of more than 7,000 RaniPill capsules in vivo and in vitro. In October 2023, we announced preclinical data from a 60-day, repeat oral-administration good laboratory practices (“GLP”) safety study of the RaniPill capsule in healthy animals. The RaniPill capsule was well tolerated with no treatment-related adverse events and all animals remained clinically healthy throughout the study.

As of January 1, 2024, we had tested more than 200 RaniPill HC devices in vivo including delivery of a peptide and multiple different antibodies. The RaniPill HC represents a significant opportunity to potentially enable the oral delivery of more than ninety additional biologics currently on the market, including therapeutics like dupilumab, secukinumab, pembrolizumab, etanercept and trastuzumab. We intend for the RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024.

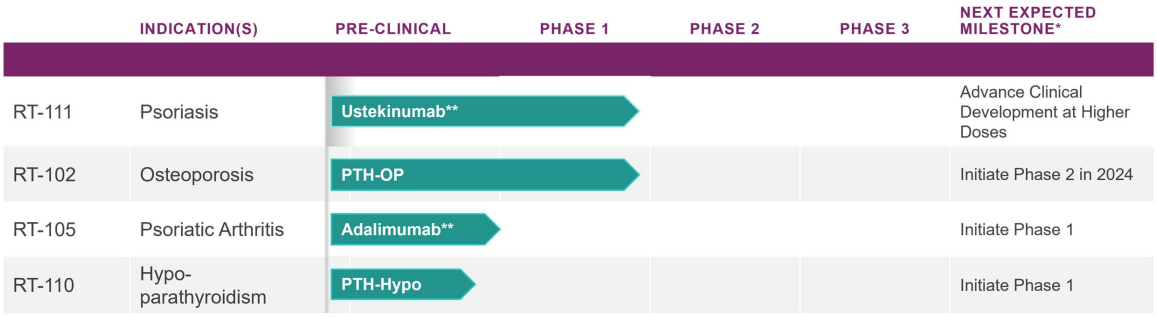
Business Update

In November 2023, we announced a strategic program prioritization, expansion of manufacturing and plans to streamline business operations to support near-term value drivers and long-term growth of the RaniPill technology platform (the "Restructuring"). The plans include strategic prioritization of its key development programs, RT-102, RT-111 and the RaniPill HC and expansion of our manufacturing footprint to support increased scale and partnerships, and cost reduction initiatives that align with our near-term goals, including a reduction in our workforce by approximately 25%. As part of the strategic focusing of the business, we have paused work on our RT-105 and RT-110 programs and we terminated our RT-101 program, which was the RaniPill capsule containing octreotide.

Pipeline Overview

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

Below is a summary of our product candidate pipeline. We envision complementing these programs with robust partnering activities to maximize the value inherent in the RaniPill capsule.



RT-XXX refers to the RaniPill capsule containing a biologic or drug.
** Clinical timelines are subject to potential regulatory agency review delays.*
*** Partnered with Celltrion, Inc. Celltrion, Inc. supplies the drug pursuant to a license and supply agreement and has a right of first negotiation for development and commercial rights following completion of a Phase 1 clinical trial that meets its primary endpoint(s).*

Our Pipeline Programs

RT-111: Ustekinumab for the treatment of inflammatory conditions

Market overview

Ustekinumab is currently approved by the FDA and European Medicines Agency ("EMA") for the treatment of various inflammatory conditions under the brand name STELARA. STELARA (ustekinumab) is an interleukin-12 and interleukin-23 antagonist marketed by Janssen Biotech, Inc. with sales of approximately $6.4 billion in the United States and approximately $9.7 billion worldwide in 2022. The latest expiring United States patent for STELARA (ustekinumab) expired in 2023. In the United States, there were estimated to be seven million patients with psoriasis and three million patients with Crohn's disease or ulcerative colitis in 2021.

Our solution: RT-111

We are developing RT-111, a RaniPill capsule containing an ustekinumab biosimilar, for the treatment of various inflammatory conditions. We entered into a License and Supply Agreement with Celltrion, under which we receive a license and supply of Celltrion's ustekinumab biosimilar for development and commercialization worldwide, subject to a right of first negotiation for Celltrion following completion of a Phase 1 clinical trial that meets its primary endpoint(s).

Clinical trials

In February 2024, we announced positive topline results from a Phase 1 study of RT-111, which is being developed for the potential treatment of inflammatory conditions. The study met all of its endpoints and RT-111 was generally well tolerated with no serious adverse events noted. In the study, RT-111 orally delivered 0.5 mg and 0.75 mg of our proprietary formulation of ustekinumab biosimilar with high bioavailability.

Study Design

The single-center, open label Phase 1 study of RT-111 was conducted in Australia. The study evaluated the safety, and tolerability of a single administration of RT-111 in healthy adult volunteers. Of the 55 participants, 20 orally ingested RT-111 containing a single 0.5 mg dose of ustekinumab biosimilar and 20 orally ingested RT-111 containing a single 0.75 mg dose of ustekinumab biosimilar, while a control group of 15 participants received a single 0.5 mg subcutaneous injection of STELARA, a commercial formulation of ustekinumab for subcutaneous ("SC") administration.

Safety Data

In the Phase 1 study, RT-111 was generally well tolerated, with no serious adverse events ("SAE") noted during the study. None of the participants withdrew from the study due to any adverse event. Two subjects in the 0.5mg RT-111 group and one subject in the 0.5mg SC STELARA® group had mild, transient adverse events which resolved without any intervention. There was no meaningful difference in incidence of anti-drug antibodies via the RaniPill route of delivery compared to STELARA® SC injection.

		Stelara® SC 0.50 mg	RT-111 0.50 mg	RT-111 0.75 mg
		N=15	N=20	N=20
Drug Signal Detected		N=15	N=19	N=16
		Number of ADA Positive Cases		
Total ADA Positive*	N	4	2	6
	%	27%	11%	38%

* ADA positive post dosing, increase in titer compared to pre-dose level

No participants reported difficulty swallowing the capsule and capsule remnants passed from all participants without sequelae.

Pharmacokinetics ("PK")

•Oral RT-111 delivered 0.5mg and 0.75mg of ustekinumab biosimilar with high bioavailability (estimated bioavailability of 84% for 0.5mg RT-111 relative to 0.5mg SC STELARA®).

	Stelara® SC 0.50mg	RT-111 0.50mg	RT-111 0.75mg
Cmax (ng/mL)	56 ± 4	67 ± 7	92 ± 8
Tmax (days)	10 ± 0.8	3.1 ± 0.2*	3.3 ± 0.2*
AUC (day*ng/mL)	1,566 ± 130	1,315 ± 150	1,814 ± 165
Bioavailability	--	84%	--

Data are Mean ± SE from all subjects, including those with anti-drug antibodies. *p<0.0001 significantly different from SC group.

License and Supply Agreement

In January 2023, we announced entering into a License and Supply Agreement with Celltrion under which we receive a license and supply of Celltrion's ustekinumab biosimilar for development and commercialization of RT-111 worldwide, subject to a right of first negotiation for Celltrion following completion of a Phase 1 clinical trial that meets its primary endpoint(s). We believe the Phase 1 clinical trial that we completed with RT-111, the topline data of which we announced in February 2024, satisfies the requirements for triggering Celltrion's right of first negotiation.

Next Steps

We intend to advance clinical development of RT-111 at higher doses.

RT-102: Parathyroid hormone (PTH) for the treatment of osteoporosis

Market overview

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 with age.

PTH is an effective bone-building treatment for osteoporosis. PTH is a hormone secreted by the parathyroid glands that regulates serum calcium concentration and promotes bone growth. PTH therapies are delivered by daily subcutaneous injections for up to two years. Approximately ten million Americans suffer from osteoporosis; however, we estimate that only a small fraction of this population is being treated with a form of PTH. While there may be other reasons for this, we believe that patient 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.

Teriparatide, a synthetic form of the natural human parathyroid hormone hPTH(1-34), 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 PTH analog injectable is Tymlos by Radius Health, Inc., which was approved in 2017. A teriparatide biosimilar injectable by Pfenex, Inc. was approved in 2019. Annual sales revenue of PTH analogs and biosimilars globally in 2021 was approximately $2.0 billion.

Our solution: RT-102

We are developing RT-102, the RaniPill capsule containing our novel formulation of PTH, for oral treatment of osteoporosis. We have worldwide commercial rights to RT-102. 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.

Preclinical pharmacodynamic study

We conducted a 6-week pharmacodynamic study of the RT-102 drug substance PTH (1-34) to evaluate the effect of daily RT-102 drug substance ("DS") intraperitoneal injections on bone mineral density in a rodent model of osteoporosis. The study compared two control groups of rodents undergoing sham surgery (N=10) and ovariectomy (N=10) receiving no drug, to three overiectomized groups each dosed with 5 mcg/kg per day of either RT-102 DS (N=10), teriparatide (N=10), or abaloparatide (N=10).

The study found that, following six weeks of treatment:

- RT-102 DS increased bone mineral density ("BMD") in a rat model of osteoporosis.

- RT-102 DS delivered via the intraperitoneal ("IP") route of administration was biologically active comparable to subcutaneously injected PTH analogs.

Clinical trials

In 2022, we completed a Phase 1 clinical trial with RT-102 in Australia. The study involved a single-ascending dose portion ("Study Part 1") and a seven-day repeat-dose portion ("Study Part 2"). The Phase 1 study met all of its endpoints, RT-102 was well tolerated and delivery yielded high bioavailability (more than 300% greater bioavailability than subcutaneous injection). No serious adverse events were reported in the study. We plan to initiate a Phase 2 clinical trial of RT-102 in 2024.

Study Part 1 - Topline Results

Study Design

The single-center, open label, Study Part 1 was conducted in Australia. The study evaluated the safety, tolerability, and pharmacokinetics of RT-102 in healthy adult female volunteers. Of the 39 participants, 15 were administered RT-102 containing a single 20 µg dose of PTH and 14 were administered RT-102 containing a single 80 µg dose of PTH, while a control group of ten participants received a single 20 µg subcutaneous injection (SC) of Forteo (teriparatide), a commercial formulation of PTH for subcutaneous administration. The endpoints of the study were safety and tolerability, and measurements of serum concentrations of RT-102 in healthy adult female volunteers.

Safety Data

- In Study Part 1, RT-102 was generally well tolerated, with no RaniPill-related adverse events ("AEs") observed in study participants:
- 0% (0/15) of participants dosed with RT-102 20 µg experienced drug-related AEs.
- 14% (2/14) of participants dosed with of RT-102 80 µg experienced drug-related AEs.
- 50% (5/10) of participants dosed with 20 µg of Forteo SC experienced drug-related AEs.
- There were no serious adverse events ("SAEs") noted during Study Part 1.

Per protocol, in instances where the RaniPill capsule did not exit the stomach within seven hours, participants were excluded from the study. Based on the exclusion criteria, three participants were excluded from Study Part 1, one of whom experienced bloating, and one additional subject was excluded due to vomiting the capsule intact. In all instances, the capsule remnants passed from all participants who ingested the RaniPill capsule.

Pharmacokinetics

- In Study Part 1, RT-102 (20 µg and 80 µg) orally delivered PTH with 300%-400% greater bioavailability than PTH delivered by Forteo SC (20 µg).
- RT-102 20 µg delivered PTH with lower, more sustained peak serum levels and higher area under the curve ("AUC") than Forteo SC 20 µg.

	Forteo SC 20 µg	**RT-102 20 µg**	**RT-102 80 µg**
Cmax (pg/mL)	128 ± 20	98 ± 10	971 ± 223
Tmax (hr)	0.217	1.13	0.994
AUC (h*pg/mL)	126 ± 64	342 ± 36	2600 ± 649
Relative BA (5)	N/A	~300%	~400%

Device Performance

- Two versions of the RaniPill capsule were used during Study Part 1: Version C, which was used in our prior Phase 1 study of octreotide (which also utilized a Version A and Version B); and Version D, the latest iteration of the RaniPill capsule.
- RaniPill Version D demonstrated a higher drug delivery success rate than Version C:
  - 95% (20/21) of participants received successful drug delivery when ingesting RaniPill Version D.
  - 75% (6/8) of participants received successful drug delivery when ingesting RaniPill Version C.

The device performance analysis does not include participants excluded from the study per protocol, as drug delivery was not measured in such participants.

Study Part 2 - Topline Results

Study Design

Study Part 2 was a continuation of Rani's single-center, open-label Phase 1 study of RT-102 conducted in Australia. The study evaluated the safety and tolerability of once-daily administration of RT-102 containing 20 µg of PTH given repeatedly for seven consecutive days in ten healthy female volunteers (five of whom were post-menopausal). Complete pharmacokinetic profiles of PTH were obtained for each subject on Day 7.

Safety Data

- RT-102 was generally well tolerated, with no serious adverse events noted during the study
  - None of the participants withdrew from the repeat-dose study due to any adverse event related to the RaniPill capsule or due to difficulty swallowing the capsule
  - Two subjects had transient, mild-to-moderate adverse events which resolved without any intervention
- Device remnants were excreted without sequelae in all subjects

Pharmacokinetics

- RT-102 delivered 20 µg of PTH with high bioavailability (relative to 20 µg SC Forteo (teriparatide) in Study Part 1, confirming the high bioavailability of PTH delivered via the RaniPill capsule observed during Study Part 1.

Device Performance

- In all ten participants who completed seven days of daily, consecutive dosing, the RaniPill capsule demonstrated an overall drug delivery success rate of 91% over the seven days (drug sampling was done at three, six and nine hours after capsule swallowing on Days 1-6).
- On Day 7, with more frequent, serial drug sampling after capsule swallowing on that day, the drug delivery success rate was 100%.
- On Days 1 through 6, participants ate food three hours after administration of the RaniPill capsule. The number of successful deployments was comparable before and after food was consumed.

Regulatory

We have completed a pre-IND meeting with the FDA with respect to RT-102. Following feedback from the meeting, we believe that a 505(b)(2) pathway is suitable for the development of RT-102 in the U.S. In addition, we obtained guidance from the FDA on our preclinical and clinical development plans for RT-102. We intend to initiate a Phase 2 clinical trial of RT-102 in 2024.

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

Market overview

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 $21.2 billion in 2022. 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 U.S. alone, there are an estimated one and one-half million patients with rheumatoid arthritis, seven million with psoriasis, and three million with Crohn's disease or ulcerative colitis. At least eight Humira biosimilars entered the U.S. market over the course of 2023.

Patients who use adalimumab administer the drug through a subcutaneous injection once every two weeks. Despite the painful injections required to administer it, adalimumab was the best-selling drug globally in 2020.

Our solution: RT-105

We are developing RT-105, the RaniPill capsule containing a formulation of adalimumab, for oral treatment of a host of inflammatory conditions, beginning with treatment of psoriatic arthritis and later expanding to other indications for which TNF-alpha inhibitors are approved. We believe that the development of an orally administered anti-TNF-alpha antibody represents a significant market opportunity. In June 2023, we entered into a License and Supply Agreement with Celltrion under which we receive an exclusive license and supply of Celltrion's adalimumab biosimilar for development and commercialization of RT-105 worldwide, subject to a right of first negotiation for Celltrion.

Preclinical studies

We evaluated the performance of RT-105 containing an adalimumab biosimilar in awake canines and compared it to the performance of the adalimumab biosimilar given by way of subcutaneous and intravenous injection. The PK profile for RT-105 was comparable to the profile for subcutaneous administration, and mean bioavailability for RT-105 was 49%, compared to 46% with subcutaneous injection.

Clinical trials

Endoscopic administration of adalimumab into the jejunum of healthy human volunteers

To assess whether the observations from preclinical studies regarding absorption of adalimumab through the intestinal wall translate to clinical trials, we conducted an endoscopic study in humans. The study involved ten 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 a 14-day study period.

PK profiles were similar with no notable differences observed in either area under the curve ("AUC") or maximum serum concentration ("Cmax"). The mean AUC was 62.7 ± 11.4 µg/ml*day*kg/mg for the subcutaneous group and 45.0 ± 29.0 µg/ml*day*kg/mg for the intrajejunal group. No serious adverse events were noted in this study, and adverse events of headache and flu-like symptoms after intrajejunal administration resolved within 48 hours. The results are consistent with data obtained in preclinical studies, confirming intrajejunal delivery as a viable route of delivery for adalimumab.

Next Steps

In November 2023, we announced the pausing of development of RT-105 as part of a strategic focusing of the business. The next milestone for this program will be to initiate a Phase 1 clinical trial of RT-105. Under the Celltrion Agreement for adalimumab, Celltrion will have a right to terminate the agreement if we do not initiate a Phase 1 clinical trial with RT-105, or fail to deliver to Celltrion topline data from a Phase 1 trial that meets its primary endpoint(s), within certain agreed time periods. We anticipate resuming this program in time to enable us to satisfy these requirements.

RT-110: PTH for the treatment of hypoparathyroidism

Market overview

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

Our solution: RT-110

We are developing RT-110, the RaniPill capsule containing our second novel formulation of PTH, for oral treatment of hypoparathyroidism. We are creating a sustained release formulation of RT-110 which is intended to provide continuous exposures of the hormone required to normalize the calcium imbalance in hypoparathyroidism patients. We have worldwide commercial rights to RT-110. We believe that there is an unmet need for a delivery method more convenient than injection, and we further believe that the RaniPill capsule could provide for a treatment regimen that can better maintain consistent and sustained plasma levels of PTH than the current treatment regimen of daily PTH injections.

Next Steps

In November 2023, we announced the pausing of development of RT-110 as part of a strategic focusing of the business. The next milestone for this program would be to initiate a Phase 1 clinical trial in healthy volunteers.

The Market and Our Strategy

More than half of the adult population of the U.S. has one or more chronic diseases. The affected population is expected to continue to grow as the population ages. Chronic conditions, including autoimmune diseases, metabolic disorders, cancers, and cardiovascular diseases are increasingly being treated with biologics. In 2022, six of the ten highest revenue-producing drugs in the world were biologics. Current treatments using biologics are primarily via injections.

Biologics, the fastest growing segment of the drug industry, refers to a broad class of drugs that are derived from living sources. Biologics are distinguished from small molecules, like aspirin, which derive from chemistry. Biologics include, for example, recombinant therapeutic proteins, peptides, and monoclonal antibodies, as well as cell and gene therapies. The global biologics market size is estimated to be $429.5 billion in 2024 and is expected to reach $601.26 billion by 2029.

Biologics must generally be administered through intravenous, intramuscular, or subcutaneous injection. Patient aversion to injections has promoted a significant interest in the development of solutions to enable the oral delivery of biologics. However, a significant hurdle is the ability to achieve sufficient bioavailability with oral biologics to produce an intended therapeutic effect. Bioavailability refers to the proportion of a delivered dose that reaches the bloodstream in active form. Attempts at oral delivery of biotherapeutics have remained largely unsuccessful due to the rapid degradation and digestion of biologics in the gastrointestinal (“GI”) environment before they can be absorbed into the bloodstream.

Our solution is a novel, proprietary and patented platform technology referred to as the RaniPill capsule, an orally ingestible pill designed to automatically deploy in the small intestine to administer a precise therapeutic dose of a biologic into the intestinal wall. Our several preclinical studies and clinical trials have demonstrated bioavailability of biologics dosed via the RaniPill capsule that is generally comparable to the bioavailability of biologics dosed subcutaneously, with high dosing accuracy: this level of bioavailability is significantly higher than any that has been demonstrated with respect to others’ attempts at oral delivery of biologics.

We are pursuing a number of clinical and preclinical pipeline programs utilizing our RaniPill capsule. In addition, our newly designed high-capacity oral biologic delivery device, the RaniPill HC, has the potential to deliver 500%-plus higher payloads than our current RaniPill GO capsule. We believe this is a significant breakthrough in drug delivery with the potential to provide expansive opportunities for the company, such that we could potentially pursue a convenient dosing option for over 50 additional biologics, for internal development or through partnership, including such biologics as dupilumab, pembrolizumab, etanercept, trastuzumab and secukinumab. We believe that oral biologics utilizing our RaniPill technology have the potential to disrupt the large and growing biologics market.

Our strategic vision is to disrupt and expand the market currently served by injectable only therapeutic biologics. We plan to do this by developing and advancing a pipeline of oral biologics therapies to unlock the value of these assets and to progress platform development and by actively pursuing partnering of the technology with third party biopharmaceutical companies for the oral delivery of their biologics and drugs. We also intend to explore opportunities to demonstrate the potential of the delivery platform in additional modalities and therapeutics areas. We believe that the RaniPill capsule has the potential to improve the lives of millions of patients with chronic diseases who currently depend on biologics and drugs available only as injections.

Our strategy includes the following aspects.

- **Pursue validated and commercially established market opportunities.** We intend to pursue high-value markets with biologics that are already approved or validated where we can develop 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.

- **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. For commercial scale manufacturing, we will consider engaging one or more third party contract manufacturers,

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

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

•**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 further innovations and new applications of the RaniPill capsule.

Rani LLC was founded by Mir Imran, our Chairman of the Board, who continues to contribute to our strategic planning and product development. Mir Imran has a background in medicine and engineering, is a prolific inventor and a serial entrepreneur, having founded more than 20 life sciences companies.

Our Platform Technology

Our technology comprises a drug-agnostic oral delivery platform, the RaniPill capsule, which is designed to deliver a wide variety of drug substances, including antibodies, proteins, peptides, and oligonucleotides. We are currently developing two configurations of the platform – the RaniPill GO and the RaniPill HC. The RaniPill GO is designed to deliver up to a 3 mg dose of drug in microtablet form with high bioavailability.We are also developing a high-capacity version of the RaniPill capsule known as the RaniPill HC, which is intended to enable delivery of drug payloads up to 200µL in liquid form with high bioavailability.

Each of our product candidates is a RaniPill capsule containing a biologic. We may use the term RaniPill platform or RaniPill device herein to refer to the physical structure and/or mechanisms of the RaniPill capsule absent a biologic.

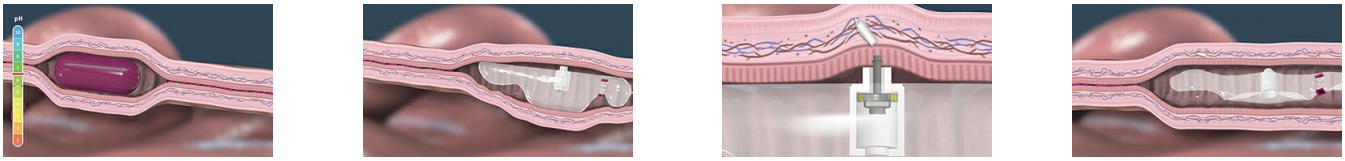
The RaniPill capsule

The RaniPill capsule is a versatile, drug-agnostic, orally ingestible pill approximately the size of a fish oil or calcium pill or a ‘000’-sized capsule.

RaniPill capsule in purple next to fish oil pills (gold) and calcium pills (white).

The capsule includes a proprietary coating designed to withstand stomach acid but dissolve in the jejunum portion of the small intestine. Dissolution of the coating leads to a series of steps that result in a biologic being delivered into the highly vascularized wall of the small intestine so that the biologic can be absorbed into the vasculature and enter the bloodstream.

The following illustrations depict the clinically tested RaniPill GO capsule traversing through and deploying within a lumen of the intestine illustrated in cross section.



Panel A Panel B Panel C Panel D

Panel A: As the RaniPill capsule exits the stomach and enters the small intestine, the higher pH environment of around 6.5 in the jejunum begins to dissolve the coating.

Panel B: Dissolution of the coating exposes a balloon in the RaniPill capsule to intestinal fluid which results in the balloon self-inflating.

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

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

The RaniPill HC operates similar to the RaniPill GO except that, instead of delivering a dissolvable microneedle containing a solid microtablet of drug, the RaniPill HC uses a dissolvable needle to deliver the drug payload in liquid form.

Features and advantages of the RaniPill capsule

The RaniPill capsule is a result of years of internal research activities to develop and optimize specialized components and systems that make up the RaniPill capsule. Several advanced features are included in the RaniPill capsule, providing what we believe to be significant and sustainable competitive advantages in the field of oral delivery of biologics. Some of the features and advantages of the RaniPill capsule are listed below.

- *High bioavailability and high dosing accuracy* – Our studies conducted to date have demonstrated that the RaniPill capsule delivers biologics with high bioavailability and high dosing accuracy. This level of bioavailability is significantly higher than that of currently marketed chemistry-based oral biologics, the best attempts of which to our awareness have resulted in peptides being delivered with only low single-digit bioavailability.

- *Protective coating avoids deployment in the stomach* – The proprietary protective coating formulation is pH-sensitive, enabling the RaniPill capsule to maintain its integrity through the acidic environment in the stomach for deployment in the small intestine.

- *Protection of the drug prior to delivery* – The microneedle and drug are protected from intestinal fluid until delivery, and then the rapid injection of the microneedle into the intestinal wall during delivery provides for little or no exposure of the microneedle or drug to intestinal fluid. This technique serves to overcome the body's natural mechanisms that break biologics down in the harsh GI environment and thus block biologics from reaching the blood stream from within the intestine.

- *Delivery in both fed and fasted states* – The RaniPill capsule is designed to deliver the drug payload regardless of whether the patient ingests the RaniPill capsule with or without food, which we expect will allow for more flexible dosing regimens and improved patient adherence to a given regimen.

•*Self-inflating balloon ensures reliable delivery* – The proprietary self-inflating balloon is designed to provide optimal pressure to deliver the payload. In addition, the novel design of the balloon positions the microneedle approximately perpendicular to the intestinal wall for reliable drug delivery, with greater than 90% cumulative drug delivery success observed with the latest version of the RaniPill capsule used in our Phase 1 clinical trials of RT-102 and RT-111. The self-inflating balloon has been designed to minimize GI discomfort.

•*Drug-agnostic design provides a standardized platform* – The RaniPill capsule is designed to deliver any molecule irrespective of its molecular mass. This allows a single platform design to be used with multiple drugs.

•*Optimized dosing regimen* – Based on the confirmed patient preference for oral delivery alternatives, we expect better treatment adherence with oral dosing versus injections, thus enabling a more clinically-favorable dosing regimen. For example, the RaniPill capsule may enable a regimen of small, more frequent doses, versus larger less frequent doses for injections, to improve treatment adherence. In addition, small, more frequent dosing may allow for therapeutic exposures to be maintained within a narrow range, whereas larger less frequent injection dosing can lead to large variations in therapeutic exposure, which may contribute to adverse events, loss of efficacy, and increased propensity for immunogenic response.

RaniPill HC

We continue to develop the RaniPill HC, a high-capacity RaniPill capsule designed to deliver drug payloads up to 200µL, 500%-plus higher than the payload capacity of the RaniPill GO. In September 2023, we announced three positive preclinical studies which support the development of the RaniPill HC device.

Rani conducted two preclinical studies of the RaniPill HC containing 40ug of teriparatide. In the first study, two RaniPill HC capsules were orally administered to 5 awake canine subjects sequentially, with a second RaniPill HC capsule administered after the deployment of the previous device was confirmed. In the second study, a single RaniPill HC capsule was administered to ten awake canines.

•RaniPill HC achieved 18/20 successful drug delivery of teriparatide in the two studies, resulting in a cumulative 90% success rate.

•Successful drug delivery was confirmed by positive drug signal for teriparatide in serum.

•Devices used in these studies were separate iterations, and may not comprise all the same components expected in a final version.

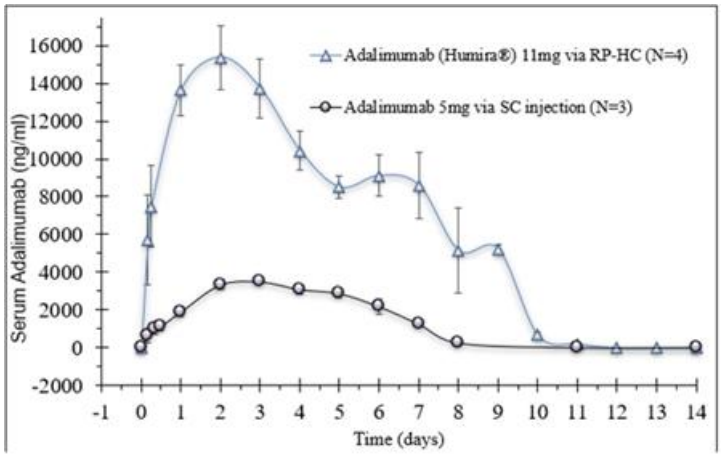
•Rani also conducted an additional preclinical study of RaniPill HC containing Fe57 (iron) in 2 canine subjects.

•The RaniPill HC containing Fe57 showed a positive drug signal comparable to subcutaneous injection.

In October and November 2023, we announced the completion of two preclinical studies of the RaniPill HC with antibodies, adalimumab and an undisclosed anti-interleukin antibody (“Undisclosed MAB”). In the two studies, the RaniPill HC achieved an oral delivery success rate of 100% (10/10). In one study, we tracked the serum concentrations of adalimumab, following the oral administration of the enteric-coated RaniPill HC capsule containing 11mg of Humira (adalimumab) to four canine models. In the second study, we tracked the serum concentrations of the Undisclosed MAB, following the oral administration of the enteric-coated RaniPill HC capsule containing 16.5mg of Undisclosed MAB to six canine models. In both studies, the RaniPill HC was well tolerated, all animals remained healthy throughout the study period with no clinical findings or adverse events, and all device remnants were excreted normally without sequelae.

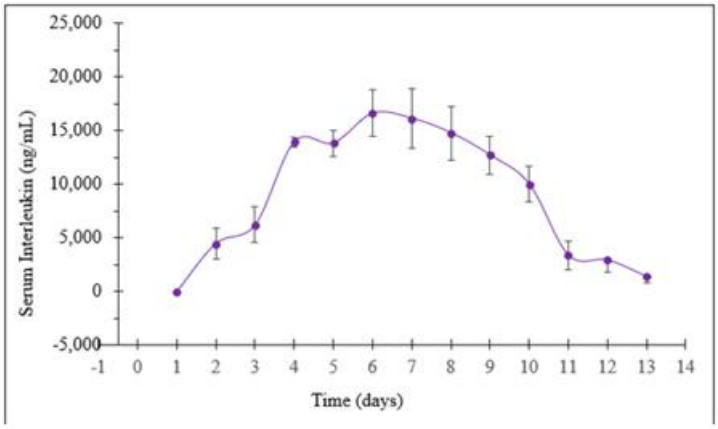
Comparing the pharmacokinetic results of 11mg of adalimumab delivered via the RaniPill HC (N=4) with historical pharmacokinetic data we generated with 5mg of an adalimumab biosimilar (GP2017) delivered via subcutaneous injection (N=3), there is a higher estimated bioavailability of adalimumab delivered via the RaniPill HC relative to the subcutaneous injection route.

Adalimumab 11mg via RaniPill HC vs Adalimumab Biosimilar 5mg via Subcutaneous Injection



All Data are Means ± SE

Pharmacokinetics of Undisclosed MAB (16.5mg) Delivered Orally via RaniPill HC Capsules to Awake Canines (N=6)



All Data are Means ± SE

Preliminary preclinical testing supports the potential for RaniPill HC to have high reliability, and initial analysis of drug delivery via the RaniPill HC shows a potential for mimicking parenteral (subcutaneous) administration. We intend for the RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024.

60-Day GLP Study

We conducted a preclinical GLP study evaluating the safety and tolerability of the RaniPill drug delivery platform, following 60-day repeat oral administration of the test article, RT-100, in healthy animals. RT-100 is an enteric-coated capsule identical to RT-102, but instead of PTH contained the pharmaceutical excipient mannitol. The control group received a RaniPill capsule (Mock-RP) of similar weight to RT-100 but filled with potato starch. Male and female (1:1) animals were divided into two groups and were administered either Mock-RP (N=12) or RT-100 (N=24) once daily for 60 days, with half of the animals completing an additional 14-day clinical observation and safety evaluation period. RT-100 was well-tolerated with no treatment-related adverse events and all animals remained clinically healthy throughout the study.

Platform study in humans confirming reliable deployment in fed and fasted states

An initial clinical assessment of the RaniPill capsule (without a drug) was conducted to evaluate the safety and tolerability of the platform and to compare device performance in fed and fasted states in twenty healthy volunteers, divided into two groups of ten. 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 total transit time for the RaniPill capsule was longer in the fed group than in the fasted group because the capsule remained in the stomach longer in the fed group. However, food did not impact the deployment time of the RaniPill capsule. This was confirmed via radiographic tracking which showed successful balloon inflation, indicating both that the protective coating dissolved as designed and the balloon inflated as designed, regardless of the presence of matter in the lumen of the intestinal tract.

No volunteers reported difficulty in swallowing the capsule, nor did any study participant report experiencing pain or sensing an awareness upon balloon deployment.

Our Regulatory Pathways

Test, approval, manufacture, and sale of our products are subject to federal, state, local, and foreign statutes and regulations. We, along with our 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. We detail the U.S. regulatory pathway in this section. In the United States, the FDA regulates biologic products such as ours under the Federal Food, Drug and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") and their implementing regulations. Other jurisdictions will have somewhat different requirements.

FDA centers: CDRH, CBER, CDER, OCP

Each of our product candidates includes the RaniPill platform and a biologic. The RaniPill platform, if marketed without a biologic, would be classified by the FDA as a device regulated by the Center for Devices and Radiological Health ("CDRH"). A biologic, if marketed without the RaniPill platform, would be classified by the FDA as either a "biological product" regulated by the Center for Biologics Evaluation and Research ("CBER") or a "drug" regulated by the Center for Drug Evaluation and Research ("CDER"). The classification as biological product or drug would depend on the FDA's definition of "biological product" with respect to the active ingredient of a product candidate at the time a request for regulatory license or approval is submitted to the FDA to market that product candidate. The FDA currently defines a biological product as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings," and defines a protein as an "alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size."

Because our product candidates each include a device and a biologic, it is expected that each of our product candidates will be classified by the FDA as a combination product. 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 center. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product, although the other centers may participate in review. The FDA has also established an Office of Combination Products, ("OCP"), which serves as a focal point for combination product issues for agency reviewers and industry. OCP 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.

It is expected that most of our product candidates will include a biologic within the FDA's definition of "biological product" and some of our product candidates may include a biologic that will be considered a "drug." CDER is the lead center for review of therapeutic proteins at this time, thus most of our product candidates will have CDER as the lead center.

For each product candidate, we will perform numerous preclinical laboratory tests and animal studies, as well as perform human clinical trials. Preclinical laboratory tests, preclinical animal studies, and/or clinical trials may be ongoing concurrently for a product candidate in focused studies to assess various properties of a formulation and/or the platform of the product candidate. Animal studies require pre-approval by an independent institutional review board ("IRB") or ethics committee. Human studies in the United States require pre-approval by the FDA. For FDA approval of a human trial, if the trial will involve a biologic alone then an IND application will be needed, and if the trial will involve the RaniPill platform alone then an investigational device exemption ("IDE") application will be needed. For a clinical trial in which the RaniPill platform will be used in combination with a biologic, we must submit an IDE application if the lead center is CDRH or an IND application if the lead center is CBER or CDER. For the RaniPill platform used in combination with a biologic, it is expected that CBER or CDER will be the lead center. IND and IDE applications are discussed in more detail below.

Approval or license to market the RaniPill capsule

The FDA has specified a BLA path for seeking a license to market a biological product and a new drug application path for seeking approval to market a drug. It is expected that most of our product candidates will follow the BLA path while some may follow the NDA path.

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 already-approved products in our own BLA or NDA. The degree to which we may be able to reduce the burden on our own development may depend on whether the API or drug substance is the same as the original approved product. Additionally, because certain products originally approved under an NDA have been reclassified by the FDA and would now follow a BLA pathway, it is unclear whether conclusions regarding such reclassified products can be leveraged in our BLA submissions. We intend to have the scope of the leverage that will be available from already-approved biologics clarified on a product-by-product basis for each product candidate in pre-IND meetings with the FDA.

We have completed a pre-IND meeting with the FDA with respect to RT-102. Following feedback from the meeting, we believe that a 505(b)(2) pathway is suitable for the development of RT-102 in the U.S.

CBER and CDER may ask for additional testing for specific biologics, disease indications, or patient populations.

Additional information regarding regulatory pathways is provided in the "*Government Regulation*" section below.

License and Evaluation Agreements

Celltrion license and supply agreements

In January 2023, we entered into a License and Supply Agreement with Celltrion regarding its ustekinumab biosimilar, CT-P43 (the "Ustekinumab Celltrion Agreement"). In June 2023, we entered into a License and Supply Agreement with Celltrion regarding its adalimumab biosimilar (the "Adalimumab Celltrion Agreement" and together with the Ustekinumab Celltrion Agreement, the "Celltrion Agreements"). Under the Celltrion Agreements, Celltrion grants us an exclusive, worldwide, royalty-free license to certain intellectual property to make, use, sell, offer for sale, import and otherwise exploit RT-111 and RT-105 and to use certain information to support the manufacture, development and commercialization of RT-111 and RT-105. Celltrion will provide, and we will purchase, supply of ustekinumab biosimilar and adalimumab biosimilar at supply prices set forth in the respective Celltrion Agreement. We will obtain ustekiunmab biosimilar and adalimumab biosimilar exclusively from Celltrion for the manufacture, development and commercialization of RT-111 and RT-105, respectively, subject to a right to obtain supply from alternative sources under certain circumstances where Celltrion experiences supply disruption.

Under the Celltrion Agreements, we have sole right to manufacture, develop and commercialize RT-111 and RT-105 worldwide, subject to an exclusive right of first negotiation ("ROFN") granted to Celltrion for each program. For each program, following our delivery to Celltrion of a data package consisting of topline safety information, pharmacokinetic results and device performance, and the raw data related to topline results from a Phase 1 clinical trial of such program that meets its primary endpoint(s), Celltrion will have 30 days to exercise its ROFN with respect to that program. If Celltrion timely exercises the ROFN, then Celltrion will have an exclusive period of 90 days to negotiate in good faith a definitive agreement with us for rights to clinically develop and commercialize the applicable program in territories selected by Celltrion. In the event Celltrion does not timely exercise the ROFN or Celltrion notifies us that it does not intend to exercise the ROFN or, after timely exercising the ROFN, notifies us that Celltrion withdraws its exercise of the ROFN, or the parties fail to enter into a definitive agreement for the development and commercialization of the applicable program within the exclusive negotiation period, then the ROFN regarding that program will terminate and we will have no further obligations under the Celltrion Agreements related to a ROFN for that program. We believe the Phase 1 clinical trial that we completed with RT-111, the topline data of which we announced in February 2024, satisfies the requirements for triggering Celltrion's ROFN with respect to that program.

The Celltrion Agreements allocate rights between the parties with respect to inventions generated in performance of the agreement for the manufacture, development and commercialization of each of RT-111 and RT-105, respectively. Celltrion will own intellectual property generated in the programs solely related to its ustekinumab biosimilar or adalimumab biosimilar, respectively. We will own all other intellectual property generated in the programs, and we grant Celltrion an exclusive, worldwide license under such intellectual property solely for use with its ustekinumab biosimilar or adalimumab biosimilar, respectively. We will own all data related to the research, development, manufacture, regulatory activities and commercialization of RT-111 and RT-105 conducted by us. The Celltrion Agreements also contain customary representations, warranties and covenants, and mutual indemnification provisions. We have a right to terminate each agreement for convenience subject to certain notice periods. Celltrion has a right to terminate each agreement if we do not achieve certain development milestones with respect to that agreement, and each party has certain rights to terminate the applicable agreement for material breach or safety concerns regarding the stekinumab biosimilar or RT-111, or adalimumab biosimilar or RT-105, respectively.

Novartis evaluation agreement

In May 2015, we entered into an Evaluation and First Rights Agreement (the "Novartis Agreement") with Novartis Pharmaceuticals Corporation ("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. Certain data from such testing was shared with Novartis pursuant to the July 2020 amendment. Following delivery of a report by us, 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 six 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 party's uncured material breach.

Novartis has paid us an aggregate of $7.0 million under the Novartis Agreement as of December 31, 2022 and made an equity investment of approximately $5 million in our Series C preferred unit financing. As part of the organizational transactions in connection with our initial public offering, the Series C preferred units were exchanged for 404,638 Paired Interests. We did not receive any payments from Novartis under the Novartis Agreement in 2023 and 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.

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 also 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 that have been optimized to consistently produce capsules of high reliability.

The RaniPill capsule manufacturing process

* Microtableting only applicable to drugs formulated for use in the RaniPill GO capsule.

For the RaniPill GO, a drug API or drug substance combined with excipients specific to the drug API or drug substance is lyophilized and compressed into a solid microtablet form. The microtablet (in the case of RaniPill GO) or liquid drug (in the case of RaniPill HC) is sealed inside a microsyringe under aseptic conditions. The microsyringe 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. In the case of ustekinumab for RT-111 and adalimumab for RT-105, we obtain supply of drug substance from Celltrion under the Celltrion Agreements. For other APIs or drug substances, we rely on non-exclusive, third-party relationships with several manufacturers for the drug API or drug substance. We maintain in-house capabilities related to the aseptic manufacturing, following FDA Current Good Manufacturing Practice ("cGMP") regulations for drugs that contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product 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

Markets

The key markets for our products, once approved, will be in the United States, Europe, and Asia.

Sales and supply infrastructure

Development of our product candidates includes identifying sources that can provide consistent quality and increasing quantities of APIs or drug substance to meet our needs through in vitro studies, preclinical studies, and clinical trials, and later into commercialization. We currently do not have agreements in place for long-term supplies of any API or drug substance, other than ustekinumab biosimilar for RT-111 and adalimumab biosimilar for RT-105. Availability of API or drug substance supply may inform our decisions regarding which product candidates present the best development opportunities.

Currently we do not have any approved products. We intend to either develop the commercialization sales and supply infrastructure as our product candidates are approved, or partner with pharmaceutical companies or distributors for commercialization.

Coverage and reimbursement of approved products by third-party payors

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 the payors. Decisions regarding whether to cover a product, the extent of coverage, and the amount of reimbursement to be provided are made separately, and these decisions are made on a plan-by-plan basis because there is no uniform policy for coverage and reimbursement. As a result, one payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product, or that any of the reimbursement rates will be adequate.

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 products 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 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 when available. Third-party payors are increasingly challenging prices charged, examining medical necessity, and reviewing cost effectiveness in addition to questioning safety and efficacy. A decrease in, or decision to stop, payor reimbursement for a product could reduce physician prescribing of, and patient demand for, the product.

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 biosimilar) manufacturers of the branded injectable versions of our pipeline drugs, manufacturers such as AbbVie Inc., Eli Lilly and Company, Janssen Biotech, Inc., etc. However, we believe that oral biologics have the potential to take significant market share from current injectable therapies. We also believe that oral biologics have the potential to expand existing markets by an early reach into new patient populations that are averse to taking injections.

We are aware of certain other companies that are pursuing oral biologics through either device-based or chemistry-based technologies. We may also face competition from companies that develop oral small molecule therapeutics to the same biological targets as biologics. Early-stage device-based technologies such as the SOMA and LUMI from the Novo Nordisk-MIT collaboration were reported to be in early clinical and preclinical stages, respectively. Two other companies pursuing a device-based approach are Biograil ApS and Biora Therapeutics, Inc., both of which were reported to be in a preclinical stage of development. Chemistry-based oral delivery companies include Oramed Pharmaceuticals, Inc., Entera Bio Ltd., Protagonist Therapeutics, Inc., i2O Therapeutics, Intract Pharma, and two with recently approved oral peptide products – Mycappssa from Chiesi Farmaceutici SpA and Rybelsus from Novo Nordisk A/S. Chemistry-based approaches have limited applications because they work only for small peptides and, even then, with low (often less than 1%) bioavailability, far lower than injections. 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.

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.

Environmental impact

We have instituted policies and procedures related to appropriate chemical and biological material handling, use, and disposal in our facilities, and we train our employees on these policies and procedures.

Regulations in certain jurisdictions may require us to submit with our marketing approval request an environmental impact assessment related to our biologics, our RaniPill platform, or both. Such assessments could cause significant expenditures. We may be able to reduce expenditures related to these assessments by our strategy of using biologics already approved for marketing.

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 development efforts have enabled us to construct an extensive intellectual property portfolio that we believe provides us a competitive advantage. 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.

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

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 United States 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.

Our initial 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 platform, including aspects of the RaniPill GO and certain aspects of the RaniPill HC, and the delivery of a wide variety of biologics using the RaniPill platform. Granted patents and pending patent applications in this core family number more than 270. As of January 1, 2024, this patent family included 79 patents issued in the United States and 144 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, Hong Kong, India, and Japan.

We also own several patent families directed to the RaniPill HC. These patent families have priority dates in 2020, 2022, and 2023, with patent term expected to extend into at least 2044 if all fees are paid. These patent families include claims directed to device aspects, devices containing specific biologics, methods of preparing such devices, and methods of delivering a wide variety of biologics using the RaniPill HC.

Our microtablet patent family includes claims covering the microtablets delivered by the RaniPill GO. This patent family has a priority date in 2014, includes several dozen granted patents and pending patent applications, and is expected to have patent terms extending into at least 2035 if all fees are paid. As of January 1, 2024, this patent family included 12 patents issued in the United States, 11 patents issued in other jurisdictions (i.e., Australia, Canada, China and Japan), with applications pending in the United States, Australia, Canada, China, Europe, India, and Japan.

We own numerous additional patents and patent applications, 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.

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 with employees, and consulting or other contractual agreements with consultants, scientific advisors, sponsored researchers, contractors, and other collaborators, prior to commencement of our relationship with them. 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.

Government Regulation

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 products such as those we are developing. We, along with our third-party contractors and/or collaboration partners, 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 applicable regulations at any time during the product development process or approval process or after approval may result in delays to the conduct of a study, regulatory review, or commercialization authorization, or may subject an applicant to administrative or judicial actions. In the United States, such actions could include, among other actions, refusal to allow proceeding with clinical trials, imposition of a clinical hold, refusal to approve pending applications, withdrawal of an approval, license suspension or revocation, 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.

Current Good Manufacturing Practices (“cGMP”)

To obtain marketing approval for a candidate product, we must finalize processes for manufacturing the product in commercial quantities in accordance with cGMP requirements. These processes must address design, monitoring, control, and maintenance of manufacturing processes and facilities, and the implemented processes must be capable of consistently producing quality batches of the product candidate. Our processes must, among other things, enable us to monitor several aspects of the interim and finished product, such as identity, purity, strength, quality, potency, and sterility as applicable. Additionally, stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life, and appropriate packaging must be selected and tested.

Preclinical and clinical development

For each product candidate, we perform numerous laboratory tests and preclinical animal studies, as well as human clinical trials. Preclinical laboratory tests, preclinical animal studies, and/or clinical trials may be ongoing concurrently for a product candidate in focused studies to assess various properties of a formulation and/or platform of the product candidate. Animal studies require pre-approval by an independent Institutional Animal Care and Use Committee ("IACUC"). Human studies in the United States require pre-approval by the FDA and an independent IRB, requested by way of an IDE or IND for investigational products such as our product candidates.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices ("GCP"), which includes 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. 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 an IRB or ethics committee 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, the trial is not being performed in accordance with the investigational plan or associated protocols, 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 the data safety monitoring board determines that there is an unacceptable safety risk for subjects, no demonstration of efficacy, or other grounds. There are also requirements governing the reporting of ongoing preclinical studies, 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.

Human clinical trials are typically conducted in three phases that may be performed sequentially, in overlapping time frames, or in combination.

- Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. The total number of subjects included in Phase 1 studies varies with the drug but is generally in the range of 20 to 80.

- Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

- Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.

For each of our product candidates, we may conduct Phase 1, Phase 2, and Phase 3 clinical trials of our formulation, the RaniPill platform, or the formulation in combination with the RaniPill platform.

In some cases, the FDA may require, or we 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 alternatively be made a condition to approval of the BLA or NDA. 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 certain regulatory programs, such as accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for the associated product.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial 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 or IDE 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 a particular or similar 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.

Investigational products

Prior to initiating a clinical trial in the United States of an investigational product such as for one of our product candidates, the FDA must grant authorization to proceed. A request for authorization is made by way of an IND or IDE application as applicable for the clinical trial.

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 protocols to be used in associated preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies already performed to assess toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product. The IND further includes chemistry, manufacturing, and controls information, and human data or literature to support the use of the investigational product.

An IDE is a request for authorization from the FDA to allow an investigational device to be used in a clinical trial to collect safety and effectiveness data. 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.

An IND or IDE must become effective before human clinical trials may begin. The IND or IDE 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 or IDE may be placed on clinical hold to resolve any outstanding concerns or questions before the clinical trial can begin.

The FDA's approval of an IND or IDE does not bind the FDA to accept the results of the trial as sufficient to prove the stated conclusions, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with FDA regulations that govern investigational product labeling, prohibit promotion, and specify an array of recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators. Required records and reports are subject to inspection by the FDA. Clinical trials must further comply with FDA regulations that govern institutional review board approval, informed consent, and other human subject protections.

An amendment to the existing IND or IDE must be made for subsequent protocol changes and also for each successive clinical trial conducted during product development.

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

BLA/NDA review process

Following completion of clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. In short, the NDA or BLA is a request for approval to market the product candidate for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity, and potency for a biological product. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use and/or from a number of alternative sources, including studies initiated by investigators or cooperative clinical groups. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act (“PDUFA”) and the Biologics Price Competition and Innovation Act of 2009 (“BPCI”), as amended, each NDA or BLA must be accompanied by a user fee. User fees may be adjusted on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug or biologic. Biosimilar User Fee Amendments impose a user fee for a biosimilar development program at the time of the first meeting with the FDA or the initial IND submission, whichever occurs first. This fee must be paid annually.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review and respond to the applicant, or six months if the submission is designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process may be extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product 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. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes specific deficiencies in the NDA or BLA identified by the FDA. A Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies, or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Pediatric Research Equity Act (PREA)

Under the Pediatric Research Equity Act (“PREA”), a BLA or NDA submission or supplement 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, (“PSP”), within 60 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.

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, presently the FDA has a fast-track designation, a priority review path, an accelerated approval path, and a breakthrough therapy designation. Any product submitted to the FDA for approval may be eligible for one or more of such FDA programs intended to expedite development and review. These expedited approvals do not change the standards for approval but may expedite the development or approval process. We may explore some of these opportunities for our product candidates as appropriate.

- New drugs may be 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 sections of the BLA or NDA for review on a rolling basis before the complete application is submitted.

- 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 to provide 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 or NDA 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.

- 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, has an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account 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 referred to as “breakthrough therapies.” 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.

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 may decide that the time period for FDA review or approval will not be shortened.

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 cGMP, 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, including 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 approved product. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. Biologics 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 cGMP, 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 cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. We are responsible for the selection and monitoring of qualified contract manufacturers, laboratories, and packagers, and, in certain circumstances, qualified suppliers to them. These facilities 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, we must continue to expend time, money, and effort on quality control for our own facilities and the facilities of others which contribute to the commercialization of our final product, to maintain compliance with cGMP 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 risk evaluation and mitigation strategy ("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, and
- 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, 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, one or more of adverse publicity, warning letters, corrective advertising, civil penalties, criminal penalties, government investigation, 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.

Orange Book; Purple Book

The FDA publishes the Orange Book for products following the NDA pathway and the Purple Book for products following the BLA pathway. Our product candidates will be listed in the Orange Book after approval for marketing or listed in the Purple Book after license for marketing, as applicable.

The Orange Book contains information about all FDA-approved drug products regulated by CDER and their exclusivities. The Orange Book also includes patent information. The applicant provides patent information to the FDA as part of its NDA, or after patent grant. Orange Book patent listing provides a 30 month stay of FDA approval of any generic submitted via an abbreviated new drug application ("ANDA"). An applicant submitting an ANDA must, for each patent listed against the approved drug in the Orange Book, either (i) state that the ANDA applicant is not seeking approval for a patented method of use, (ii) ask the FDA to delay approval until that patent is expired (a "Paragraph III" certification), or (iii) attest that the patent is invalid, unenforceable, or will not be infringed by the generic product (a "Paragraph IV" certification), which can trigger ANDA litigation over the associated patent.

The purple book contains information about all FDA-licensed biological products regulated by CBER, including licensed biosimilar and interchangeable products and their reference products, and FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by CBER. The Purple Book includes granted exclusivity information. The Purple Book also includes for each biological product a list of patents identified to a biosimilar applicant during biosimilar litigation under the BPCIA.

Exclusivities

Some of our product candidates may be eligible for exclusivities provided under various FDA programs. Exclusivity refers to certain delays and prohibitions on approval of competitor drugs available under an applicable statute that take effect upon FDA's approval of a biologic or drug, or of certain supplements to the BLA or NDA. Exclusivities do not convey any advantage in or shorten the duration of the regulatory review and approval process.

For an applicant to be able to take advantage of the Pediatric exclusivity, the FDA must make a written request for a pediatric study to be performed, although the applicant may request for the FDA to make the request for a pediatric study. After the study is performed, the applicant may request Pediatric exclusivity. If granted, 180 days of patent term are added to the patent term listed in the Orange Book.

With respect to other FDA exclusivity programs, in some cases the exclusivity programs will not apply to our product candidates due to our unique formulation or oral capsule technology, or it is unclear the extent to which they will apply, or they will not apply to most or all of the product candidates in our pipeline.

For exclusivity programs that apply to our product candidates, we will consider pursuing such exclusivities at the appropriate time. However, we do not expect any of the exclusivities to provide us significant competitive advantage. Exclusivities granted to our competitors could block approval and/or commercialization of one or more of our product candidates, possibly for several years.

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, ("HIPAA"), and similar foreign, federal, and state fraud and abuse, transparency, and data 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 and so 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.

The U.S. federal Physician Payments Sunshine Act requires applicable manufacturers of prescription drugs, devices, biological products, 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), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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 ("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, and their covered subcontractors 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.

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.

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. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), which was enacted in March 2010, 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, 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, on June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031 unless additional action is taken by Congress. Further, Congress is considering additional health reform measures. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain

single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. 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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

Data privacy and security obligations

In the ordinary course of our business, we may collect, receive, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share and store ("process") proprietary, confidential and sensitive information, including personal data, intellectual property, trade secret, clinical trial data, and proprietary information owned or controlled by ourselves or third parties (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations related to data privacy and security. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA"), other U.S. state comprehensive privacy laws (such as Virginia, Colorado, Connecticut, and Utah), the European Union's General Data Protection Regulation 2016/679 ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR"). Obligations related to the processing of personal data worldwide is rapidly evolving. The number and scope of data privacy and security laws, regulations and other obligations is changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions, or in conflict with other data processing obligations. Efforts to ensure that our current and future business operations and arrangements, including our relationship with our CROs or other vendors who process data on our behalf, comply with applicable data privacy and security obligations involve substantial costs.

Employees

As of December 31, 2023, we had 140 full-time employees and no part-time employees. The majority of our employees are based at our facilities in San Jose and Milpitas, California, with a contingent of employees based outside of 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.

Organizational Transactions

Rani Holdings was formed as a Delaware corporation in April 2021 for the purpose of facilitating an initial public offering ("IPO") of its Class A common stock, to facilitate certain organizational transactions, and to operate the business of Rani LLC and its consolidated subsidiary at such time, RMS. In connection with the IPO, we established a holding company structure with Rani Holdings as a holding company and its principal asset is the Class A common units ("Class A Units") of Rani LLC that it owns. As the sole managing member of Rani LLC, Rani Holdings operates and controls all of Rani LLC's operations, and through Rani LLC, conducts all of Rani LLC's business.

In connection with the IPO, we were party to the following organizational transactions (the “Organizational Transactions”):

•Amended and restated Rani LLC’s operating agreement (the “Rani LLC Agreement”) to appoint Rani Holdings as the sole managing member of Rani LLC and effectuated an exchange of all outstanding interests in Rani LLC into Class A Units and an equal number of voting noneconomic Class B units.

•Amended and restated our certificate of incorporation to provide for the issuance of (i) Class A common stock, each share of which entitles its holders to one vote per share, (ii) Class B common stock, each share of which entitles its holders to ten votes per share on all matters presented to the Company's stockholders, (iii) Class C common stock, which has no voting rights, except as otherwise required by law and (iv) preferred stock.

•Certain holders of Class A Units tendered their Class A Units for shares of our Class A common stock. Certain holders of Class A Units continued to hold such Class A Units (“Continuing LLC Owners”) and received shares of our Class B common stock.

•Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of our Class B common stock (together referred to as a "Paired Interest"), in return for shares of the Company’s Class A common stock on a one-for-one basis provided that, at our election, we may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be canceled on a one-for-one basis if we, at the election of the Continuing LLC Owners, redeem or exchange such Paired Interest pursuant to the terms of the Rani LLC Agreement.

•Entered into a registration rights agreement and tax receivable agreement (“Tax Receivable Agreement” or “TRA”) with certain of the Continuing LLC Owners.

Corporate Information

Our principal offices are located at 2051 Ringwood Ave., San Jose, California 95131. Our telephone number is 408-457-3700. Our website address is www.ranitherapeutics.com. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

Copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, filed with or furnished to the Securities and Exchange Commission (“SEC”) pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended may be obtained from the SEC’s on-line database, which is located at www.sec.gov. Our common stock is traded on the Nasdaq Stock Market (“Nasdaq”) under the symbol “RANI.”

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation.

Item 1A. Risk Factors.

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

Risks Related to Operating History, Financial Position and Capital Requirements

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms. If we are unable to raise additional capital when needed, we may be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since our inception. We are in early clinical development with certain product candidates and have conducted or are in preclinical development with other product candidates. We intend to advance our product candidates into initial and later stages of clinical development, which requires significant capital. In addition, we are developing the RaniPill HC. 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.

As of December 31, 2023, our cash, cash equivalents and marketable securities totaled $48.5 million. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our existing capital resources, including the net proceeds from our IPO and term loans we received under a loan and security agreement and related supplement (the “Loan Agreement”) with Avenue Venture Opportunities Fund, L.P (the “Lender”), will not be sufficient to enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates.

If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our audited financial statements, and investors may lose all or a part of their investment.

We may not be able to obtain additional funding on acceptable terms, or at all. As a result of geopolitical events, including the conflicts in Ukraine and Gaza, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. In addition, the report from our independent registered public accounting firm issued in connection with this Annual Report on Form 10-K contains statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

If we are unable to obtain funding on a timely basis, or to generate sufficient revenues, if at all, from collaboration arrangements, we may be required to:

- significantly curtail, delay or discontinue one or more of our research or development programs, the development of our oral delivery technology, including the RaniPill HC, the commercialization of any product candidates or cease operations altogether;
- 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
- forego expansion of our operations or refrain from pursuing business opportunities.

For example, in November 2023, we underwent a reduction in our workforce and paused or discontinued certain programs to reduce our expenses and focus our financial resources on key priorities. As a result of any of the foregoing types of actions, our business, financial condition and results of operations could be materially affected.

Our efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop the RaniPill platform, including the RaniPill HC, to progress development of our product candidates or to automate our manufacturing processes.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants and other operating restrictions that could adversely impact our ability to conduct our business. The Lender already has a security interest in substantially all of our assets, including our intellectual property, which may prevent or limit our ability to incur additional indebtedness.

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 and timing of our preclinical studies and clinical trials;
- the progress, costs, and results of our research pipeline;
- the progress and costs of development of the RaniPill HC device and other improvements or advancements to our delivery technologies;
- the willingness of the FDA or other regulatory authorities to accept data from our clinical trials, as well as data from our completed and planned preclinical studies and clinical trials and other work, as the basis for review and approval of our product candidates;
- the outcome, costs, and timing of seeking and obtaining FDA, and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of the RaniPill capsule;
- our need to expand our research and development activities;
- the costs associated with manufacturing, and obtaining drug supply for, our product candidates, including for clinical and commercial supplies;
- the costs associated with securing and establishing commercial infrastructure, including establishing sales, marketing, and distribution capabilities;
- the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and engineering personnel;
- the effect of competing drugs and product candidates and other market developments;
- the timing, receipt, and amount of sales from our potential products, if approved;
- our ability to establish strategic collaborations;

•our need to implement additional internal systems and infrastructure, including financial and reporting systems;

•security breaches, data losses or other disruptions affecting our information systems;

•our ability to realize savings from any restructuring plans and cost-containment measures we propose to implement;

•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 geopolitical conflicts or other such disruptions.

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.

We have incurred operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue from commercial products 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 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. We are in early clinical development with a limited number of product candidates, and are in preclinical development with other product candidates. 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 oral therapeutic products.

We have incurred significant operating losses since our formation. Our net loss for the year ended December 31, 2023 was approximately $67.9 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 are in early clinical development with a limited number of product candidates, and are in preclinical development with other product candidates. As an early clinical stage company, we have not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as biologics development and delivery. Consequently, the ability to accurately assess our future operating results or business prospects is significantly more limited than if we had a longer operating history or approved products on the market.

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

- the clinical outcomes from the continued development of our product candidates;
- occurrence of adverse events or serious adverse events in preclinical studies or clinical trials of our product candidates;
- potential side effects of our product candidates, whether caused by the biologic formulation or the RaniPill capsule, that could delay or prevent approval or cause an approved product to be taken off the market;
- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop, and potentially manufacture and commercialize our product candidates and develop the RaniPill HC;
- 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 enter into collaboration agreements with third parties who may desire to license our oral delivery technology for use with their own product candidates;
- our ability to expand our commercial reach by selectively entering into strategic partnerships on favorable terms or at all;
- our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to manufacture our product candidates in accordance with current Good Manufacturing Practices, 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.

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

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

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

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

•incur or assume certain debt;

•merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;

•enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;

•change the nature of our business;

•change our organizational structure or type;

•license, transfer, or dispose of certain assets;

•grant certain types of liens on our assets;

•make certain investments;

•pay cash dividends; and

•enter into material transactions with affiliates.

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

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

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

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

Any restructuring actions that we undertake may not deliver the expected results and these actions may adversely affect our business operations.

We may undertake various restructuring activities in an effort to better align our resources, organizational structure and costs with our strategic priorities, including streamlining of business operations and development program priorities and reduction in force. For example, in November 2023, we committed to a restructuring plan involving the reduction of our workforce by approximately 25%. As a result of the restructuring activities, we estimate we will incur approximately $0.3 million in costs of which nearly all are cash expenditures related to severance and half of which was incurred in the fourth quarter of 2023. The restructuring is expected to be substantially completed by the end of the second quarter of 2024. The estimates of costs that we expect to incur in connection with the restructuring and the timing thereof are subject to a number of assumptions and actual results may differ materially from estimates. We may also incur other charges or cash expenditures not currently contemplated in connection with the restructuring due to unanticipated events that may occur, including in connection with the implementation of the restructuring. In connection with such activities, and any other future restructuring activities, we may experience a disruption in our ability to perform functions critical to our strategy or business objectives. While we strive to reduce the negative impact of such restructuring actions, such actions could result in significant disruptions to our operations, including adversely affecting our clinical program development, technology platform development, the successful implementation and completion of our strategic objectives and the results of our operations. We expect to continue to actively manage our costs. However, if we do not fully realize or maintain the anticipated benefits of our restructuring plans and cost reduction initiatives, our business could be adversely affected. Restructuring activities may also yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our results of operations or financial condition.

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

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

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

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

- successful enrollment in clinical trials and completion of preclinical studies and clinical trials with favorable results;

•acceptance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;

•demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;

•receipt of marketing approvals from applicable regulatory authorities, including BLAs or NDAs, from the FDA, and maintaining such approvals;

•establishing clinical and commercial manufacturing capabilities, and securing adequate supply of drugs for our product candidates;

•expanding automation of our manufacturing machinery and procedures;

•establishing and maintaining multiple suppliers for our critical manufacturing materials;

•establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

•establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;

•maintaining an acceptable safety profile and shelf life of our products following approval;

•the class of drugs that are included in our product candidates continuing to represent the standard-of-care for the respective disease target and continuing to have a long-term favorable safety profile; and

•maintaining and growing an organization of people who can develop our products and technology.

The success of our business, including our ability to finance our company and generate any revenue in the future, will depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. We may not be able to successfully deliver the biologic payload to the intestinal wall with great enough certainty to achieve adequate efficacy or safety for any of our product candidates or to the satisfaction of the FDA or other regulatory bodies or potential collaborators. 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 our product candidates. 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, or a marketing authorization application, ("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.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. The results of preclinical studies and early clinical trials of our product candidates and studies and trials of other products may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, the results generated to date in preclinical studies and the Phase 1 clinical trials ofRT-102 and RT-111 do not ensure that future Phase 2 or later clinical trials of these product candidates will have similar results or be successful. In the Phase 1 clinical trials of RT-102 and RT-111, we tested the RaniPill capsule in a limited number of healthy volunteers. While we have not observed any serious adverse events as a result of these clinical trials, we have not widely tested the RaniPill capsule in humans and cannot be certain how the RaniPill capsule will perform when more widely tested in humans in any additional or later clinical trials. In addition to our ongoing and planned preclinical studies and clinical trials, we expect to have to complete at least two large scale, or adequate, well-controlled trials to demonstrate substantial evidence of efficacy and safety for each product candidate we intend to commercialize. Further, given the patient populations for which we are developing biologics, we expect to have to evaluate long-term exposure to establish the safety of our biologics in a chronic dose setting.

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

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

- obtaining regulatory approvals to commence a clinical trial;
- fraud or negligence on the part of consultants or contractors;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites deviating from the clinical trial's protocol or dropping out of a clinical trial;
- the impacts of the conflict between Russia and Ukraine on our ongoing and planned preclinical studies and clinical trials;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in our preclinical studies and clinical trials, including product candidates manufactured in accordance with our specifications.

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

Moreover, 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 the integrity of data from our clinical trials may be compromised or not accepted by the FDA or comparable foreign regulatory authorities, which would represent a significant setback for the applicable program.

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

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities disagreeing with the design or implementation of our clinical trials or the risks and benefits of the product candidate;
- obtaining regulatory authorizations to commence a trial, or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional volunteers or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of a product candidate or obtaining sufficient quantities of other therapies or active pharmaceutical ingredients for use in clinical trials;
- volunteers failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- volunteers choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- volunteers experiencing severe or unexpected drug-related or device-related adverse effects;

•occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies;

•selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;

•a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

•any changes to our manufacturing process or product formulation that may be necessary or desired;

•shortages in, or delays in obtaining, raw materials for manufacturing our product candidates or adequately scaling our manufacturing processes and procedures to deliver sufficient quantities for use in our clinical trials;

•third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical protocol or relevant regulatory requirements;

•third-party contractors not performing data collection or analysis in a timely or accurate manner; or

•third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or comparable foreign regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Regulatory authorities may require that filings related to the commencement, continuation or termination of a clinical trial be submitted through specific electronic systems or in a specific manner (e.g. format), which may differ from one jurisdiction to another. We may seek to conduct a clinical trial in multiple jurisdictions in an effort to enroll sufficient numbers of patients or to do so in a timely manner or for other reasons. Meeting the requirements of various regulatory agencies could be costly and any delay in meeting, or inability to meet, the regulatory requirements of different jurisdictions regarding submissions could delay or negatively impact our ability to initiate or complete our clinical trials as planned. Any failure or inability by us to submit required regulatory documents for our planned or future clinical trials or any failure or inability to do so in the required manner could delay or prevent us from initiating or completing our planned or future clinical trials when we are otherwise ready or at all.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

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

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

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

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

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 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 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-102, 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. Also, any undesirable side effects caused by or safety concerns related to our delivery device apart from a drug or biologic could delay, limit or prevent us from developing and commercializing any product candidates.

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

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

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

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

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

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

In addition, we are still 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 trials, 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 our clinical trials, we have not widely tested the RaniPill capsule in humans and cannot be certain how the RaniPill capsule will perform when more widely tested in humans in any later clinical trials.

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/or any 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 have conducted our Phase 1 clinical trials in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice regulations; 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 the Centers for Medicare and Medicaid Services, 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. Certain 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, Janssen Biotech, Inc. 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., Protagonist Therapeutics, Inc., Chiesi Farmaceutici SpA, i2O Therapeutics, Biora Therapeutics, Inc., Intract Pharma, and Novo Nordisk A/S. 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-102, an oral administration of PTH for the treatment of osteoporosis, for which we estimate the patient population is approximately ten million in the United States as of 2018, and RT-111 for the treatment of inflammatory conditions, for which we estimate the patient population to be seven million for psoriasis and three million for Crohn's disease or ulcerative colitis in the United States as of 2021. These estimates, and estimates for our other product candidates, 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 European Economic Area ("EEA"). As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Foreign regulatory authorities in countries outside of the United States and the EEA also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by comparable foreign regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

Risks Related to Our Reliance on Third Parties

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

In the past, we have entered into evaluation agreements with Takeda and certain other pharmaceutical companies concerning the formulation and manufacture of oral versions of Factor VIII and other molecules. In January 2023, we entered into a License and Supply Agreement with Celltrion, under which we receive supply of ustekinumab biosimilar from Celltrion for RT-111 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-111 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). In May 2023, we entered into another License and Supply Agreement with Celltrion, under which we receive supply of adalimumab biosimilar from Celltrion for RT-105 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-105 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). We believe the Phase 1 clinical trial that we completed with RT-111, the topline data of which we announced in February 2024, satisfies the requirements for triggering Celltrion's right of first negotiation with respect to that program. If the parties enter into an agreement granting Celltrion development and commercialization rights for RT-111 or RT-105, we may be reliant on Celltrion to develop and commercialize the applicable product(s) in certain countries or worldwide.

Future evaluation agreements, supply agreements or 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 their primary mode of action as a biologic. Third-party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to biologic-device combination products, including applicable provisions of the FDA's drug and biologics cGMP regulations, device cGMP requirements embodied in the medical device Quality System Regulations ("QSRs"), or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit any BLA or NDA 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 and manufacture of a product candidate under a collaboration, and the payments we receive from our partner may be insufficient to cover the cost of this work 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 APIs and drug substances. We do not have long-term supply arrangements in place for APIs and drug substances. The loss of third-party suppliers or their inability to supply us with adequate materials and APIs or drug substances could prevent or delay the conduct of our clinical trials and the commercialization of our products, if approved, and could harm our business.

We rely on third-party suppliers for the supply of the raw materials and APIs or drug substances 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 and for use in our clinical trials.

Our dependence on these third parties and the challenges we may face in obtaining adequate supplies of raw materials, APIs and drug substances 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 drug substances 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 prevent us from conducting, or cause delays to, our current or planned clinical trials, commercialization of our products, if approved, and 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. In addition, we may seek to enter into collaborations, joint ventures, licenses and other similar arrangements with third party biopharmaceutical companies for use of the RaniPill technology in developing and commercializing their own molecules. We may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, our product candidates or technology 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 or technology 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.

In January 2023, we entered into a License and Supply Agreement with Celltrion, under which Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-111 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). In June 2023, we entered into another License and Supply Agreement with Celltrion, under which we receive supply of adalimumab biosimilar from Celltrion for RT-105 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-105 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). We believe the Phase 1 clinical trial that we completed with RT-111, the topline data of which we announced in February 2024, satisfies the requirements for triggering Celltrion's right of first negotiation. However, even if we complete the requisite clinical trial for RT-111 or RT-105, Celltrion has no obligation to exercise its right of first negotiation, and if it does exercise such right we may not be able to agree on terms favorable to us or acceptable to us or Celltrion. Accordingly, there can be no assurance that the parties will enter into an agreement granting Celltrion development and commercialization rights for the applicable product following completion of a Phase 1 trial that meets its primary endpoint(s) or any exercise of the right of first negotiation. In November 2023, we announced that we have paused the RT-105 program until we have appropriate resources to continue the development. While the License and Supply Agreement with Celltrion regarding adalimumab biosimilar for RT-105 remains in place, if we do not initiate a Phase 1 trial with RT-105 within a certain time period specified in the agreement or fail to deliver Phase 1 data to Celltrion within a later timepoint specified in the agreement, Celltrion will have a right to terminate that License and Supply Agreement. In addition, as a result of a pausing of the RT-105 program, Celltrion's interest in exercising its right of first negotiation with respect to that program or negotiating a collaboration for that program could diminish.

Even if we are successful in our efforts to establish a collaboration with Celltrion or collaborations with other third parties, 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, if approved, commercialization of our product candidates, 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 a limited number of product candidates in early clinical development. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the development of the RaniPill platform that is designed to enable the oral administration of a broad range of biologics and drugs used to treat multiple diseases and disorders. The RaniPill capsule may not receive regulatory approval in connection with any biologic or drug or, if approved, it may not be successfully commercialized. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of our product candidates for the indications we are seeking will remain subject to extensive regulation by the FDA and comparable foreign regulatory authorities in the United States and other countries, each of which has differing regulations. In addition, even if approved, pricing and reimbursement will be subject to further review and discussions with payors. We are not permitted to market any product candidate in the United States until after approval of a BLA or NDA from the FDA, or a similar marketing authorization from comparable authorities in any foreign countries until after approval of a marketing application by corresponding foreign regulatory authorities. We have conducted early clinical development of some of our product candidates. We will need to conduct larger, more extensive clinical trials in the target patient populations for these product candidates and their indications to support a potential application for regulatory approval by the FDA or corresponding foreign regulatory authorities.

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

- we may not be able to demonstrate that any of our product candidates is safe and effective to the satisfaction of the FDA or comparable foreign regulatory authorities;
- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials prior to granting approval, which would increase our costs and extend the pre-approval development process;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or statistical analysis of one or more of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with, or not accept, our interpretation of data from our preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in our manufacturing processes or facilities which would be required to be corrected prior to regulatory approval;
- the success or further approval of competitor products approved in indications in which we undertake development of our product candidates may change the standard of care or change the standard for approval of our product candidate in our proposed indications; and
- the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations.

Our product candidates will require additional research, clinical development, manufacturing activities, regulatory approval in multiple jurisdictions (if regulatory approval can be obtained at all), securing sources of commercial manufacturing supply and building of or partnering with a commercial organization. Our planned clinical trials for our product candidates 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 and partnered programs.

A key element of our strategy is to leverage the RaniPill platform to expand our pipeline of product candidates and to enter into collaborations, licenses or similar arrangements with third party biopharmaceutical companies to use the RaniPill technology in developing and commercializing the third party's molecules. 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 (alone or with partners), we may not prove to be successful at doing so. Potential partners may not see the opportunities created by the RaniPill platform the same way we do, or at all, and even if they do we may not be able to negotiate and enter into licensing or other transactions with potential partners on favorable terms, or at all. Even if we are successful in continuing to build our pipeline or establishing licensing arrangements with third parties regarding use of our platform for their molecules, the potential product candidates that we or they 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 or potential partners cannot successfully develop or commercialize products using the RaniPill technology, 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 ethics committees 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.

Most of our product candidates 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, certain of the product candidates contemplated by our current product pipeline may require use of the RaniPill HC, which is in preclinical testing and has not been tested clinically. There is no guarantee that we will be able to complete development of the RaniPill HC or that it will be compatible for use with product candidates or that it will achieve test results sufficient to advance it or our product candidates to later stages of development and/or commercialization,, any of which could adversely affect the commercial potential of the RaniPill platform. Additionally, to the extent we are able to develop RaniPill HC or another device 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 a failure in any one of these factors, our business, financial condition and results of operations could be adversely affected.

Our high-capacity oral delivery device, RaniPill HC, is in early stages of development, and it is subject to the inherent risks and uncertainties of developing a novel, innovative technology. Our efforts to develop RaniPill HC may not be successful.

RaniPill HC is in early stages of development, and it is subject to the inherent risks and uncertainties of developing a novel, innovative potential technology. Development of a new delivery device is time-consuming and costly, and could distract the attention of our management or other employee resources from our existing and future business. Our efforts to develop RaniPill HC may not be successful or RaniPill HC may require modifications that could limit its utility or viability as an oral delivery device. We may not be able to complete development of RaniPill HC in a timely manner, or at all, or such development may require an amount of time and resource that we are not able to devote to it or believe is not warranted based on the estimated benefits. The potential value of RaniPill HC may never be realized for a variety of reasons, including that we are not able to successfully develop RaniPill HC, third parties develop competitive technologies or products similar to or more effective or attractive than RaniPill HC, we are not able to develop manufacturing processes to produce RaniPill HC consistently and reliably or within a cost range that makes RaniPill HC products commercially viable. Any such factor could reduce or eliminate the potential value of RaniPill HC or product candidates that could be developed using RaniPill HC. In addition, while we currently expect that RaniPill HC will be able to leverage many of the same components and manufacturing processes as are used for our existing delivery device, it may turn out that such components or manufacturing processes are not suited for RaniPill HC or RaniPill HC may require modifications that negatively affect our ability to use common components or processes between the RaniPill GO and RaniPill HC. Any of the foregoing factors or circumstances may adversely affect our business prospects, our attractiveness as a business partner or collaborator, our ability to raise additional capital, and our financial results.

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 of 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. Although we maintain clinical trial liability 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 ingredients or drug substances 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. We or third-party 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 or drug substance, 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 and drug substance suppliers will likely use a different method to manufacture API or drug substance, 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.

As a vertically-integrated manufacturer of a novel oral delivery technology, we may require significant time to develop manufacturing operations and processes capable of producing safe and reliable product at sufficient scale to meet business needs, if we are able to do so at all.

Since our RaniPill capsule employs novel technologies, we manufacture many of the components and have customized equipment needed for manufacturing the RaniPill capsule and we are required to develop novel manufacturing processes. This requires the development of new methods and know-how, as well as specifications and testing appropriate for manufacture of the RaniPill capsule. It may take significant time to develop manufacturing operations and processes capable of producing safe and reliable product at sufficient scale to meet business needs, if we are able to do so at all. We may find that certain materials used for the RaniPill capsule are not suitable for use with some or any product candidates, that certain processes as designed do not perform as intended and must be re-designed, or that certain operations as currently performed cannot be scaled up or automated as planned or at all. Even if we are able to develop manufacturing operations and processes that perform as we intend, the FDA, EMA or other regulatory authorities or potential collaboration partners may not deem such operations or processes to be acceptable, in which event we may need to change such operations, processes, specifications or testing or develop new operations, processes, specifications or testing, which may result in delays in or adversely affect the development or potential approval of product candidates or the negotiation or completion of third party collaboration arrangements, or require us to divert resources and attention from our product candidates or other business opportunities. Any such event could have a material adverse impact on 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. Violations of such laws and regulations could subject us to significant penalties.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws data 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;

- 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), other healthcare professionals (such as physician assistants and nurse practitioners), 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

•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 data 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. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented 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 expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031 unless additional action is taken by Congress. Further, Congress is considering additional health reform measures.

In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on

February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

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

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

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 existing senior management team. 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 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.

Although in November 2023 we underwent a reduction in our workforce and paused or discontinued certain programs, we are continuing development of other programs and expanding our manufacturing footprint to support scale-up and automation. At such time 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, our stock price may decrease, 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, California, 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.

A public health crisis could adversely impact our business including our ongoing and planned preclinical studies and clinical trials.

A public health crisis may cause delays in our preclinical and planned clinical development activities and may impact our third-party manufacturers and suppliers, which could disrupt its supply chain or the availability or cost of materials. If governmental authorities reinstate or issue new public health directives as a result of a public health crisis, these may negatively impact productivity, disrupt our 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 our ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact business, results of operations and financial condition, including our ability to obtain financing. Such disruptions could severely impact our business, current and planned clinical trials and preclinical studies, including as a result of:

- 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 future planned clinical trials of our product candidates;

•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 a public health crisis or other such disruptions 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 a public health crisis, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect trial participants, 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 crisis are collected pursuant to the trial protocol and consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. In addition, 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 during any such crisis.

Additionally, governmental and medical resources and attention may be focused on the applicable crisis, which may make it more difficult to obtain required reviews or approvals, necessary materials, or clinical or preclinical sites or slots, or manufacturing slots for the products needed for our planned clinical trials, which could lead to delays in these trials.

A continued and prolonged public health crisis could have a material negative impact on our business, financial condition, and operating results. It could also have the effect of heightening many of the other risks described in this “Risk Factors” section.

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, and data we collect about trial participants in connection with clinical trials (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to privacy, security, and transmission of individually identifiable health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments.

These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties on which we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU GDPR, the UK GDPR and China's Personal Information Protection Law ("PIPL"), impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We conduct clinical trials in Australia, may conduct clinical studies in the EU and other countries and may be subject to EU GDPR, UK GDPR or other data privacy regulations, and we work with companies and vendors in Asia and may be subject to new and emerging data privacy regimes in Asia, including China's PIPL, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activitist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish a privacy policy on our website. If this policy or other privacy or security-related statements or materials we may publish is found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on which we rely may fail to comply with such obligations, which could negatively impact our business operations.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data; and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If our information technology systems or those of third parties on which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely process sensitive data, and as a result, we face a variety of evolving threats that could cause security incidents.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, develop, test and distribute our capsules, product candidates, and other goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We regularly have employees that work remotely. Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party collaborators, consultants, contractors, suppliers, and service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, contract research organizations, employee email, and other functions. We also rely on third parties to provide other products, services, parts, or otherwise to operate our business.

Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third parties experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties on which we rely fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties on which we rely. A security incident or other interruption could disrupt our ability (and that of third parties on which we rely) to provide our products. 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.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party on which we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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 U.S. Patent and Trademark Office (“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 United States 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 InCube Labs, LLC (“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 with ICL effective January 1, 2021, as amended in March 2022 and March 2024 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests, and Rani LLC occupies certain facilities leased by ICL. Pursuant to the Rani LLC-ICL 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 (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 European patents are presently being challenged in Europe, and if one or more of such challenges is successful it could encourage such party or other parties to challenge additional patents of ours in Europe or other jurisdictions.

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

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

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

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

The fourth opposition proceeding involves European Patent No. 3653223, which is generally directed to a swallowable device. In October 2023, the EPO Opposition Division issued a decision resulting in an amendment to the claims of the patent. Both parties subsequently filed a notice of appeal with the EPO Appeal Board and we are awaiting a final decision.

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

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

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 us regarding inventions related to our business, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. If we fail in defending any such challenges, we may lose valuable intellectual property rights, including the loss of exclusive ownership of, or right to use, such intellectual property.

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

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

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

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

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

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

Risks Related to Our Organizational Structure

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

We are a holding company and have no material assets other than our ownership of LLC Interests of Rani LLC. As such, we have no independent means of generating net sales or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, is dependent upon the financial results and cash flows of Rani LLC and distributions we receive from Rani LLC. Rani LLC 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. In August 2021, in connection with the IPO and Organizational Transactions, we entered into a Tax Receivable Agreement with certain of the Continuing LLC Owners. See the risk factor below entitled "The Tax Receivable Agreement with certain of the Continuing LLC Owners requires us to make cash payments to them in respect of certain benefits to which we may become entitled. In certain circumstances, payments under the Tax Receivable Agreement may be accelerated and/or significantly exceed the actual tax benefits we realize."

We 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. 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. 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. 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.

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 holders of units of Rani LLC 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 units of Rani LLC.

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 operating 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.

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

We are a party to the Tax Receivable Agreement with certain of the Continuing LLC Owners. Under the Tax Receivable Agreement, we will be required to make cash payments to certain of the Continuing LLC Owners equal to 85% of the tax benefits, if any, that we are deemed to realize (calculated using certain assumptions) as a result of (i) increases in the tax basis of assets of Rani LLC resulting from (a) any future redemptions or exchanges of LLC Interests and (b) payments under the Tax Receivable Agreement and (ii) certain other tax benefits arising from payments under the Tax Receivable Agreement. While the actual amount and timing of any payments under the Tax Receivable Agreement, will vary depending upon a number of factors, including the timing of exchanges, the price of shares of our Class A common stock at the time of the redemption or exchange, the extent to which such redemptions or exchanges are taxable, future tax rates, and the amount and timing of our taxable income (prior to taking into account the tax depreciation or amortization deductions arising from the basis adjustments), we expect that, as a result of the size of the increases in the tax basis of the tangible and intangible assets of Rani 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 ("IRS"), or another tax authority may challenge all or part of the tax basis increases, as well as other related tax positions we take, and a court could sustain such challenge. The Continuing LLC Owners who are parties to the Tax Receivable Agreement will not reimburse us for any payments previously made under the Tax Receivable Agreement if such basis increases or other benefits are subsequently disallowed, except that any excess payments made by us to the Continuing LLC Owners under the Tax Receivable Agreement will be netted against future payments that we might otherwise be required to make to the Continuing LLC Owners under the Tax Receivable Agreement. However, a challenge to any tax benefits initially claimed by us may not arise for a number of years following the initial time of such payment or, even if challenged early, such excess cash payment may be greater than the amount of future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement and, as a result, there might not be sufficient future cash payments against which the prior payments can be fully netted. The applicable U.S. federal income tax rules are complex and factual in nature, and there can be no assurance that the IRS or a court will not disagree with our tax reporting positions. Therefore, payments could be made under the Tax Receivable Agreement in excess of the tax savings that we realize in respect of the tax attributes with respect to the Continuing LLC Owners that are the subject of the Tax Receivable Agreement.

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

If we were deemed to be an investment company under the 1940 Act as a result of our ownership of Rani 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 United States 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 supports certain of our general and administrative corporate functions and we occupy space within facilities owned or leased by ICL pursuant to service agreements. If we were required to replicate or replace these services sooner than planned or if one or both of the service agreements is terminated, our operations could be adversely affected.

Pursuant to the Rani LLC-ICL Service Agreement, ICL provides us certain general and administrative corporate support services. In addition, pursuant to the Rani LLC-ICL Service Agreement and a separate service agreement dated January 1, 2021 originally between RMS and ICL but which was assigned by RMS to Rani LLC in April 2022 and amended in March 2024 (the "RMS-ICL Service Agreement"), we sublease from ICL the office, laboratory and manufacturing space used for our operations ("Occupancy Services"). In March 2024, we entered into an amendment to the RMS-ICL Service Agreement to increase the Occupancy Services from 23,000 square feet to 24,000 square feet. In March 2024, we also entered into an amendment to the Rani LLC-ICL Service Agreement to extend the term of the Occupancy Services in Milpitas, California from February 2024 to August 2024 and to increase the payment for such Occupancy Services during the extension period.

Pursuant to the Rani LLC-ICL Service Agreement, we will wholly own intellectual property resulting from ICL's development work that relates only to the oral delivery of sensors, small molecule drugs or biologic drugs 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 field of oral delivery of sensors, small molecule drugs and biologic drugs, but we may not obtain a license on favorable terms.

The Rani LLC-ICL Service Agreement will automatically renew for successive one-year terms unless sooner terminated by either party. Termination of individual services under the Rani LLC-ICL Service Agreement or RMS-ICL Service Agreement requires 60 days' notice, and termination of Occupancy Services under the Rani LLC-ICL Service Agreement or RMS-ICL Service Agreement requires six months' notice; except that the Occupancy Services in Milpitas, California will expire in August 2024, following the amendment entered into in March 2024. In the event the Rani LLC-ICL Service Agreement or RMS-ICL Service Agreement is terminated by us or ICL, we will need to replicate or replace certain functions, systems, equipment or facilities to which we will no longer have the same access. Such changes may be costly to implement and disruptive to our business. In February 2024, we began to occupy a facility in Fremont, California. We intend to transition certain of our operations to that facility so that we will no longer need the Occupancy Services in Milpitas, California.

In addition, we may not be able to replace these services, systems, equipment or facilities or enter into appropriate third-party agreements therefor on terms and conditions, including cost, comparable to those that we receive from ICL under the Rani LLC-ICL Service Agreement or RMS-ICL Service Agreement, or in a time period that minimizes disruption to our operations. The loss of services or the use of systems, equipment or facilities under the Rani LLC-ICL Service Agreement or RMS-ICL Service Agreement or our inability to replace such services, systems, equipment or facilities in a timely or cost-effective manner could have an adverse effect on our operations and financial results.

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

As of March 10, 2024, certain of the Continuing LLC Owners controlled more than 80% 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 we should terminate the Tax Receivable Agreement and accelerate its obligations thereunder. In addition, the determination of future tax reporting positions and the structuring of future transactions may take into consideration these Continuing LLC Owners' tax or other considerations, which may differ from the considerations of us or our other stockholders.

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

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

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

Our Class B common stock has ten votes per share, our Class A common stock has one vote per share and Class C common stock has no voting rights, except as required by law. As of March 10, 2024, holders of our outstanding Class B common stock collectively held more than 80% of the voting power of our outstanding capital stock. Because of the 10-to-1 voting ratio between our Class B common stock and Class A common stock, the holders of our Class B common stock collectively control a majority of the combined voting power of our capital stock and therefore are able to control all matters submitted to our stockholders for approval so long as the shares of our Class B common stock represent more than 9% of all outstanding shares of our Class A common stock and Class B common stock. These holders of our Class B common stock may also have interests that differ from other stockholders and may vote in a way which may be adverse to other stockholder interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of our company and might ultimately affect the market price of our Class A common stock.

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

Risks Related to Our Class A Common Stock

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

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

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

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

- our ability to obtain and maintain regulatory approvals for our current or any of our future product candidates;
- changes in laws or regulations applicable to our current or any of our future product candidates;
- adverse developments concerning any of our third-party collaborators and suppliers;
- our inability to obtain adequate product supply for our current or any of our future product candidates or our inability to do so at acceptable prices; our ability to scale, optimize and expand automation of our manufacturing processes for our product candidates for the conduct of preclinical studies and clinical trials and, if approved, for successful commercialization;
- the degree and rate of physician and market adoption of our current or any of our future product candidates;
- announcements by us or our competitors of significant business developments, new 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;

•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 war, terrorism and other international conflicts, such as the conflict between Ukraine and Russia, and public health issues including health epidemics or pandemics; and

•other events or factors, many of which are beyond our control.

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

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

As of March 10, 2024, our Chairman, Mir Imran beneficially owned more than 80% of the combined voting power of our Class A and Class B common stock. As a result, we will continue to be a "controlled company" within the meaning of the Nasdaq corporate governance standards. Under these corporate governance standards, a company of which more than 50% of the voting power in the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements. For example, controlled companies are not required to have:

•a board that is composed of a majority of "independent directors," as defined under the Nasdaq rules;

•a compensation committee that is composed entirely of independent directors; and

•director nominations be made, or recommended to the full board of directors, by its independent directors, or by a nominations/governance committee that is composed entirely of independent directors.

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

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

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

- increased operating expenses and cash requirements;
- volatility with respect to the financial reporting related to such arrangements;
- assumption of indebtedness or contingent liabilities;
- issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- diversion of our management’s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology, and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

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

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

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

We have registered all of the shares of Class A common stock currently issuable upon exercise of outstanding stock options, and upon exercise or settlement of any options or other equity incentives and we intend to register all shares or such Class A common stock that 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.

Continuing LLC Owners are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. As a result of certain stockholders requesting such registration, in December 2022 we filed a registration statement on Form S-3 to register 6,009,542 shares of our Class A common stock held by certain of our stockholders. Accordingly, these shares are freely tradeable without restriction under the Securities Act.

Any sales of securities by the foregoing or other stockholders could have a material adverse effect on the trading price of our Class A common stock.

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

As of March 10, 2024, our named executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially held outstanding stock representing over 80% of our voting power. Therefore, these stockholders have substantial influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could, among other things, delay or prevent an acquisition of our company on terms that other stockholders may desire, which in turn could depress our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

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

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

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

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

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

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

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

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

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

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

- a requirement that special meetings of stockholders be called only by holders of at least 25% of the voting power of our Class A common stock and Class B common stock, voting together as a single class, the chairperson of the board of directors, the chief executive officer, or by a majority of the board of directors;

- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation, with protective provisions in our certificate of incorporation requiring approval of a majority of the voting power of the Class B common stock then outstanding;

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of Class A common stock; and

- the authorization of three classes of common stock as described above.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States 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: (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 Delaware General Corporation Law, 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 Delaware General Corporation Law 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 and our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

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

General Risk Factors

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting on an annual basis. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, we will be required to obtain attestation as to the effectiveness of our internal control over financial reporting by an independent registered public accounting firm in our first annual report required to be filed with the SEC following the date we become an accelerated filer.

If we are unable to conclude that our internal control over financial reporting is effective, or if we or 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.

Business disruptions could seriously harm our business, financial condition, and results of operations.

Our operations, and those of our CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics, geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), terrorism, insurrection or war, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our business and the business of our suppliers of APIs or drug substances and the raw materials or components for our RaniPill capsule could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis. A significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect our planned operations. Such events could result in the complete or partial closure of one or more manufacturing facilities which could impact our supply of APIs, drug substances, and critical materials for manufacturing our RaniPill capsules. In addition, an outbreak or other business disruption near where our clinical trials occur could impact our ability to recruit subjects, delay our clinical trial, and could affect our ability to complete our clinical trials within the planned time periods. In addition, business disruptions of the kind noted above, including geopolitical events like the ongoing conflict between Ukraine and Russia or disruptions to bank deposits and lending commitments due to bank failures, could impact economies and financial markets, resulting in economic worsening and/or inflation that could impact our ability to raise capital, increase the costs of goods and services, cause us to have to de-prioritize or stop certain business activities, diminish potential partnering opportunities, and have an adverse effect on our results of operations.

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 stock-based compensation;
- changes in tax laws, regulations or interpretations thereof; or
- future earnings being lower than anticipated in countries where we have lower statutory tax rates and higher than anticipated earnings in countries where we have higher statutory tax rates.

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

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

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

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. 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 United States Export Administration Regulations, United States Customs regulations, and various economic and trade sanctions regulations administered by the United States Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the Foreign Corrupt Practices Act ("FCPA"), the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States 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. 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 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.

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial and other trial participant data ("Information Systems and Data").

The head of our information security team (Svai Sanford, Chief Financial Officer ("CFO")), our information security team and our legal team help identify, assess and manage our cybersecurity threats and risks. This group works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example deploying certain automated tools, subscribing to reports and services that identify certain cybersecurity threats, conducting scans of certain threat environments, evaluating certain threats reported to us, using external intelligence feeds, and conducting vulnerability assessments in certain environments and systems to identify vulnerabilities.

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, and processes designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response processes, disaster recovery and business continuity plans, encryption of certain data, network security controls and access controls in certain environments and systems, monitoring certain systems, physical security of certain assets, asset management, employee training, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the information security team works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example threat intelligence service providers and dark web monitoring services.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, and clinical data management and processing service providers. We have a vendor management program to manage cybersecurity risks associated with our use of certain of these providers. The program includes a review of certain information security measures of certain vendors. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including “If our internal technology systems or sensitive information, or those used by our third-party collaborators, vendors, contractors or consultants, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.”

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors’ is responsible for overseeing our cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain of our management, including our CFO, who oversees our information security team and has over 2 years of experience overseeing such function.

Our CFO is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our CFO is also responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances. The incident management team helps us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes include reporting to the board of directors for certain cybersecurity incidents. The board receives periodic reports from management concerning the Company’s significant cybersecurity threats and risk and the processes the Company has implemented to address them. The board also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

Our corporate headquarters are currently located in San Jose, California. We lease approximately 88,000 square feet of office, research and development, production and manufacturing, and laboratory space for our business. In February 2024, we began occupying approximately 33,000 square feet in Fremont, California under a lease with a third party. The term of the lease is 63 months. Subject to certain conditions, we have an option to renew the lease for one additional 5-year term at the then-prevailing market rate. We also lease approximately 55,0000 square feet in San Jose and Milpitas, California and San Antonio, Texas, pursuant to service agreements with ICL, a related party. The lease for the San Jose facility has a twelve month term that renews automatically on January 1st of each year for a successive twelve month period, subject to termination by either party upon a six months’ notice. In March 2024, we amended our lease for the San Jose facility to increase our use from 23,000 square feet to 24,000 square feet. In March 2024, we also extended the term of our lease for the Milpitas facility from February 2024 to August 2024. We intend to transition certain of our operations to the Fremont facility so that we will no longer need the space in Milpitas, California. Our San Antonio lease will continue until terminated by either party upon six months’ notice. We provided to ICL notice of termination of the San Antonio lease in December 2023. The lease will terminate in June 2024. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

Our Class A common stock is traded on the Nasdaq Stock Market LLC under the symbol “RANI.”

Dividend Policy

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any future determination to declare or pay dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions, capital requirements general business conditions and other factors that our board of directors may deem relevant. Our future ability to pay cash dividends on our capital stock is limited by the terms of the Loan Agreement and may also be limited by the terms of any future debt or preferred securities.

Stockholders

As of March 14, 2024, we had 140 holders of record of our Class A common stock and 18 holders of record of our Class B common stock. The actual number of stockholders of Class A common stock is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities. Shares of our Class B common stock are paired with LLC Units of Rani LLC and are held by Continuing LLC Owners. Shares of Class B common stock are not transferable independent of the LLC Units. Upon exchange of the LLC Units for Class A common stock, the corresponding shares of Class B common stock paired with such LLC Units are cancelled.

Recent Sales of Unregistered Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following management's discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with, and is qualified in its entirety by reference to, our consolidated financial statements and the related notes and other information included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks and uncertainties which could cause our actual results to differ materially from those anticipated in these forward-looking statements, including, but not limited to, risks and uncertainties discussed under "Special Note Regarding Forward-Looking Statements," "Risk Factors" and in Part I and elsewhere in this Annual Report on Form 10-K.

Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," and "Rani" and similar references refer to Rani Therapeutics Holdings, Inc. and its consolidated subsidiaries.

Overview

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

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

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

As of December 31, 2023, our cash, cash equivalents and marketable securities totaled $48.5 million. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our existing capital resources, including the net proceeds from our initial public offering in 2021 ("IPO") and term loans we received under a loan and security agreement and related supplement (the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P (the "Lender"), will not be sufficient to enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates.

If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our audited financial statements, and investors may lose all or a part of their investment.

In November 2023, we underwent a reduction in our workforce and paused or discontinued certain programs to reduce our expenses and focus our financial resources on key priorities. If we are unable to obtain funding on a timely basis, or to generate sufficient revenues, if at all, from collaboration arrangements or product sales, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, the development of our oral delivery technology, including the RaniPill HC, the commercialization of any product candidates or cease operations altogether, 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 forego expansion of our operations or refrain from pursuing business opportunities; any of which could have a material adverse effect on our business, financial condition and results of operations.

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

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

Clinical Update

Business Update

In November 2023, we announced a strategic program prioritization, expansion of manufacturing and plans to streamline business operations to support near-term value drivers and long-term growth of the RaniPill technology platform. The plans include strategic prioritization of its key development programs, RT-102, RT-111 and the RaniPill HC and expansion of its manufacturing footprint to support increased scale and partnerships, and cost reduction initiatives that align with our near-term goals, including a reduction in our workforce by approximately 25%. As part of the strategic focusing of the business, we have paused work on our RT-105 and RT-110 programs and we terminated our RT-101 program, which was the RaniPill capsule containing octreotide. Cost savings are expected to support our operating plans into 2025.

Program Updates

RT-111

In February 2024, we announced positive topline results from a Phase 1 study of RT-111, which is being developed for the potential treatment of inflammatory conditions. The study met all of its endpoints and RT-111 was generally well tolerated with no serious adverse events noted. In the study, RT-111 orally delivered 0.5 mg and 0.75 mg of our proprietary formulation of ustekinumab biosimilar with high bioavailability. There was no meaningful difference in incidence of anti-drug antibodies in the groups receiving RT-111 compared to the group that received STELARA® (ustekinumab) via subcutaneous injection.

In January 2023, we announced entering into a License and Supply Agreement with Celltrion under which we receive a license and supply of Celltrion’s ustekinumab biosimilar for development and commercialization of RT-111 worldwide, subject to a right of first negotiation for Celltrion following completion of a Phase 1 clinical trial that meets its primary endpoint(s). We believe the Phase 1 clinical trial that we completed with RT-111, the topline data of which we announced in February 2024, satisfies the requirements for triggering Celltrion’s right of first negotiation.

RaniPill HC

We continue to develop the RaniPill HC, a high-capacity RaniPill capsule designed to deliver drug payloads up to 200µL, 500%-plus higher than the payload capacity of the RaniPill GO. In September 2023, we announced three positive preclinical studies which support the development of the RaniPill HC device.

In October and November 2023, we announced the completion of two preclinical studies of the RaniPill HC with antibodies, adalimumab and an undisclosed anti-interleukin antibody (“Undisclosed MAB”). In the two studies, the RaniPill HC achieved an oral delivery success rate of 100% (10/10). In one study, we tracked the serum concentrations of adalimumab, following the oral administration of the enteric-coated RaniPill HC capsule containing 11mg of Humira (adalimumab) to four canine models. In the second study, we tracked the serum concentrations of the Undisclosed MAB, following the oral administration of the enteric-coated RaniPill HC capsule containing 16.5mg of Undisclosed MAB to six canine models. In both studies, the RaniPill HC was well tolerated, all animals remained healthy throughout the study period with no clinical findings or adverse events, and all device remnants were excreted normally without sequelae.

Preliminary preclinical testing supports the potential for RaniPill HC to have high reliability, and initial analysis of drug delivery via the RaniPill HC shows a potential for mimicking parenteral (subcutaneous) administration. We intend for the RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024.

RT-102

In January 2023, we announced that we completed a pre-IND meeting with the FDA with respect to RT-102. Following feedback from the meeting, we believe that a 505(b)(2) pathway is suitable for the development of RT-102 in the U.S. In addition, we obtained guidance from the FDA on its preclinical and clinical development plans for RT-102. We intend to initiate a Phase 2 clinical trial of RT-102 in 2024.

RT-105

In June 2023, we entered into a License and Supply Agreement with Celltrion under which we receive an exclusive license and supply of Celltrion’s adalimumab biosimilar for development and commercialization of RT-105 worldwide, subject to a right of first negotiation for Celltrion following completion of a Phase 1 clinical trial that meets its primary endpoint(s). RT-105 is the RaniPill capsule containing an adalimumab biosimilar, which is intended for the treatment of inflammatory conditions. In November 2023, we announced the pausing of development of RT-105 as part of a strategic focusing of the business.

60-Day GLP Study

In October 2023, we announced preclinical data from a 60-day repeat oral administration study of the RaniPill capsule in healthy animals. The preclinical GLP study evaluated the safety and tolerability of the RaniPill drug delivery platform, following 60-day repeat oral administration of the test article, RT-100, in healthy animals. RT-100 is an enteric-coated capsule identical to RT-102, but instead of PTH contained the pharmaceutical excipient mannitol. The control group received a RaniPill capsule (Mock-RP) of similar weight to RT-100 but filled with potato starch. Male and female (1:1) animals were divided into two groups and were administered either Mock-RP (N=12) or RT-100 (N=24) once daily for 60 days, with half of the animals completing an additional 14-day clinical observation and safety evaluation period. RT-100 was well-tolerated with no treatment-related adverse events and all animals remained clinically healthy throughout the study.

Financial Update

In August 2022, we entered into the Loan Agreement with the Lender for term loans (the “Loans”) in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. The Loan Agreement also contains various covenants and restrictive provisions. As of December 31, 2023, we were in compliance with all applicable debt covenants under the Loan Agreement and had cash, cash equivalents, and marketable securities totaling $48.5 million.

In addition, in August 2022, we entered into a Controlled Equity^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively, the “Agents”), pursuant to which we may offer and sell from time to time through the Agents up to $150.0 million of shares of our Class A common stock, in such share amounts as we may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement (“ATM Sales”). As of December 31, 2023, we had not delivered any placement notices to either of the Agents and there had been no ATM Sales.

Reduction in Force

In November 2023, we committed to a plan for strategic prioritization of our programs, expansion of our manufacturing and streamlining of our business operations to support potential near-term value drivers and long-term growth (the “Restructuring”). The Restructuring includes a reduction of our workforce by approximately 25%.

As a result of the Restructuring, we estimate that we will incur approximately $0.3 million in costs of which nearly all are cash expenditures related to severance and half of which was incurred in the fourth quarter of 2023. We expect the Restructuring to be substantially completed by the end of the second quarter of 2024. The estimates of costs that we expect to incur in connection with the Restructuring and the timing thereof are subject to a number of assumptions and actual results may differ materially from estimates. We may also incur other charges or cash expenditures not currently contemplated in connection with the Restructuring due to unanticipated events that may occur, including in connection with the implementation of the Restructuring.

CEO Compensation Reduction

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

Lease

In November 2023, Rani LLC and BKM South Bay 240, LLC (“Landlord”) entered into the Standard Industrial/Commercial Multi-Tenant Lease - Net (the “Lease”). Pursuant to the terms of the Lease, we are leasing 33,340 square feet of space in Fremont, California, which is part of a two-building project (the “Project”).

The initial term of the Lease commenced in February 2024, and the duration of the initial term is 63 months. Subject to certain conditions, we have an option to renew the Lease for one additional 5-year term at the then-prevailing market rate. The monthly base rent for the initial term of the Lease is approximately $95,000 per month, subject to a 4% increase each year. We are also responsible for the payment of additional rent to cover our share of common area operating expenses, including taxes, insurance, utilities, and repair and maintenance of the premises and common areas of the Project.

Organizational Transactions

The Company was incorporated in April 2021 and formed for the purpose of facilitating an IPO of its Class A common stock, and to facilitate certain organizational transactions (“Organizational Transactions”) and to operate the business of Rani LLC and its consolidated subsidiary at such time, Rani Management Services, Inc. (“RMS”). In connection with the IPO, we established a holding company structure with the Company as the holding company and its principal asset being the Class A common units (“Class A Units”) of Rani LLC that it owns. As the sole managing member of Rani LLC, the Company operates and controls all of Rani LLC’s operations, and through Rani LLC, conducts all of Rani LLC’s business and the financial results of Rani LLC and RMS (prior to December 15, 2022) are included in the consolidated financial statements of the Company. RMS was dissolved as of December 15, 2022

Rani LLC has been, and after the IPO continues to be, treated as a pass-through entity for U.S. federal and state income tax purposes and accordingly has not been subject to U.S. federal or state income tax. The wholly owned subsidiary of Rani LLC, RMS, which was incorporated in 2019 and dissolved in December 2022, was taxed as a corporation for U.S. federal and most applicable state, local income tax and foreign tax purposes. As a result of its ownership of interests in Rani LLC ("LLC Interests"), the Company is subject to U.S. federal, state and local income taxes with respect to its allocable share of any taxable income of Rani LLC and will be taxed at the prevailing corporate tax rates. In addition to tax expenses, we also incur expenses related to our operations and may be required to make payments under the Tax Receivable Agreement with certain of the individuals and entities that continue to hold interests in Rani LLC after the IPO (the "Continuing LLC Owners"). The Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of our Class B common stock (together referred to as a "Paired Interest"), in return for shares of our Class A common stock on a one-for-one basis provided that, at our election, we may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be canceled on a one-for-one basis if, at the election of the Continuing LLC Owners, we redeem or exchange such Paired Interest pursuant to the terms of the Rani LLC Agreement. These exchanges and redemptions may result in increases in the tax basis of the assets of Rani LLC that otherwise would not have been available. Increases in tax basis resulting from such

exchanges may reduce the amount of income tax that the Company would otherwise be required to pay in the future. This tax basis may also decrease the gains (or increase the losses) on future dispositions of certain assets to the extent tax basis is allocated to those assets. Due to the uncertainty of various factors, we cannot estimate the likely tax benefits we will realize as a result of exchanges, and the resulting amounts we will likely pay out to the Continuing LLC Owners pursuant to the Tax Receivable Agreement; however, we estimate that such payments may be substantial in the event we are profitable. Certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company's Class B common stock ("non-corresponding Class A Units") have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,345,067 shares of the Company's Class A common stock.

Components of Results of Operations

Operating Expenses

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

Research and Development Expense

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

External expenses, consisting of:

- expenses associated with contract research organizations ("CROs,"), for managing and conducting clinical trials;
- expenses associated with laboratory supplies, drug material for clinical trials, developing and manufacturing of the RaniPill GO, RaniPill HC and other materials;
- expenses associated with preclinical studies performed by third parties;
- expenses associated with consulting, advisors, and other external services; and
- other research and development costs related to compliance with quality and regulatory requirements.

Internal expenses, consisting of:

- expenses including salaries, bonuses, stock-based compensation and benefits for personnel engaged in the research and development functions; and
- expenses associated with equipment depreciation and allocated facility costs for research and development.

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 development of the RaniPill GO and RaniPill HC and complete the development of, and obtain regulatory approval for, our product candidates. We expect our research and development expenses to increase significantly for the foreseeable future as we continue to invest in activities related to testing and developing the RaniPill GO and RaniPill HC and the development of our product candidates, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for our product candidates upon successful completion of clinical trials, and incur expenses associated with hiring additional personnel to support the research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, the successful development of the RaniPill platform and our product candidates is highly uncertain, and we may never succeed in successfully developing the RaniPill GO and/or RaniPill HC or achieve the development of, and regulatory approval for, our product candidates.

General and Administrative Expenses

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

Other Income (Expense), Net

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

Non-Controlling Interest

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

In August 2021, based on the Organizational Transactions, the Company became the sole managing member of Rani LLC. As of December 31, 2023, the Company held approximately 51% of the Class A Units of Rani LLC, and approximately 49% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. Therefore, we report NCI based on the Class A Units of Rani LLC held by the Continuing LLC Owners on our consolidated balance sheet as of December 31, 2023. Income or loss attributed to the NCI in Rani LLC is based on the Class A Units outstanding during the period for which the income or loss is generated and is presented on the consolidated statements of operations and comprehensive income or loss.

Future exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC will result in a change in ownership and reduce or increase the amount recorded as NCI and increase or decrease additional paid-in-capital when Rani LLC has positive or negative net assets, respectively. From the date of the Organizational Transactions to December 31, 2023, there were 5,173,947 exchanges of Paired Interests and 200,455 exchanges of non-corresponding Class A Units of Rani LLC for an equal number of shares of our Class A common stock.

Tax Receivable Agreement

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

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

Relationship with InCube Labs, LLC

Service Agreements

In June 2021, Rani LLC entered into a service agreement with InCube Labs, LLC (“ICL”) effective retrospectively to January 1, 2021, and subsequently amended such agreement in March 2022 and March 2024 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests. Under the amendment in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas (“Occupancy Services”) for general office, research and development, and light manufacturing. In March 2024, Rani LLC entered into an amendment to extend the term of the Occupancy Services in Milpitas, California from February 2024 to August 2024 and to increase the payment for such Occupancy Services during the extension period.

The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for a successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have a term until August 2024, and the Occupancy Services in San Antonio, Texas continue until either party gives six months’ notice of termination. Except for the Occupancy Services, Rani LLC or ICL may terminate services under the Rani LLC-ICL Service Agreement upon 60 days' notice to the other party. The Rani LLC-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively. In December 2023, we provided to ICL notice of termination of the Occupancy Services in San Antonio, which termination will take effect in June 2024.

In June 2021, RMS entered into a service agreement with ICL effective retrospectively to January 1, 2021. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. In March 2024, Rani LLC entered into an amendment to increase the Occupancy Services from 23,000 square feet to 24,000 square feet (such agreement, as assigned and amended, the “RMS-ICL Service Agreement”). Pursuant to the RMS-ICL Service Agreement, ICL agreed to rent a specified portion of its facility in San Jose, California to RMS. Additionally, RMS and ICL agreed to provide personnel services to the other upon requests based on rates specified in the RMS-ICL Service Agreement. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated. Rani LLC or ICL may terminate services under the RMS-ICL Service Agreement upon 60 days' notice to the other party, except for occupancy which requires six months’ notice. The RMS-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively, as well as allocations of expenses based upon Rani LLC’s utilization of ICL’s facilities and equipment.

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

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,254	$ 1,170
General and administrative	254	222
Total	$ 1,508	$ 1,392

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

As of December 31, 2023, all of our facilities are owned or leased by an entity affiliated with our Chairman. Rani LLC pays for the use of these facilities through our services agreements with ICL.

Exclusive License Agreement

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

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

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

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

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

Tax Receivable Agreement

ICL is party to the TRA, entered into in August 2021 pursuant to the IPO and Organizational Transactions. The TRA provides that we pay to ICL and the other Continuing LLC Owners 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests. During the years ended December 31, 2023 and 2022, these parties to the TRA exchanged zero and 2,317,184 Paired Interests, respectively, that resulted in tax benefits subject to the TRA.

Registration Rights Agreement

In connection with the IPO, we entered into a Registration Rights Agreement with the Continuing LLC Owners, including ICL. The Registration Rights Agreement provides the Continuing LLC Owners certain registration rights whereby, at any time following the IPO and the expiration of any related lock-up period, the Continuing LLC Owners can require us to register under the Securities Act shares of Class A common stock issuable to them upon, at our election, redemption or exchange of their LLC Interests. The Registration Rights Agreement also provides for piggyback registration rights for the Continuing LLC Owners. As a result of certain stockholders exercising their registration rights under the Registration Rights Agreement, in December 2022 we filed a registration statement on Form S-3 to register 6,009,542 shares of our Class A common stock held by certain of our stockholders.

Rani LLC Agreement

We operate our business through Rani LLC and, prior to December 15, 2022, its subsidiary, RMS. RMS was dissolved on December 15, 2022. In connection with the IPO, we and the Continuing LLC Owners, including ICL, entered into the Fifth Amended and Restated LLC Agreement of Rani LLC (the "Rani LLC Agreement"). The governance of Rani LLC, and the rights and obligations of the holders of LLC Interests, are set forth in the Rani LLC Agreement. As a Continuing LLC Owner, ICL is entitled to exchange, subject to the terms of the Rani LLC Agreement, Paired Interests for our Class A common stock; provided that, at our election, we may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed.

During the years ended December 31, 2023 and 2022, these related parties that are party to the Rani LLC Agreement exchanged zero and 2,317,184 Paired Interests, respectively, for the Company's Class A common stock.

Results of Operations

The results of operations presented below should be reviewed in conjunction with the consolidated financial statements and notes included elsewhere in this Annual Report on Form 10-K.

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

	Year Ended December 31,		
	2023	2022	Change
Operating expenses			
Research and development	$ 39,624	$ 36,607	8.2 %
General and administrative	26,475	26,844	(1.4) %
Total operating expenses	$ 66,099	$ 63,451	4.2 %
Loss from operations	(66,099)	(63,451)	4.2 %
Other income (expense), net			
Interest income and other, net	3,301	1,248	164.5 %
Interest expense and other, net	(5,085)	(1,071)	374.8 %
Loss before income taxes	(67,883)	(63,274)	7.3 %
Income tax expense	—	(70)	*
Net loss	$ (67,883)	$ (63,344)	7.2 %
Net loss attributable to non-controlling interest	(33,913)	(32,756)	3.5 %
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (33,970)	$ (30,588)	11.1 %

*Not meaningful

Research and Development Expenses

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

	Year Ended December 31,	
	2023	2022
Payroll, stock-based compensation and related benefits	$ 26,247	$ 24,838
Third-party services	6,864	5,682
Facilities, materials and supplies	6,300	5,727
Other	213	360
Total	$ 39,624	$ 36,607

The increase of $3.0 million in research and development expenses was primarily attributed to higher compensation costs of $1.4 million, an increase of $1.2 million in third-party services and an increase of $0.6 million in facilities, materials and supplies expense related to preclinical and clinical development activities, offset by a decrease in other costs of $0.2 million.

General and Administrative Expenses

The decrease of $0.3 million in general and administrative expenses was primarily attributed to lower third-party services of $1.8 million related to support for compliance with public company requirements and lower facilities, material and supplies and other costs of $0.3 million, offset by higher compensation costs of $1.8 million.

Other Income (Expense), Net

The increase of $1.9 million in other expense, net, was primarily attributed to an increase in interest expense of $4.0 million from our debt, partially offset by an increase in interest income of $2.1 million from our investment in marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2023, our cash, cash equivalents and marketable securities totaled $48.5 million. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates. If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our audited financial statements, and investors may lose all or a part of their investment.

We may not be able to obtain additional funding on acceptable terms, or at all. As a result of geopolitical events, including the conflicts in Ukraine and Gaza, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. In addition, the report from our independent registered public accounting firm issued in connection with this Annual Report on Form 10-K contains statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

In November 2023, we underwent a reduction in our workforce and paused or discontinued certain programs to reduce our expenses and focus our financial resources on key priorities. If we are unable to obtain funding on a timely basis, or to generate sufficient revenues, if at all, from collaboration arrangements or product sales, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, the development of our oral delivery technology, including the RaniPill HC, the commercialization of any product candidates or cease operations altogether, 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 forego expansion of our operations or refrain from pursuing business opportunities; any of which could have a material adverse effect on our business, financial condition and results of operations.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Common Stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants and other operating restrictions that could adversely impact our ability to conduct our business. The Lender already has a security interest in substantially all of our assets, including our intellectual property, which may prevent or limit our ability to incur additional indebtedness.

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

In August 2022, we entered into the Loan Agreement with the Lender. The Loan Agreement provides for Loans in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. The Loan Agreement also contains various covenants and restrictive provisions. As of December 31, 2023, we were in compliance with all applicable debt covenants under the Loan Agreement and had cash, cash equivalents and marketable securities totaling $48.5 million.

In August 2022, we entered into the Sales Agreement with the Agents, pursuant to which we may offer and sell from time to time through the Agents up to $150.0 million of shares of our Class A common stock in ATM Sales. As of December 31, 2023, we had not delivered any placement notices to either of the Agents and there had been no ATM Sales.

Since our inception, we have incurred significant losses and negative cash flows from operations. Our net losses were $67.9 million and $63.3 million for the year ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $72.9 million. We expect to continue to incur significant losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. Until such time as we can generate sufficient revenue from commercial product sales, if ever, we expect to finance our operations through a combination of equity offerings and debt financings, which may include ATM Sales, or other capital sources, which may include strategic collaborations or other arrangements with third parties. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all.

Tax Receivable Agreement

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

As of December 31, 2023, we have not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits. To the extent the Company is able to realize the income tax benefits associated with the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC subject to the TRA, the TRA payable would range from zero to $22.9 million at December 31, 2023.

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

Future Funding Requirements and Going Concern

Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to fund our projected operating requirements for a twelve-month period and will not enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates.

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

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

- the progress, costs, trial design, results of and timing of our preclinical studies and clinical trials;
- the progress, costs, and results of our research pipeline;
- the willingness of the FDA, or other regulatory authorities to accept data from our clinical trials, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for review and approval of our product candidates or collaborator drugs or biologics paired with the RaniPill GO and/or RaniPill HC for various indications;
- the outcome, costs, and timing of seeking and obtaining FDA, and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of the RaniPill capsules;
- our need to expand our research and development activities;
- the costs associated with manufacturing our product candidates, including establishing commercial supplies and sales, marketing, and distribution capabilities;
- the costs associated with securing and establishing commercial infrastructure;
- the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and engineering personnel;
- the effect of competing drugs and product candidates and other market developments;
- the timing, receipt, and amount of sales from our potential products, if approved;
- our ability to establish strategic collaborations;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- security breaches, data losses or other disruptions affecting our information systems;
- our ability to realize savings from any restructuring plans or cost-containment measures we have implemented or additional measures we may implement;
- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future.

If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us. If we raise funds through collaborations, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or delay investments in our manufacturing scale-up and automation. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets.

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

	December 31,	
	2023	2022
Cash and cash equivalents	$ 5,864	$ 27,007
Marketable securities	42,675	71,475
Total cash, cash equivalents and marketable securities	$ 48,539	$ 98,482

As of December 31, 2023, we had cash and cash equivalents and marketable securities of $48.5 million, compared to $98.5 million as of December 31, 2022. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to fund our projected operating requirements for a twelve-month period from the issuance of our financial statements.

Cash Flows

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

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (51,236)	$ (46,515)
Net cash provided by (used in) investing activities	29,860	(72,436)
Net cash provided by financing activities	233	29,005
Net decrease in cash, cash equivalents and restricted cash equivalents	$ (21,143)	$ (89,946)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $51.2 million, which was primarily attributable to a net loss of $67.9 million and net accretion and amortization of investments in marketable securities of $2.3 million, partially offset by the stock-based compensation expense of $19.0 million and depreciation and amortization expense of $0.8 million Additionally, there was a combined decrease in accounts payable and accrued expenses and other current liabilities of $1.1 million.

Net cash used in operating activities for the year ended December 31, 2022 was $46.5 million, which was primarily attributable to a net loss of $63.3 million and net accretion and amortization of investments in marketable securities of $0.9 million, partially offset by the equity-based compensation expense of $15.8 million and depreciation and amortization expense of $0.5 million. Additionally, there was a decrease in prepaid expenses and other current assets of $0.5 million and an increase in accrued expenses of $0.7 million.

Investing Activities

For the year ended December 31, 2023, net cash provided by investing activities was $29.9 million consisting of $104.4 million in proceeds from maturities of marketable securities partially offset by $73.3 million and $1.2 million in purchases of marketable securities and property and equipment, respectively.

For the year ended December 31, 2022, net cash used in investing activities was $72.4 million consisting of $73.8 million in purchases of marketable securities, $3.0 million in proceeds from maturities of marketable securities and $1.6 million in purchases of property and equipment.

Financing Activities

For the year ended December 31, 2023, there were no significant financing activities.

For the year ended December 31, 2022, net cash provided by financing activities was $29.0 million, which was primarily attributable to proceeds from the issuance of long-term debt and warrants, net of issuance costs of $29.6 million. These items were partially offset by a $0.6 million decrease for employee taxes paid on net share settlement on the vesting of restricted stock units and payment of deferred financing costs of $0.3 million.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2023 (in thousands):

	As of December 31, 2023		
	Total	Short-term	Long-term
Operating leases (1)	$ 7,582	$ 2,104	$ 5,478
Debt obligations (2)	31,031	4,897	26,134
Total	$ 38,613	$ 7,001	$ 31,612

(1) Represents operating lease payments. See Note 7 to the consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

(2) Represents long-term debt principal maturities and final payment equal to 5.5% of aggregate amount funded, excluding interest. See Note 12 to the consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

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

Critical Accounting Policies and Estimates

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

While our significant accounting policies are described in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

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, we do 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. We accrue and expense 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.

Recently Adopted Accounting Standards

None.

Other Information

JOBS Act Accounting Election

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

We will remain an emerging growth company until the earliest of (1) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our initial public offering), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our Class A common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Rani Therapeutics Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rani Therapeutics Holdings, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations, negative cash flows from operating activities, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

San Francisco, California
March 20, 2024

RANI THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 5,864	$ 27,007
Marketable securities	42,675	71,475
Prepaid expenses and other current assets	2,308	2,442
Total current assets	50,847	100,924
Property and equipment, net	6,105	6,038
Operating lease right-of-use asset	718	1,065
Other assets	246	—
Total assets	$ 57,916	$ 108,027
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 648	$ 1,460
Accrued expenses and other current liabilities	1,726	2,349
Current portion of long-term debt	4,897	—
Current portion of operating lease liability	718	1,006
Total current liabilities	7,989	4,815
Long-term debt, less current portion	24,484	29,149
Operating lease liability, less current portion	—	59
Total liabilities	32,473	34,023
Stockholders' equity:		
Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Class A common stock, $0.0001 par value - 800,000 shares authorized; 26,036 and 25,295 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	3	3
Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of December 31, 2023 and December 31, 2022	2	2
Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	85,762	75,842
Accumulated other comprehensive loss	(12)	(73)
Accumulated deficit	(72,889)	(38,919)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	12,866	36,855
Non-controlling interest	12,577	37,149
Total stockholders' equity	25,443	74,004
Total liabilities and stockholders' equity	$ 57,916	$ 108,027

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

RANI THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year Ended December 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 39,624	$ 36,607
General and administrative	26,475	26,844
Total operating expenses	$ 66,099	$ 63,451
Loss from operations	(66,099)	(63,451)
Other income (expense), net		
Interest income and other, net	3,301	1,248
Interest expense and other, net	(5,085)	(1,071)
Loss before income taxes	(67,883)	(63,274)
Income tax expense	—	(70)
Net loss	$ (67,883)	$ (63,344)
Net loss attributable to non-controlling interest	(33,913)	(32,756)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (33,970)	$ (30,588)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	$ (1.33)	$ (1.28)
Weighted-average Class A common shares outstanding—basic and diluted	25,505	23,817

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

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

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (67,883)	$ (63,344)
Other comprehensive loss		
Net unrealized gain (loss) on marketable securities	121	(149)
Comprehensive loss	$ (67,762)	$ (63,493)
Comprehensive loss attributable to non-controlling interest	(33,852)	(32,832)
Comprehensive loss attributable to Rani Therapeutics Holdings, Inc.	$ (33,910)	$ (30,661)

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

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

	Class A Common Stock		Class B Common Stock						
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2021	19,712	$ 2	29,290	$ 3	$ 55,737	$ —	$ (8,331)	$ 74,156	$ 121,567
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	5,332	1	(5,174)	(1)	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	12,377	—	—	(12,377)	—
Issuance of warrants	—	—	—		503	—	—	—	503
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	204	—	—	—	(626)	—	—	—	(626)
Issuance of common stock under employee stock purchase plan	39	—	—	—	271	—	—	—	271
Issuance of common stock	13	—	—	—	—	—	—	—	—
Forfeiture of restricted stock awards	(5)	—	—	—	(7)	—	—	(6)	(13)
Equity-based compensation	—	—	—	—	7,587	—	—	8,208	15,795
Net loss	—	—	—	—	—	—	(30,588)	(32,756)	(63,344)
Other comprehensive loss	—	—	—	—	—	(73)	—	(76)	(149)
Balance at December 31, 2022	25,295	$ 3	24,116	$ 2	$ 75,842	$ (73)	$ (38,919)	$ 37,149	$ 74,004
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	557	—	—	—	(162)	—	—	—	(162)
Issuance of common stock under employee stock purchase plan	144	—	—	—	355	—	—	—	355
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	42	—	—	—	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	181	—	—	(181)	—
Forfeiture of restricted stock awards	(2)	—	—	—	(6)	—	—	(6)	(12)
Equity-based compensation	—	—	—	—	9,552	—	—	9,468	19,020
Net loss	—	—	—	—	—	—	(33,970)	(33,913)	(67,883)
Other comprehensive gain	—	—	—	—	—	61	—	60	121
Balance at December 31, 2023	26,036	$ 3	24,116	$ 2	$ 85,762	$ (12)	$ (72,889)	$ 12,577	$ 25,443

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

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (67,883)	$ (63,344)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	19,008	15,782
Depreciation and amortization	822	548
Non-cash operating lease expense	1,041	764
Amortization of debt discount and issuance costs	232	77
Net accretion and amortization of investments in marketable securities	(2,316)	(851)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	282	505
Other assets	(245)	—
Accounts payable	(595)	163
Accrued expenses and other current liabilities	(540)	605
Operating lease liabilities	(1,042)	(764)
Net cash used in operating activities	(51,236)	(46,515)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	104,350	3,000
Purchases of marketable securities	(73,261)	(73,817)
Purchases of property and equipment	(1,229)	(1,619)
Net cash provided by (used in) investing activities	29,860	(72,436)
Cash flows from financing activities		
Issuance of common stock under employee stock purchase plan	355	271
Proceeds from employee stock purchase plan	40	46
Tax withholdings paid on behalf of employees for net share settlement	(162)	(626)
Proceeds from the issuance of long-term debt and warrants, net of issuance costs	—	29,574
Payment of deferred financing costs	—	(260)
Net cash provided by financing activities	233	29,005
Net decrease in cash, cash equivalents and restricted cash equivalents	(21,143)	(89,946)
Cash, cash equivalents and restricted cash equivalents, beginning of period	27,507	117,453
Cash, cash equivalents and restricted cash equivalents, end of period	$ 6,364	$ 27,507
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 4,182	$ 730
Cash paid for income taxes	$ 35	$ 48
Supplemental disclosures of non-cash investing and financing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 578	$ 514
Exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	$ 169	$ 78,487
Interest income receivable included in prepaid expenses	$ 148	$ 44
Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities	$ 18	$ 355
Issuance of costs deducted from long-term debt proceeds	$ —	$ 851
Deferred financing costs included in prepaid expenses	$ —	$ 260

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

1. Organization and Nature of Business

Description of Business

Rani Therapeutics Holdings, Inc. (“Rani Holdings”) was formed as a Delaware corporation in April 2021 for the purpose of facilitating an initial public offering (“IPO”) of its Class A common stock, and to facilitate certain organizational transactions and to operate the business of Rani Therapeutics, LLC (“Rani LLC”) and its consolidated subsidiary, Rani Management Services, Inc. (“RMS”). Rani Holdings and its consolidated subsidiaries, Rani LLC and RMS (prior to December 15, 2022), are collectively referred to herein as “Rani” or the “Company.” RMS was dissolved on December 15, 2022.

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

Organizational Transactions

In connection with the IPO in August 2021, the Company was party to the following organizational transactions (the “Organizational Transactions”):

- Amended and restated Rani LLC’s operating agreement (the “Rani LLC Agreement”) to appoint the Company as the sole managing member of Rani LLC and effectuated an exchange of all outstanding (i) convertible preferred units, automatic or net exercised warrants to purchase preferred units and common units, and common units of Rani LLC, into economic nonvoting Class A units (“Class A Units”) and an equal number of voting noneconomic Class B units (“Class B Units”) and (ii) all non-vested incentive units (“Profits Interests”) into Class A Units. In connection with the closing of the IPO, each LLC interest was exchanged 1 for 0.5282 as determined and predicated on the initial public offering price of the Company’s Class A common stock;

- Amended and restated the Company’s certificate of incorporation in July 2021, to provide for the issuance of (i) Class A common stock, each share of which entitles its holders to one vote per share, (ii) Class B common stock, each share of which entitles its holders to 10 votes per share on all matters presented to the Company's stockholders, (iii) Class C common stock, which has no voting rights, except as otherwise required by law and (iv) preferred stock;

- Exchanged 12,047,925 shares of Class A common stock for existing Class A Units of Rani LLC held by certain individuals and entities (the “Former LLC Owners”) on a one-for-one basis;

- Issued 29,290,391 shares of Class B common stock to certain individuals and entities that continued to hold Class A Units in Rani LLC after the IPO (the “Continuing LLC Owners”) in return for an equal amount of Rani LLC Class B Units;

- Entered into a Registration Rights Agreement with certain of the Continuing LLC Owners.

The Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of the Company Class B common stock (together referred to as a "Paired Interest"), in return for shares of the Company’s Class A common stock on a one-for-one basis provided that, at the Company’s election, the Company has the ability to effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be canceled on a one-for-one basis if, at the election of the Continuing LLC Owners, the Company redeems or exchanges such Paired Interest pursuant to the terms of the Rani LLC Agreement. As of December 31, 2023, certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company’s Class B common stock (“non-corresponding Class A Units”) have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,345,067 shares of the Company’s Class A common stock.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $67.9 million for the year ended December 31, 2023. As of December 31, 2023, the Company had an accumulated deficit of $72.9 million and for the year ended December 31, 2023 had negative cash flows from operations of $51.2 million. As of December 31, 2023, cash, cash equivalents and marketable securities totaled $48.5 million. Based on its available cash resources and current operating plan, there is substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that its financial statements for the year ended December 31, 2023 are issued. The Company's existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to enable it to initiate any pivotal clinical trials. The Company will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of its product candidates and seek regulatory approval thereof, to expand its manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of its product candidates.

In August 2022, the Company entered into a loan and security agreement and related supplement (the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P (the "Lender"). The Loan Agreement provides for term loans (the "Loans") in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $15.0 million of Loans ("Tranche 2") is uncommitted and is subject to certain conditions and approval by the Lender.

In August 2022, the Company entered into a Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively the "Agents"), pursuant to which the Company may offer and sell from time to time through the Agents up to $150 million of shares of its Class A common stock, in such share amounts as the Company may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of December 31, 2023, the Company has no sales under the Sales Agreement.

In November 2023, the Company underwent a reduction in workforce and paused or discontinued certain programs to reduce expenses and focus its financial resources on key priorities. The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop the RaniPill capsule. The Company expects to finance its future operations with its existing cash and through strategic financing opportunities that could include, but are not limited to, future offerings of its equity, such as "at the market offerings" as defined in Rule 415(a)(4) under the Securities Act, collaboration or licensing agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

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"). Certain prior period amounts have been reclassified to be consistent with current period presentation.

The Company operates and controls all of the business and affairs of Rani LLC and, through Rani LLC conducts its business. Because the Company manages and operates the business and controls the strategic decisions and day-to-day operations of Rani LLC and also has a substantial financial interest in Rani LLC, the Company consolidates the financial results of Rani LLC, and a portion of its net loss is allocated to the non-controlling interests in Rani LLC held by the Continuing LLC Owners. All intercompany accounts and transactions have been eliminated in consolidation.

Variable Interest Entities

The Company consolidates all entities that it controls through a majority voting interest or as the primary beneficiary of a variable interest entity ("VIE"). In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation event.

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. The Company evaluates its estimates on an ongoing basis. The Company bases its estimates on its historical experience and also on assumptions that we believe are reasonable; however, actual results may differ materially and adversely from these estimates.

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.

Cash, Cash Equivalents and Restricted Cash Equivalents

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

The following table provides a reconciliation of cash and cash equivalents and restricted cash equivalents reported as a component of prepaid expenses and other current assets on the consolidated balance sheet which, in aggregate, represents the amount reported in the consolidated statements of cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
End of Period:		
Cash and cash equivalents	$ 5,864	$ 27,007
Restricted cash equivalents	500	500
Total cash, cash equivalents and restricted cash equivalents	$ 6,364	$ 27,507

Marketable Securities

The Company invests its excess cash in marketable securities with high credit ratings including securities issued by U.S. and international governments and their agencies, corporate debt securities and commercial paper. The Company has assessed U.S. government treasuries as Level 1 and all other marketable securities as Level 2 within the fair value hierarchy. All the Company's marketable securities have been accounted for as available-for-sale and carried at fair value. The Company classifies all its available-for-sale marketable securities, including those with maturity dates beyond one year, as current assets on the consolidated balance sheets as the Company may sell these securities at any time for use in current operations even if they have not yet reached maturity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income and other, net on the consolidated statements of operations and comprehensive loss. Realized gains and losses on marketable securities are included in other income (expense) on the consolidated statements of operations. Gains and losses on sales are recorded based on the trade date and determined using the specific identification method.

The Company regularly reviews its investments for declines in fair value below their amortized cost basis to determine whether the impairment is due to credit-related factors or noncredit-related factors. The Company's review includes the creditworthiness of the security issuers, the severity of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of its amortized cost bases. When the Company determines that a portion of the unrealized loss is due to an expected credit loss, the Company recognizes the loss amount in Other income (expense), net, with a corresponding allowance against the carrying value of the security the Company holds. The portion of the unrealized loss related to factors other than credit losses is recognized in Accumulated other comprehensive loss. The Company has made an accounting policy election to not measure an allowance for credit loss for accrued interest receivables and will recognize a credit loss for accrued interest receivables when the loss becomes probable and estimable. As of December 31, 2023 and 2022, interest income receivable recorded as a component of prepaid expenses and other current assets on the consolidated balance sheet was $0.2 million and de minimis, respectively.

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.

As of December 31, 2023 and 2022, the carrying values of current assets and liabilities approximates fair value due to their short-term nature, respectively. The fair value of the Company’s long-term debt approximated 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. 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.

Leases

The Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present at the inception of the arrangement and if such a lease is classified as a financing lease or operating lease. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. For any arrangement that is considered to be a lease with a term greater than one year, the Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the Company’s consolidated balance sheet as of December 31, 2023.

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

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

Long-Term Debt with Detachable Warrants

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

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 the Company's 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.

Stock-Based Compensation

In July 2021, the Company adopted and its stockholders approved, the Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan (the “2021 Plan”). The Company has subsequently granted stock options to purchase shares of its Class A common stock as well as restricted stock units (“RSUs”) and restricted stock awards ("RSAs") from the 2021 Plan to both employees and non-employees. The Company measures stock-based compensation at fair value on the grant date of the award. The fair value of employee and nonemployee RSUs is determined based on the number of shares granted and the closing market price of the Company’s Class A common stock on the date of grant. The fair value of employee RSAs is determined based on the estimated fair value of the Company’s Class A common stock on the grant date and is subject to the Company's reacquisition right which is accounted for as a forfeiture provision (Note 10). For awards that vest subject to the satisfaction of service requirements, compensation expense is measured based on the fair value of the award on the date of grant and expense is recognized on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they occur. Stock-based compensation is classified in the accompanying consolidated statements of operations and comprehensive loss based on the function to which the related services are provided.

The Company determines the grant-date fair value of options to purchase common shares using the Black-Scholes option-pricing model which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company’s expected dividend yield. Such assumptions represent management’s best estimates and involve inherent uncertainties and the application of management’s judgment. 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 compensation expense, which could be material to the Company’s consolidated results of operations.

Income Taxes

The Company is the managing member of Rani LLC and, as a result, consolidates the financial results of Rani LLC and, prior to December 15, 2022, its taxable subsidiary RMS in the consolidated financial statements. RMS was dissolved on December 15, 2022. Rani LLC is a pass-through entity for United States federal and most applicable state and local income tax purposes following the IPO and Organizational Transactions. As an entity classified as a partnership for tax purposes, Rani LLC is not subject to United States federal and certain state and local income taxes. Any taxable income or loss generated by Rani LLC is passed through to, and included in the taxable income or loss of, its members, including the Company. The Company is taxed as a corporation and pays corporate federal, state and local taxes with respect to income allocated to it, based on its economic interest in Rani LLC. The Company's tax provision also includes the activity of RMS prior to its dissolution, which is taxed as a corporation for United States federal and state income tax purposes.

The Company accounts for income taxes under the asset and liability method of accounting. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. The Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as for operating loss and tax credit carryforwards. The Company measures deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which the Company expects to recover or settle those temporary differences. The Company recognizes the effect of a change in tax rates on deferred tax assets and liabilities in the results of operations in the period that includes the enactment date. The Company reduces the measurement of a deferred tax asset, if necessary, by a valuation allowance if it is more likely than not that the Company will not realize some or all of the deferred tax asset.

The Company's tax positions are subject to income tax audits. 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 income tax expense in the accompanying consolidated statements of operations and comprehensive loss. No such interest and penalties were recognized for any period presented.

Tax Receivable Agreement

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

A liability for the payable to parties subject to the TRA, and a reduction to stockholders’ equity, is accrued when (i) an exchange of a Paired Interest or non-corresponding Class A Units of Rani LLC has occurred and (ii) when it is deemed probable that the Tax Attributes associated with the exchange will be used to reduce the Company's taxable income based on the contractual percentage of the benefit of Tax Attributes that the Company expects to receive over a period of time (Note 13).

Comprehensive Loss

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

Non-Controlling Interest

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

In August 2021, based on the Organizational Transactions, Rani Holdings became the sole managing member of Rani LLC. As of December 31, 2023, Rani Holdings held approximately 51% of the Class A Units of Rani LLC, and approximately 49% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. Therefore, the Company reports NCI based on the Class A Units of Rani LLC held by the Continuing LLC Owners on its consolidated balance sheet as of December 31, 2023. Income or loss attributed to the NCI in Rani LLC is based on the Class A Units outstanding during the period for which the income or loss is generated and is presented on the consolidated statements of operations and comprehensive loss.

Future exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC will result in a change in ownership and reduce or increase the amount recorded as NCI and increase or decrease additional paid-in-capital when Rani LLC has positive or negative net assets, respectively. From the date of the Organizational Transactions to December 31, 2023, there were 5,173,947 exchanges of Paired Interests and 200,455 exchanges of non-corresponding Class A Units of Rani LLC for an equal number of shares of the Company's Class A common stock.

Property and Equipment, Net

Property and equipment, net are stated at cost, less accumulated depreciation and amortization calculated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized over the shorter of the related lease term or useful life. Maintenance and repairs are charged to operations when incurred, while betterments or renewals are capitalized. When property and equipment are sold or otherwise disposed of, the asset account and related accumulated depreciation and amortization accounts are relieved, and any gain or loss is included in the results of operations. Construction-in-progress consists of production equipment that will be used to scale-up the manufacturing of the RaniPill capsule 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.

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, 2023.

Net Loss Per Class A Common Share Attributable to Rani Holdings

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

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (“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 consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

3. Cash Equivalents, Restricted Cash Equivalents and Marketable Securities

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

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

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 25,313	$ —	$ —	$ 25,313
Total cash equivalents	25,313	—	—	25,313
Restricted cash equivalents:				
Money market funds	500	—	—	500
Total cash equivalents and restricted cash equivalents	25,813	—	—	25,813
Marketable securities:				
U.S. Treasuries and agencies	36,563	—	(107)	36,456
Commercial paper	26,631	—	—	26,631
Corporate debt securities	6,939	—	(39)	6,900
International government	1,491	—	(3)	1,488
Total marketable securities	71,624	—	(149)	71,475
Total cash equivalents, restricted cash equivalents and marketable securities	$ 97,437	$ —	$ (149)	$ 97,288

All marketable securities are classified as short-term. The Company regularly reviews its available-for-sale marketable securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. As of December 31, 2023, the aggregate difference between the amortized cost and fair value of each security in an unrealized loss position was de minimis. Since any provision for expected credit losses for a security held is limited to the amount the fair value is less than its amortized cost, no allowance for expected credit loss was deemed necessary at December 31, 2023.

4. Fair Value Measurements

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

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

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 25,313	$ —	$ —	$ 25,313
Restricted cash equivalents:				
Money market funds	500	—	—	500
Marketable securities				
U.S. Treasuries and agencies	36,456	—	—	36,456
Commercial paper	—	26,631	—	26,631
Corporate debt securities	—	6,900	—	6,900
International government	—	1,488	—	1,488
Total assets	$ 62,269	$ 35,019	$ —	$ 97,288

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

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

In 2022, as further discussed in Note 8, the Company issued Level 3 equity classified warrants totaling $0.5 million in connection with the loan and security agreement that were estimated on the date of issuance using the Black-Scholes valuation model which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. Such assumptions represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

5. Balance Sheet Components

Property and equipment, net

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 4,023	$ 2,661
Leasehold improvements	1,588	1,549
Software	104	104
Office equipment	157	157
Total	5,872	4,471
Less accumulated depreciation and amortization	(3,671)	(2,849)
Total	2,201	1,622
Construction-in-progress	3,904	4,416
Total property and equipment, net	$ 6,105	$ 6,038

Depreciation and amortization expense totaled $0.8 million and $0.5 million for the years ended December 31, 2023 and 2022, respectively.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued interest	$ 500	$ 69
Accrued preclinical and clinical trial costs	424	1,130
Payroll and related	313	394
Accrued professional fees	235	165
Related party payable	52	53
Other	202	538
Total accrued expenses and other current liabilities	$ 1,726	$ 2,349

6. Related Party Transactions

InCube Labs, LLC (“ICL”) is wholly-owned by the Company’s founder and Chairman and his family. The founder and Chairman is the father of the Company’s Chief Executive Officer. The Company’s Chief Scientific Officer is also the brother of the founder and Chairman and thus uncle of the Company’s Chief Executive Officer.

Service Agreements

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

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

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

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,254	$ 1,170
General and administrative	254	222
Total	$ 1,508	$ 1,392

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

As of December 31, 2023, all of the Company's facilities are owned or leased by an entity affiliated with the Company’s Chairman (Note 7). The Company pays for the use of these facilities through its services agreements with ICL.

Exclusive License, Intellectual Property and Common Unit Purchase Agreement

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

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

Non-Exclusive License Agreement between Rani and ICL (“Non-Exclusive License Agreement”)

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

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

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

Tax Receivable Agreement

Certain parties to the TRA, entered into in August 2021 pursuant to the IPO and Organizational Transactions are related parties of the Company. The TRA provides that the Company pay to ICL and the other Continuing LLC Owners 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests (Note 2). During the years ended December 31, 2023 and 2022, these parties to the TRA exchanged zero and 2,317,184 Paired Interests, respectively, that resulted in tax benefits subject to the TRA (Note 13).

Registration Rights Agreement

In connection with the IPO, the Company entered into a Registration Rights Agreement. ICL and its affiliates are parties to this agreement. The Registration Rights Agreement provides certain registration rights whereby, at any time following the IPO and the expiration of any related lock-up period, ICL and its affiliates can require the Company to register under the Securities Act of 1933, as amended (the "Securities Act") shares of Class A common stock issuable to ICL and its affiliates upon, at the Company's election, redemption or exchange of their Paired Interests. The Registration Rights Agreement also provides for piggyback registration rights. In March 2022, certain holders of the Company's Class A common stock considered to be related parties were made parties to the Registration Rights Agreement. As a result of certain stockholders exercising their registration rights under the Registration Rights Agreement, in December 2022, the Company filed a registration statement on Form S-3 to register 6,009,542 shares of Class A common stock of the Company held by certain of its stockholders.

Rani LLC Agreement

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

During the years ended December 31, 2023 and 2022, certain related parties that are party to the Rani LLC Agreement exchanged zero and 2,317,184 Paired Interests, respectively, for an equal number of shares of the Company's Class A common stock.

7. Leases

The Company pays for the use of its office, laboratory and manufacturing facility in San Jose, California as part of the RMS-ICL Service Agreement. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless Rani LLC or ICL terminate occupancy under the RMS-ICL Service Agreement upon six months' notice. The Company determined it to be reasonably certain that it would exercise its renewal option for a successive twelve-month period and has considered it in the determination of the right-of-use assets and lease liabilities associated with the RMS-ICL Service Agreement as of December 31, 2023.

Under the Rani LLC-ICL Service Agreement amended in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for a successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have a term until February 2024, following an extension granted in July 2022, with the potential for one additional annual renewal, subject to approval by the landlord upon a nine months' notice of renewal prior to the end of the lease term, and the Occupancy Services in San Antonio, Texas continue until either party gives six months' notice of termination. The Company accounted for the lease extension as a lease modification that did not result in a separate contract and recognized the right-of-use asset and lease liabilities associated with the Rani LLC-ICL Service Agreement in the consolidated balance sheet as of December 31, 2023. As of December 31, 2023, the second renewal option for the facility in Milpitas, California was not deemed reasonably certain to be exercised. The Company provided to ICL notice of termination of the Occupancy Services in San Antonio in December 2023, which termination will take effect in June 2024.

The Company's leases are accounted for as operating leases and require certain fixed payments of real estate taxes and insurance in addition to future minimum lease payments, and certain variable payments of common area maintenance costs and building utilities. Variable lease payments are expensed in the period in which the obligation for those payments is incurred. These variable lease costs are payments that vary in amount beyond the commencement date, for reasons other than passage of time. Variable lease payments are excluded in the total operating lease expense and immaterial for the periods presented.

Supplemental information on the Company's consolidated balance sheet and statements of cash flows as of December 31, 2023 related to leases was as follows (in thousands):

	December 31,	
	2023	2022
Weighted-average remaining lease term (in years)	0.9	1.1
Weighted-average discount rate	10.4%	7.0%

As of December 31, 2023, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands):

Year ending December 31,	
2024	$ 749
Total undiscounted future minimum lease payments	$ 749
Less: Imputed interest	(31)
Total operating lease liability	$ 718
Less: Current portion of operating lease liability	718
Operating lease liability, net current portion	$ -

In November 2023, Rani LLC and BKM South Bay 240, LLC ("Landlord") entered into the Standard Industrial/Commercial Multi-Tenant Lease - Net (the "Lease"). Pursuant to the terms of the Lease, Rani LLC is leasing approximately 33,000 square feet of space in Fremont, California, which is part of a two-building project (the "Project"). The initial term of the Lease commenced in February 2024, and the duration of the initial term is 63 months. Subject to certain conditions, Rani LLC has an option to renew the Lease for one additional 5-year term at the then-prevailing market rate. The monthly base rent for the initial term of the Lease is approximately $95,000 per month, subject to a 4% increase each year. Rani LLC is also responsible for the payment of additional rent to cover its share of common area operating expenses, including taxes, insurance, utilities, and repair and maintenance of the premises and common areas of the Project. The Company will further evaluate the Lease and record its impact on the Company's consolidated financial statements on the commencement date of the Lease in February 2024. Future minimum lease payments for the Lease total $6.5 million through 2029 and are excluded from the table above.

8. Warrants

In August 2022, in conjunction with a loan and security agreement (Note 12), the Company issued warrants to purchase 76,336 shares of the Company's Class A common stock. The warrants are exercisable for a period of five years from the grant date, as may be adjusted for certain anti-dilution adjustments, dividends, stock splits, and reverse stock splits, at an exercise price per share equal to $11.79, which may be net share settled at the option of the holder. As of December 31, 2023, there were 76,336 warrants outstanding.

9. Stockholders' Equity

For the years ended December 31, 2023 and 2022, certain of the Continuing LLC Owners executed an exchange of zero and 5,173,947 Paired Interests, respectively, and 42,404 and 158,051 non-corresponding Class A Units of Rani LLC, respectively, in return for an equal number of shares of the Company's Class A common stock. The corresponding shares of the Company's Class B common stock included in the exchange of Paired Interests were subsequently canceled and retired pursuant to the terms of the Rani LLC Agreement.

In August 2022, the Company entered into a Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively the "Agents"), pursuant to which the Company may offer and sell from time to time through the Agents up to $150.0 million of shares of its Class A common stock, in such share amounts as the Company may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of December 31, 2023, the Company has no sales under the Sales Agreement. In connection with the Sales Agreement, the Company recognized deferred offering costs totaling $0.3 million as a component of prepaid expenses and other current assets in the consolidated balance sheet as of December 31, 2023 which will be offset against proceeds upon a sale under the Sales Agreement within the consolidated statement of changes in stockholders' equity.

As of December 31, 2023, the Company reserved 0.5 million shares of Class A Common Stock for issuance under the Rani Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan (the "ESPP") and 3.0 million shares of Class A common stock for future issuance under the 2021 Plan.

10. Stock-Based Compensation

Stock Option Repricing

On December 16, 2023 (the "Repricing Date"), the Company's Board of Directors approved a stock option award repricing whereby certain previously granted and still outstanding unvested stock option awards issued under the 2021 Plan and the 2016 Equity Incentive Plan, were reduced to $2.84 per share, which represented the most recent closing market price of the Company's Class A common stock to the Repricing Date (the "Option Repricing"). These stock option awards are held by employees, including the Company's named executive officers, certain consultants, and non-employee members of the Board of Directors. No other terms of the options were modified, and the stock option awards will continue to vest according to their original vesting schedules, remain subject to the same service requirements and will retain their original expiration dates. The Option Repricing was fair valued using the Black-Scholes option pricing model, which approximated the Lattice model, resulting in $1.8 million of incremental stock-based compensation expense and is expected to be recognized over a weighted-average period of approximately 2.3 years.

Stock Options

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

	Number of Stock Option Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2022	3,788,586	$ 13.40	8.81	$ —
Granted	3,159,210	$ 4.93	9.33	$ 125
Canceled	(307,985)	$ 13.04		
Balance at December 31, 2023	6,639,811	$ 6.37	8.48	$ 13,377
Exercisable at December 31, 2023	2,581,713	$ 11.81	7.87	$ 279
Nonvested at December 31, 2023	4,058,098	$ 2.92	8.87	$ 13,098

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

- *Expected term* - The expected term represents the period of time that stock option awards are expected to remain outstanding. The Company estimates the expected term as the midpoint between actual or expected vesting date and the contractual term.

•*Expected volatility* - The expected volatility was derived from the historical stock volatilities of peer public companies within the Company's industry that are considered to be comparable businesses over a period equivalent to the expected term of the stock option awards, since there has been limited trading history of the Company's stock.

•*Risk-free interest rate* - The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock option awards' expected term.

•*Expected dividend yield* - The expected dividend yield is zero as the Company has no plans to make dividend payments.

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

	Year Ended December 31,	
	2023	2022
Expected volatility	84.0 - 85.8 %	77.2 %
Risk-free interest rate	3.73 - 3.93 %	2.44 %
Expected term (in years)	5.1 - 5.9	5.9
Expected dividend yield	— %	— %

As of December 31, 2023, there was $21.4 million of unrecognized stock-based compensation expense related to stock options which is expected to be recognized over a weighted-average period of approximately 2.3 years.

Restricted Stock Units

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

	Number of Restricted Stock Units	Weighted Average Grant-Date Fair Value per Share
Balance at December 31, 2022	665,500	$ 15.64
Granted	1,311,671	$ 5.43
Vested	(590,713)	$ 12.66
Forfeited	(110,347)	$ 8.27
Balance at December 31, 2023	1,276,111	$ 7.16

As of December 31, 2023, there was $8.1 million of unrecognized stock-based compensation expense related to RSUs which is expected to be recognized over a weighted-average period of approximately 3.0 years. The total fair value of RSUs vested was $2.2 million for the year ended December 31, 2023.

Restricted Stock Awards

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

	Number of Restricted Stock Awards	Weighted Average Grant-Date Fair Value per Share
Balance at December 31, 2022	67,389	$ 6.14
Vested	(31,411)	$ 6.14
Forfeited	(2,392)	$ 6.12
Balance at December 31, 2023	33,586	$ 6.15

As of December 31, 2023, unrecognized stock-based compensation expense related to RSAs was de minimis which is expected to be recognized over a weighted-average period of approximately 0.5 years. The total fair value of RSAs vested was $0.1 million for the year ended December 31, 2023.

ESPP

As of December 31, 2023, 0.2 million shares of Class A common stock have been issued under the ESPP. During the years ended December 31, 2023 and 2022, the Company recognized $0.3 million and $0.2 million, respectively, of stock-based compensation expense related to the ESPP. As of December 31, 2023, contributions withheld from employees were de minimis and recorded as a component of accrued expenses and other current liabilities in the consolidated balance sheet. As of December 31, 2023, there was $0.1 million of unrecognized stock-based compensation expense related to the ESPP which is expected to be recognized over a weighted-average period of approximately 0.4 years.

Stock-Based Compensation Expense

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

	Year Ended December 31,	
	2023	2022
Research and development	$ 6,407	$ 6,237
General and administrative	12,601	9,545
Total stock-based compensation	$ 19,008	$ 15,782

11. Commitments and Contingencies

Legal Proceedings

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation as the Company operates in an industry susceptible to patent legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal costs associated with these matters are expensed when incurred. The Company is currently involved in several opposition proceedings at the European Patent Office, all of which were asserted against us by Novo Nordisk A/S. 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 prevent third parties from commercializing in Europe products with characteristics similar to those of the Company's RaniPill technology.

Tax Receivable Agreement

The Company is party to a TRA with certain of the Continuing LLC Owners (Note 2). As of December 31, 2023, the Company has not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits. To the extent the Company is able to realize the income tax benefits associated with the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC subject to the TRA, the TRA payable would range from zero to $22.9 million at December 31, 2023.

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

12. Long-Term Debt

In August 2022, the Company entered into a loan and security agreement and related supplement (the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P (the "Lender"). The Loan Agreement provides for term loans (the "Loans") in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $15.0 million of Loans ("Tranche 2") is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. In exchange for access to this facility, the Company agreed to issue warrants (Note 8).

Pursuant to the Loan Agreement, the maturity date for the Loans is August 1, 2026 (the "Maturity Date"). The Loan principal is repayable in equal monthly installments beginning September 2024 extendable to March 2025 under certain conditions. The Loans bear interest at a variable rate per annum equal to the greater of (A) the prime rate, as published by the Wall Street Journal from time to time plus 5.60% or (B) 10.35%. The Loan Agreement is collateralized by substantially all of the Company's assets, in which the Lender is granted continuing security interests. The Loans includes customary events of default, including instances of a material adverse change in the Company's operations, which may require prepayment of the outstanding Loans. At December 31, 2023, the effective interest rate on the Loans was 15.70% and there were no events of default during the year ended December 31, 2023. The Company is also subject to certain covenants. There have been no material adverse events in connection with the Loan Agreement and the substantial doubt regarding our ability to continue as a going concern does not currently constitute a material adverse event under the terms of the Loan Agreement. As of December 31, 2023, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of December 31, 2023, future principal payments for the Company's debt are as follows (in thousands):

Year ending December 31,	
2024	$ 5,000
2025	15,000
2026	10,000
Total principal payments	$ 30,000
Less: amount representing debt discount	(619)
Total long-term debt	$ 29,381
Less: current portion of long-term debt	4,897
Total long-term debt, less current portion	$ 24,484

13. Income Taxes

There was no income tax expense for the year ended December 31, 2023. Income tax expense totaled $0.1 million for the year ended December 31, 2022. The effective tax rate for the years ended December 31, 2023 and 2022 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 loss 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:

	Year Ended December 31,	
	2023	2022
Federal statutory rate	21.0 %	21.0 %
State tax, net of federal tax benefit	3.5	3.4
Non-controlling interest	(10.5)	(10.4)
Research and development credits	2.4	2.1
Uncertain tax position	(0.4)	(0.3)
Liquidating distribution	—	(2.1)
Other	0.1	—
Change in valuation allowance	(16.1)	(13.8)
Effective tax rate	— %	(0.1) %

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):

	Year Ended December 31,	
	2023	2022
Deferred tax assets		
Investment in partnership	$ 45,470	$ 44,923
Net operating loss carryforward	12,979	6,807
Research and development credits	2,550	1,085
Total deferred tax assets	60,999	52,815
Valuation allowance	(60,999)	(52,815)
Total deferred tax assets, net of valuation allowance	$ —	$ —

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 recognized a full valuation allowance on its deferred tax assets. The valuation allowance increased by $8.2 million and $24.1 million for the years ended December 31, 2023 and 2022, respectively, primarily due to the increase in the Company's net operating losses ("NOL") during the period.

As of December 31, 2023, the Company had the following tax attribute carryforwards that will expire on various dates as follows:

	Amount (in thousands)	Expiration Years
Net operating losses, federal (post December 31, 2017)	$ 39,983	Indefinite
Net operating loss, state (definite)	65,615	2041 - 2043
Research and development tax credits, federal	2,037	2041 - 2043
Research and development tax credits, state	1,220	Indefinite

Pursuant to 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 cumulative change in ownership of more than 50% occurs within a three-year period. As of December 31, 2023, 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 United States 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 2018 through 2023 remain open to examination.

The following table summarizes the changes in the amount of the unrecognized tax benefits (in thousands):

	Year Ended December 31,	
	2023	2022
Balance at the beginning of the year	$ 211	$ 358
Increase related to current year positions	260	222
Increase related to prior year positions	18	4
Decrease related to prior year positions	—	(373)
Balance at the end of the year	$ 489	$ 211

Included in the balance of unrecognized tax benefits at December 31, 2023 is $0.5 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.

Tax Receivable Agreement

The Company is party to a TRA with the Continuing LLC Owners (Note 2). As of December 31, 2023, the Company has not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interests or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits (Note 11).

14. Net Loss Per Share

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

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.	$ (33,970)	$ (30,588)
Denominator:		
Weighted average Class A common share outstanding—basic and diluted	25,505	23,817
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted	$ (1.33)	$ (1.28)

The following table shows the total outstanding securities considered anti-dilutive and therefore excluded from the computation of diluted net loss per Class A common share attributable to Rani Holdings (in thousands):

	As of December 31,	
	2023	2022
Paired Interests	24,116	24,116
Stock options	6,640	3,789
Non-corresponding Class A Units	1,345	1,387
Restricted stock units	1,276	666
Shares issuable pursuant to the ESPP	114	66
Warrants	76	76
Restricted stock awards	34	67
	33,601	30,167

Shares of Class B Common Stock do not share in the Company's earnings and are not participating securities. Accordingly, separate presentation of loss per share of Class B common stock under the two-class method has not been provided. The outstanding shares of Class B Common Stock were determined to be anti-dilutive for the year ended December 31, 2023. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.

15. Subsequent Events

Amended Service Agreements

In March 2024, the Company entered into an amendment to the RMS-ICL Service Agreement to increase the Occupancy Services from 23,000 square feet to 24,000 square feet. In March 2024, the Company also entered into an amendment to the Rani LLC-ICL Service Agreement to extend the term of the Occupancy Services in Milpitas, California from February 2024 to August 2024 and to increase the payment for such Occupancy Services during the extension period.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15(d)-15(e) under the Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2023.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission.

Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item and not set forth below is incorporated by reference to the information set forth in the sections titled "Election of Directors" and "Information Regarding the Board of Directors and Corporate Governance" in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the SEC within 120 days after December 31, 2023.

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. The code of business conduct and ethics is available on our website at https://www.ranitherapeutics.com under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the information set forth in the section titled "—Executive Compensation" in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated by reference to the information in the section titled "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement.

The information required by Item 201(d) of Regulation S-K will be set forth in the section titled "—Equity Compensation Plan Information" in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to the information set forth in the sections titled "Transactions with Related Persons and Indemnification" and "—Independence of The Board of Directors" in our Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to the information set forth in the section titled "Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement.

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements.

The financial statements and reports of independent registered public accounting firm are filed as part of this Annual Report (see "Index to Consolidated Financial Statements" at Item 8).

2. Financial Statement Schedules

No financial statement schedules are included because the information is either provided in the consolidated financial statements, is not required under the instructions or is immaterial, and such schedules, therefore have been omitted.

3. Exhibits.

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

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
3.2	Amended and Restated Bylaws of the Registrant as currently in effect (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
4.1	Specimen Class A common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
4.2	Description of Securities (incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022).
10.1	Tax Receivable Agreement, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022).
10.2	Class B Unit Exchange Agreement, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022).
10.3	Registration Rights Agreement, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022).
10.4	Fifth Amended and Restated Limited Liability Company Agreement of Rani Therapeutics, LLC, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022).
10.5+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.6+	Rani Therapeutics, LLC 2016 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.7+	Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
10.8+	Forms of Agreement under the Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022).
10.9+	Rani Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
10.10+	Rani Therapeutics Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.11+	Form of Participation Agreement under the Rani Therapeutics Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.12+	Rani Therapeutics Holdings, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 16, 2021).

10.13+	Service Agreement, by and between Rani Therapeutics, LLC and InCube Labs, LLC, dated January 1, 2021 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.14+	Amendment No. 1 to Service Agreement, dated March 21, 2022, by and between Rani Therapeutics, LLC and InCube Labs, LLC (incorporated by reference to Exhibit 10.14 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.15*+	Amendment No. 2 to Service Agreement, dated March 15, 2024, by and between Rani Therapeutics, LLC and InCube Labs, LLC.
10.16+	Service Agreement, by and between Rani Management Services, Inc. and InCube Labs, LLC, dated January 1, 2021 (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.17*+	Amendment No. 1 to RMS Service Agreement, dated March 15, 2024, by and between Rani Therapeutics, LLC and InCube Labs, LLC.
10.18+	Amended and Restated Exclusive License Agreement, by and between Rani Therapeutics, LLC and InCube Labs, LLC, dated June 22, 2021 (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.19+	Non-Exclusive License Agreement, by and between Rani Therapeutics, LLC and InCube Labs, LLC, dated June 22, 2021 (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.20+	Intellectual Property Agreement, by and between Rani Therapeutics, LLC and Mir A. Imran, dated June 22, 2021 (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.21+	Amended and Restated Employment Agreement, dated August 31, 2022, by and between Rani Therapeutics, LLC and Talat Imran (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on form 10-K for the year ended December 31, 2022, filed with the SEC on March 22, 2023).
10.22+	Amended and Restated Employment Agreement, dated August 31, 2022, by and between Rani Therapeutics, LLC and Mir Hashim (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on form 10-K for the year ended December 31, 2022, filed with the SEC on March 22, 2023).
10.23+	Amended and Restated Employment Agreement, dated August 31, 2022, by and between Rani Therapeutics, LLC and Svai Sanford (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on form 10-K for the year ended December 31, 2022, filed with the SEC on March 22, 2023).
10.24+	Employment Agreement, dated April 12, 2022, by and between Rani Therapeutics, LLC and Eric Groen (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 11, 2022).
10.25+x	Employment Agreement, dated May 17, 2023, by and between Rani Therapeutics, LLC and Kate McKinley (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 11, 2023).
10.26	Loan and Security Agreement, dated August 8, 2022, by and among the Registrant, its subsidiaries Rani Therapeutics, LLC and Rani Management Services, Inc., and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.27	Supplement to the Loan and Security Agreement, dated August 8, 2022, by and among the Registrant, its subsidiaries Rani Therapeutics, LLC and Rani Management Services, Inc., and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.28	Form of Warrant to purchase shares of Class A common stock of Registrant, issued to Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.29	Controlled Equity℠ Sales Agreement, dated August 24, 2022, by and among Rani Therapeutics Holdings, Inc., and Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 25, 2022).
10.30x	License and Supply Agreement by and between Rani Therapeutics, LLC and Celltrion, Inc. dated January 6, 2023 (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 22, 2023).
10.31x	License and Supply Agreement by and between Rani Therapeutics, LLC and Celltrion, Inc. dated May 26, 2023 (incorporated by reference to Exhibit.10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 11, 2023).
10.32x	Standard Industrial/Commercial Multi-Tenant Lease – Net, by and between Rani Therapeutics, LLC and BKM South Bay 240, LLC, dated as of November 1, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the SEC on November 8, 2023).

21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney. Reference is made to the signature page hereto.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
† The certifications attached as Exhibit 32.1 which accompanies this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-K), irrespective of any general incorporation language contained in such filing.
+ Indicates management contract or compensatory plan.
x Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Rani Therapeutics Holdings, Inc.

Date: March 20, 2024

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Talat Imran and Svai Sanford, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Talat Imran Talat Imran	Chief Executive Officer and Director *(Principal Executive Officer)*	March 20, 2024
/s/ Svai Sanford Svai Sanford	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 20, 2024
/s/ Mir Imran Mir Imran	Chairman of the Board	March 20, 2024
/s/ Dennis Ausiello Dennis Ausiello	Director	March 20, 2024
/s/ Jean-Luc Butel Jean-Luc Butel	Director	March 20, 2024
/s/ Laureen DeBuono Laureen DeBuono	Director	March 20, 2024
/s/ Andrew Farquharson Andrew Farquharson	Director	March 20, 2024
/s/ Maulik Nanavaty Maulik Nanavaty	Director	March 20, 2024
/s/ Lisa Rometty Lisa Rometty	Director	March 20, 2024

Exhibit 10.15

Amendment No. 2 to Service Agreement

This Amendment No. 2 to Service Agreement ("the "**Amendment**") is made and entered into effective as of March 1, 2024 (the "**Amendment Effective Date**") by and between InCube Labs, LLC, a Delaware limited liability company ("**InCube**"), and Rani Therapeutics, LLC, a California limited liability company ("**Rani**"), each a "Party" and collectively the "**Parties**."

WHEREAS, the Parties entered into a Service Agreement effective as of January 1, 2021, amended by Amendment No. 1 to Service Agreement (as amended, the "**Service Agreement**") for the purpose of providing and/or receiving certain services between the Parties; and

WHEREAS, the Parties desire to amend the Service Agreement as set forth herein;

NOW, THEREFORE, in consideration of the mutual promises contained herein, and intending to be bound hereby, the Parties agree as follows:

1. Defined Terms . Capitalized terms used but not defined in this Amendment shall have the meanings assigned to such terms in the Service Agreement.

2. Occupancy Services . The Parties agree that Provider will provide Occupancy Services to Recipient as set forth in Appendix 1 to this Amendment.

3. Miscellaneous . This Amendment may be executed in counterparts, each of which will be deemed an original, but all of which together will be deemed to be one and the same agreement. This Amendment may be executed by electronic signatures (e.g., using DocuSign or e-SignLive) or signatures transmitted by electronic means (e.g., facsimile, email, pdf format), each of which shall be deemed a valid and enforceable signature and means of delivery . Neither Party may assign or otherwise transfer this Amendment except in connection with a permitted assignment of the Service Agreement. Subject to the foregoing, this Amendment shall bind and inure to the benefit of the Parties hereto and their successors and assigns. This Amendment shall be governed by the laws of the state of California without reference to conflict of laws principles. Resolution of any dispute under or related to this Amendment shall be subject to and handled in accordance with the dispute resolutions set forth in Section 15 of the Service Agreement. This Amendment, together with the Service Agreement, contains the entire understanding and agreement between the Parties with respect to the subject matter hereof. Headings are included for convenience only and shall not be used in interpreting this Amendment. If any provision of this Amendment is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. Any failure to enforce any provision of this Amendment shall not constitute a waiver thereof or of any other provision. This Amendment may not be amended, nor any obligation waived, except by a writing signed by both Parties hereto.

[signature page immediately follows]

IN WITNESS WHEREOF, each Party hereto has caused this Amendment to be signed by its duly authorized representative.

InCube Labs, LLC Rani Therapeutics, LLC

By: /s/ Mir Imran By: /s/ Svai Sanford

Name: Mir Imran Name: Svai Sanford

Title: Chairman and CEO Title: Chief Financial Officer

Date: March 15, 2024 Date: March 14, 2024

Appendix 1 to Exhibit A – Occupancy Services for 518 Sycamore Dr.

1. **PROVIDER** : InCube Labs, LLC

2. **RECIPIENT** : Rani Therapeutics, LLC

3. **PREMISES** : Approximately 11,331 square feet of 20,626 square feet within a building (the “Building”) located at 518 Sycamore Dr., Milpitas, CA

4. **COMMENCEMENT** : The occupancy shall have an effective date of March 1, 2024.

5. **OCCUPANCY** : Recipient shall occupy on an exclusive basis the portion of the Building that constitutes the Premises, and Recipient shall share use of the common areas of the Building (e.g., two restrooms, kitchen, and lobby) with Provider.

6. **RENT** : Recipient shall pay $32,750.00 per month for the term. Provider can invoice on a monthly basis.

7. **PARKING** : Recipient shall have the right to use 46 parking spaces on site at no cost for the duration of the Occupancy Services for the Premises.

8. **USE** : The Premises shall be used and occupied for general office, research and development, light manufacturing, and any such other purposes as are permitted under Provider’s lease.

9. **TERM** : The term shall be March 1, 2024 through August 31, 2024.

10. **OPERATING EXPENSES** : Recipient shall pay a common area maintenance charge of $0.25 per square foot per month, which is subject to true up (based on Recipient’s pro rata percentage of the overall leased space (“Recipient’s Share”)) and landlord adjustment. Any adjustment to the charge by the landlord will be passed through based on Recipient’s Share.

11. **SHARED COSTS** : Recipient shall bear Recipient’s Share and Provider shall bear Provider’s Share of third-party service Shared Costs, except that the cost of office supplies shall be shared between Provider and Recipient based on estimated usage, considering the number of people of each party in the Building utilizing office supplies and the nature of the work performed by each party in the Building.

12. **STORAGE:** Provider rents certain storage space near the Premises. Recipient shall have a right to utilize such storage space and agrees to pay the rental fee for such storage space for the current term plus one month.

13. **EQUIPMENT** : Provider will permit Recipient to use the equipment located at the Premises (for clarity, excluding equipment in the Building used within the business of Modulus in the ordinary course) without additional charge, including without limitation, lab tables, microscopes, and other equipment (ovens, etc.), cubicles, monitors, docking stations, and printers.

14. **TRUE-UP** : Recipient will be billed at the end of the term (August 31, 2024) for the Recipient’s portion of the true-up of CAM (common area maintenance) charges that the Provider is billed by Provider’s landlord.

Exhibit 10.17

Amendment No. 1 to RMS Service Agreement

This Amendment No. 1 to Service Agreement ("the "**Amendment**") is made and entered into as of the date of the last signature below (the "**Amendment Effective Date**") by and between InCube Labs, LLC, a Delaware limited liability company ("**InCube**"), and Rani Therapeutics, LLC, a California limited liability company ("**Rani**"), each a "Party" and collectively the "**Parties**."

WHEREAS, InCube and Rani Management Services, Inc. ("**RMS**") entered into a Service Agreement effective as of January 1, 2021 (the "**Service Agreement**") for the purpose of providing and/or receiving certain services between the Parties; and

WHEREAS, RMS assigned to Rani, and Rani assumed from RMS, the Service Agreement pursuant to an Assignment and Assumption Agreement made and effective as of April 1, 2022;

WHEREAS, the Parties desire to amend the Service Agreement as set forth herein;

NOW, THEREFORE, in consideration of the mutual promises contained herein, and intending to be bound hereby, the Parties agree as follows:

1. Defined Terms. Capitalized terms used but not defined in this Amendment shall have the meanings assigned to such terms in the Service Agreement.

2. Occupancy Services. Effective as of the Amendment Effective Date, Exhibit A of the Service Agreement is hereby amended by replacing Exhibit A of the Service Agreement with Exhibit A attached to this Amendment.

3. Miscellaneous. This Amendment may be executed in counterparts, each of which will be deemed an original, but all of which together will be deemed to be one and the same agreement. This Amendment may be executed by electronic signatures (e.g., using DocuSign or e-SignLive) or signatures transmitted by electronic means (e.g., facsimile, email, pdf format), each of which shall be deemed a valid and enforceable signature and means of delivery. Neither Party may assign or otherwise transfer this Amendment except in connection with a permitted assignment of the Service Agreement. Subject to the foregoing, this Amendment shall bind and inure to the benefit of the Parties hereto and their successors and assigns. This Amendment shall be governed by the laws of the state of California without reference to conflict of laws principles. Resolution of any dispute under or related to this Amendment shall be subject to and handled in accordance with the dispute resolutions set forth in Section 15 of the Service Agreement. This Amendment, together with the Service Agreement, contains the entire understanding and agreement between the Parties with respect to the subject matter hereof. Headings are included for convenience only and shall not be used in interpreting this Amendment. If any provision of this Amendment is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. Any failure to enforce any provision of this Amendment shall not constitute a waiver thereof or of any other provision. This Amendment may not be amended, nor any obligation waived, except by a writing signed by both Parties hereto.

IN WITNESS WHEREOF, each Party hereto has caused this Amendment to be signed by its duly authorized representative.

InCube Labs, LLC Rani Therapeutics, LLC

By: /s/ Mir Imran By: /s/ Svai Sanford

Name: Mir Imran Name: Svai Sanford

Title: Chairman and CEO Title: Chief Financial Officer

Date: March 15, 2024 Date: March 14, 2024

Exhibit-A

Service Rates – 2024

Any modification to, or replacement of, this Exhibit A must be made in accordance with Section 16.2 of this Agreement.

Definitions:

- The "**InCube Facility**" is the building and grounds (including parking spaces) at 2051 Ringwood Ave., San Jose, CA 95131.
- "**Markup**" = 25% = 0.25
- "**Fringe**" = 22% = 0.22
- "**Hourly Billing Rate**":
    - for salaried employees, Hourly Billing Rate = (salary/2080) x (1 + Markup + Fringe)
    - for hourly employees, Hourly Billing Rate = (hourly wage) x (1 + Markup + Fringe)
- "**Actual Hours**" = actual hours incurred by Provider's employees on the requested Services, limited for salaried employees to 40 hours total per week per individual for all provided Services combined; and PTO, Flex, sick, holiday, bereavement, jury duty, or other time-off hours are not to be included in Actual Hours

Service	Obligations; Charges
Occupancy	The effective date for Occupancy Services is January 1, 2024. Premises: InCube will make available to Rani Therapeutics, LLC ("**Rani**") as its Exclusive Portion approximately 24,000 square feet of the InCube Facility (including offices, work cubicles, laboratories, and manufacturing areas), which constitutes the entire InCube Facility. There will be no Shared Portion. Invoice: InCube can invoice to Rani an amount equal to $60,000 per month (calculated at $2.50 per square foot). Tax and insurance: Rani will pay to InCube the insurance and real property tax on the InCube Facility. Real property tax includes any charge, levy, assessment, or fee imposed by any authority having direct or indirect power to tax, including, without limitation, any city, county, state or federal government, or any improvement district. Invoice: InCube can invoice to Rani an amount equal to $7,600 per month initially. The Parties will true-up the actual tax and insurance at least quarterly and may then adjust the monthly payment to reflect estimated costs for the next quarter. Additional parking: InCube will provide Rani with extended parking capability under the parking license agreement between InCube and McNeal Enterprises, Inc. ("**McNeal**"). RMS and InCube executed a Parking Agreement dated January 1, 2021, which was assigned by RMS to Rani effective July 1, 2022 pursuant to an Assignment and Assumption Agreement. Rani will directly pay McNeal the sum of $1,850 per month, and Rani agrees to pay any increased amount that may be charged by McNeal, or any additional amount McNeal may charge for additional parking spaces that may be requested by Rani. Time of access to the extended parking may be limited by McNeal as acknowledged by Rani.

Administrative	None specified.
Personnel (other than Administrative)	Rani may provide Personnel Services to InCube upon request subject to availability of resources. Invoice: • Rani can invoice InCube for all Personnel Services performed by its employees, using the following formula: Invoiced amount = (Actual Hours) x (Hourly Billing Rate). • Rani can invoice InCube all amounts paid to a Subcontractor of Rani to perform the Personnel Services, without markup. • Rani can invoice InCube for Out-of-Pocket Costs related to performance of the Personnel Services, without markup.
Special	Either Party (as Provider) may provide Special Services to the other Party (as Recipient) upon request subject to availability of resources. Invoice: • Provider can invoice for all Special Services performed by its employees using the following formula: Invoiced amount = (Actual Hours) x (Hourly Billing Rate). • Provider can invoice Recipient all amounts paid to a Subcontractor of Provider to perform the Special Services, without markup. • Provider can invoice Recipient for Out-of-Pocket Costs related to performance of the Special Services, without markup.

Exhibit 21.1

List of subsidiaries of Rani Therapeutics Holdings, Inc.

Name of Subsidiary	Jurisdiction of Organization
Rani Therapeutics, LLC	California, United States of America

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statements (Form S-3 Nos. 333-266444 and 333-268855) of Rani Therapeutics Holdings, Inc., and

2. Registration Statements (Form S-8 Nos. 333-258415 and 333-264018) pertaining to the Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan, the Rani Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan and the Rani Therapeutics, LLC 2016 Equity Incentive Plan of Rani Therapeutics Holdings, Inc.;

of our report dated March 20, 2024, with respect to the consolidated financial statements of Rani Therapeutics Holdings, Inc. included in this Annual Report (Form 10-K) of Rani Therapeutics Holdings, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Francisco, California
March 20, 2024

Exhibit 31.1

CERTIFICATION

I, Talat Imran, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rani Therapeutics Holdings, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 20, 2024

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

Exhibit 31.2

CERTIFICATION

I, Svai Sanford, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rani Therapeutics Holdings, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 20, 2024

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 20, 2024

In Witness Whereof, the undersigned have set their hands hereto as of the 20th day of March, 2024.

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

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

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