UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended March 31, 2025

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 001-38596

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-2082553**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

500 Unicorn Park Drive

Suite 303

Woburn MA 01801

(Address of principal executive offices)
(Zip Code)

(781) 222-9600

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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, a 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 Act). Yes ☐ No ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $523.2 million, based on the closing price of the registrant's Common Stock on September 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter.

There were 77,086,750 shares of Common Stock outstanding as of May 19, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended March 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

REPLIMUNE GROUP, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended March 31, 2025

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Special note regarding forward-looking statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, including statements regarding our expectations about our cash runway, the design and advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, and other statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include, among other things:

- the timing, progress, and results of preclinical studies and clinical trials for our product candidates, including the timing of initiation and completion of studies or trials and related preparatory work and the period during which the results of the trials will become available;
- our ability to obtain additional funding as necessary;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of approval by the U.S. Food and Drug Administration, or the FDA, of, RP1 or any of our other product candidates;
- the timing, scope, or likelihood of foreign regulatory filings and approvals;
- our ability to develop our product candidates for use in combination with other checkpoint blockade therapies, including anti-PD-1;
- our ability to develop and advance any future product candidates into, and successfully complete, clinical trials;
- our expectations regarding the size of the patient populations for RP1, RP2 and/or RP3 or any other product candidates from our RPx platform if approved for commercial use;
- our ability to successfully qualify, obtain approval for, and maintain successful operation, approval and qualification of our in-house manufacturing operations;
- our ability to obtain and maintain sufficient quantities of raw material supplies or access single or limited sources of goods or services needed to build or maintain our product candidate supplies or otherwise operate our in-house manufacturing facility;
- the costs of operating our in-house manufacturing facility;
- our estimates regarding expenses and capital requirements;
- the implementation of our business model and our strategic plans for our business, RP1 and our other product candidates;
- the rate and degree of market acceptance and clinical utility of RP1 and our other product candidates;
- the potential benefits of and our ability to establish or maintain future collaborations or strategic relationships;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation of any third-party intellectual property rights;
- our competitive position, and developments and projections relating to our competitors and our industry;
- negative developments in the fields of immuno-oncology or oncolytic immunotherapy;
- the impact of laws and regulations; and
- the other risks and uncertainties described under "Risk factors."

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Annual Report on Form 10-K. Moreover, we operate in a competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except to the extent required by applicable law. You should not rely on forward-looking statements as predictions of future events. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

PART I

Item 1. Business

Overview

We are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients through our novel oncolytic immunotherapies. Our proprietary oncolytic immunotherapy product candidates are designed and intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy is an emerging drug class. Oncolytic immunotherapy exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Our product candidates incorporate multiple mechanisms into a practical “off-the-shelf” approach that is intended to maximize the immune response against a patient’s cancer and to offer significant advantages over other approaches to inducing anti-tumor immunity. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will increase clinical efficacy and simplify the development path of our product candidates, while also improving patient outcomes.

Our proprietary RPx platform is based on a novel, engineered strain of herpes simplex virus 1, or HSV-1, backbone with payloads added that are intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform is intended to have unique dual local and systemic activity consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor-derived antigens and altering of the tumor microenvironment to ignite a strong and durable systemic response. Our product candidates are expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform is expected to have the versatility to be developed alone or combined with a variety of other treatment options. We currently have three RPx product candidates in our development pipeline, RP1 (vusolimogene oderparepvec), our lead product candidate, RP2 and RP3. Although our fiscal year ends March 31st, our programs and program updates are reported on a calendar year basis.

We are conducting a number of clinical trials of RP1, both as a monotherapy and in combination with anti-PD-1 therapy, with the goal of establishing a major skin cancer treatment franchise.

Our leading clinical trial of RP1 is referred to as the IGNYTE trial, which is a multi-cohort clinical trial being conducted in collaboration with Bristol Myers Squibb Company, or BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1.

The leading tumor specific cohort in the IGNYTE trial is our registration directed Phase 2 expansion cohort in anti-PD-1 failed cutaneous melanoma. The anti-PD-1 failed melanoma cohort from the IGNYTE trial includes 140 patients who received RP1 in combination with nivolumab. The primary analysis by independent central review was triggered once all patients had been followed for at least 12 months. The topline results showed the overall response rate, or ORR, was 33.6% by modified RECIST 1.1 criteria, the primary endpoint as defined in the protocol, and 32.9% by RECIST 1.1 criteria, an additional analysis requested by the FDA. Responses from baseline were highly durable with 85% of responses lasting more than 12 months. The median duration of response from baseline was 27.6 months and the median duration of response from treatment initiation was 21.6 months. RP1 combined with nivolumab continues to be well-tolerated, with mainly Grade 1-2 "on target" side effects, observed. In September 2024, we presented the independently reviewed data from the IGNYTE trial, including key secondary endpoints and subgroup analysis as a late-breaking abstract during an oral session at the European Society for Medical Oncology, or ESMO. Data presented at ESMO showed activity across all subgroups, including patients who had prior anti-PD-1 and anti-CTLA-4 treatment had an ORR of 27.7% and patients who had primary resistance to anti-PD-1 had an ORR of 35.9% by modified RECIST v1.1. In November 2024, we presented a late-breaking abstract featuring the IGNYTE trial primary analysis that had been selected for oral presentation at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2024). The data presented at SITC 2024 included further clinical subgroup and initial biomarker data from the IGNYTE trial.

In November 2024, we announced submission of a biologics license application, or BLA, to the FDA for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD-1 containing regimen and that the FDA has granted Breakthrough Therapy designation to RP1 in combination with nivolumab in the same setting. The submission was made under the accelerated approval pathway. The FDA accepted our BLA and granted priority review with a Prescription Drug User Fee Act, or PDUFA, goal date of July

22, 2025. The FDA recently completed their late-cycle review meeting and all manufacturing inspections for the BLA and we believe we remain on track for the July 22, 2025 PDUFA date.

In August 2024, we announced the dosing of the first patient in the IGNYTE-3 trial, or the I-3 trial, a confirmatory study design concept consisting of a 2-arm randomized Phase 3 clinical trial with physician's choice of treatment as a comparator arm in anti-PD-1 failed melanoma patients. With over 100 sites planned globally and an expectation to enroll 400 patients, the I-3 trial will assess RP1 in combination with nivolumab in patients with advanced melanoma who have progressed on anti-PD-1 and anti-CTLA-4 therapies or are ineligible for anti-CTLA-4 treatment. We continue to enroll patients in the I-3 trial.

In our non-melanoma skin cancer, or NMSC, cohort of the IGNYTE trial, we provided a data update in December 2023 from the first 30 patients with at least 6 months of follow up including patients with cutaneous squamous cell carcinoma, or CSCC, Merkel cell carcinoma, or MCC, basal cell carcinoma, and angiosarcoma in this cohort. The data showed that treatment with RP1 in combination with nivolumab led to an ORR of 30% which is consistent with data from the anti-PD-1 failed melanoma cohort with approximately one-third of patients responding and 60% demonstrating clinical benefit. The combination of RP1 and nivolumab was well tolerated in this patient population with a safety profile consistent with the overall experience seen with this treatment regimen to date. Enrollment remains open in this cohort.

Furthering development of RP1, we have open for enrollment a Phase 1b/2 clinical trial of single agent RP1 in solid organ transplant recipients with skin cancers, including CSCC, which we refer to as the ARTACUS trial. We believe that the ARTACUS trial will be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients, including as a potential label expansion after an initial approval of RP1 in a different indication). We are currently enrolling up to 65 patients in the ARTACUS trial to assess the safety and efficacy of RP1 in liver, kidney, heart, lung, and hematopoietic cell transplant patients with skin cancers. In November 2023 we presented initial data from the ARTACUS trial of RP1 monotherapy in solid organ transplant recipients with skin cancers at the Society for Immunotherapy of Cancer’s, or SITC, 38th Annual Meeting. The data included 23 evaluable patients with CSCC (n=20) and MCC (n=3), demonstrating an ORR of 34.5% and a complete response, or CR, of 21%. RP1 monotherapy was well tolerated in these patients and the safety profile was similar to that observed in our other RP1 clinical trials in patients who are not immune suppressed. No immune-mediated adverse events or evidence of allograft rejection were observed to result from RP1. This data was also presented during oral presentation at the American Association of Cancer Research 2024 Annual Meeting in April 2024. We continue to enroll patients into the ARTACUS trial.

As previously reported, our clinical trial of RP1 in patients with CSCC, which we refer to as the CERPASS trial, continues as planned to follow patients that were dosed in the trial.

We are also developing or are continuing to develop additional product candidates, RP2 and RP3, that have been further engineered to enhance anti-tumor immune responses and are intended to address additional tumor types, including traditionally less immune responsive tumor types. In addition to the expression of GALV-GP R(-) and human GM-CSF as in RP1, RP2 has been engineered to express an antibody-like molecule intended to block the activity of CTLA-4, a protein that inhibits the full activation of an immune response, including to tumors. RP3 has been engineered with the intent to further stimulate an anti-tumor immune response through activation of immune co-stimulatory pathways through the additional expression of the ligands for CD40 and 4-1BBL, as well as anti-CTLA-4 and GALV-GP R(-), but without the expression of GM-CSF.

We continue the development of our product candidate RP2 with the goal of moving beyond skin cancers and aiming to treat the more prevalent tumor types commonly found in liver and lung metastasis and including those involving primary liver cancer. Notably, as previously reported, from our Phase-1 clinical trial of RP2 alone and in combination with nivolumab, we have seen durable responses from a monotherapy cohort in a variety of difficult to treat tumors as well as in combination with anti-PD1 and in particular in patients with metastatic uveal melanoma, or mUM. In November 2023, we presented updated data from a cohort of mUM patients during a Plenary Session at the 20th Annual International Society for Melanoma Research Congress. The updated data showed RP2 led to an ORR of 29.4% (5 of 17 patients; one of the responding patients was treated with RP2 monotherapy and four of the responding patients were treated with RP2 combined with nivolumab), including responses in patients with liver, lung, and bone metastases. The median DOR at the data cutoff was 11.47 months (range of 2.78 to 21.22 with responses ongoing). Nearly all patients (15 of 17, 88.2%) in the study had progressed on or after immunotherapy with 12 of 17 patients (70.6%) having previously received both anti-PD1 and anti-CTLA-4 therapies, including four of the responding patients. RP2 was generally well tolerated both as monotherapy and in combination with nivolumab with no additive adverse events observed. The most common grade 1 or 2 treatment related adverse events, or TRAEs, overall in both cohorts were pyrexia, chills, fatigue, hypotension and pruritis. Six patients had grade 3 TRAEs, including two cases of hypotension. There were no grade 4 or 5 TRAEs. In June 2024, we presented that the disease control rate for this cohort of mUM patients was 58.8%.

We have initiated and are enrolling patients in a registration-directed study, or the REVEAL study, of RP2 in mUM patients who are immune checkpoints inhibitor-naive. The REVEAL study is a randomized, phase 2/3 open label study to investigate the efficacy and safety of RP2 in combination with nivolunab vs. ipilimumab in combination with nivolunab in immune checkpoint inhibitor naive adult patients with metastatic uveal melanoma.

We continue our signal finding trial of RP2 in combination with atezolizumab and bevacizumab in the 2L setting of patients with hepatocellular carcinoma, or HCC, in collaboration with Roche. This Phase 2 clinical trial is currently open and enrollment is underway.

RP1, RP2 and RP3 are administered by direct injection into solid tumors, guided either visually or by ultrasound, computerized tomography or other imaging methods. We believe that direct injection maximizes virus-mediated tumor cell death, provides the most efficient delivery of virus-encoded immune activating proteins into the tumor with the goal of activating systemic immunity, and limits the systemic toxicities that could be associated with intravenous administration. Activation of systemic immunity through local administration is intended to lead to the induction of anti-tumor immune responses leading to clinical response of tumors that have not themselves been injected.

Our approach — Oncolytic immunotherapy

Our product candidates are designed to induce a robust immune response against a patient's cancer. To achieve this objective, we use oncolytic immunotherapies that combine multiple mechanisms in a single product candidate. We believe our product candidates will initiate or enhance an immune response in patients with no or minimal pre-existing cancer immunity, including to tumor neo-antigens, and thereby increase the effectiveness of immune checkpoint blockade therapies.

Our product candidates are intended to act at several key points in the pathways involved in the initiation of an immune response. Following direct injection into tumors, our viruses are intended to replicate in cancer cells and then lyse, or break them open, releasing tumor antigens, including neo-antigens specific to the patient, which could otherwise be hidden from the immune system. This process of necrotic cell death releases intra-cellular markers of "danger," the danger associated molecular patterns, or DAMPs, while the virus produces pathogen associated markers of danger, or PAMPs. These trigger various pathways of the innate immune system, including the STING pathway and pathways mediated through toll-like receptors, or TLRs, each resulting in the production of interferon. Innate immune activation would be expected to itself provide anti-tumor effects, as interferon activates natural killer cells which can destroy tumor cells. Innate immune activation would also be expected to help trigger adaptive anti-cancer immunity, in which antigen presenting cells, or APCs, are attracted to the injected tumor. APCs internalize cancer antigens, including neo-antigens, and traffic back to the draining lymph nodes where they present the antigens to T cells. Primed with the antigens, these T cells then proliferate and disperse systemically to seek and destroy cancer cells with the same antigen profile throughout the body, resulting in the potential destruction of distant tumor deposits.

To further augment these intended effects, our product candidates are genetically encoded with multiple strong, cell-killing and immune-stimulating proteins — in other words, our product candidates are "armed" with these therapeutic genes. The foundation of our oncolytic immunotherapy product candidates consists of a proprietary strain of HSV-1 that we have engineered to replicate selectively in tumors and to express a fusogenic glycoprotein, a protein that triggers the fusion of the membranes between cells. HSV-1 is both highly cell lytic and inflammatory, and also has a large carrying capacity, which makes it possible to incorporate multiple genes encoding therapeutic proteins. We believe our combination of HSV-1 with the expression of the fusogenic glycoprotein increases the natural ability of HSV-1 to kill tumor cells and to induce an anti-tumor immune response. The fusogenic functionality of our product candidates is intended not only to increase the number of tumor cells that are killed, but also to cause highly immunogenic death of tumor cells. We believe that these factors will increase the potency of the systemic anti-tumor immune response that is generated by our product candidates. With the intention of further amplifying the anti-tumor response, we have also engineered product candidates that express a range of additional potent, immune activating genes encoding therapeutic proteins in tumors.

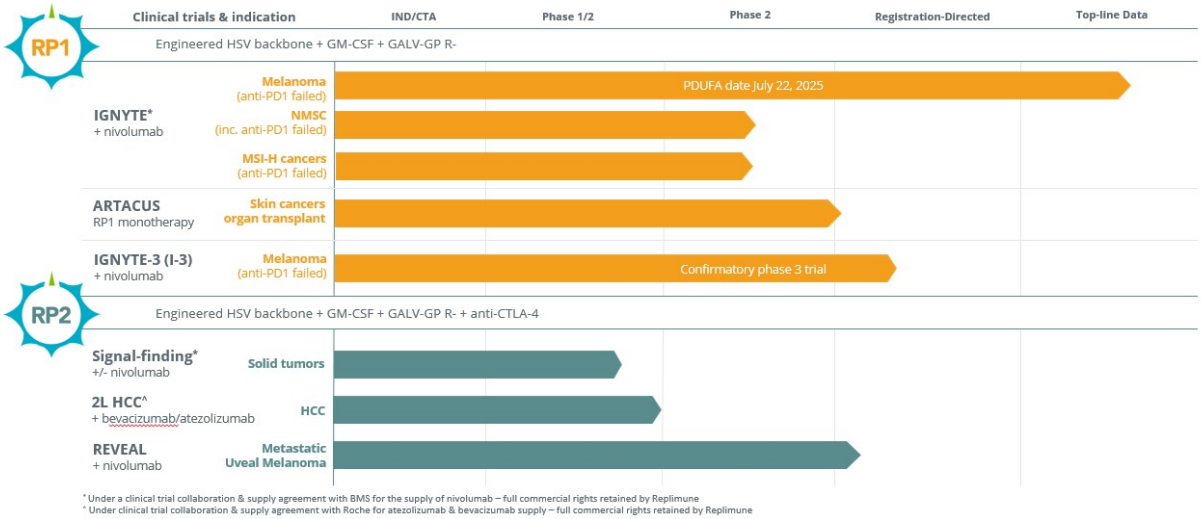
RP1 serves as our lead product candidate, with additional product candidates, RP2 and RP3, designed to express additional therapeutic proteins. We believe that our development approach of further enhancing our product candidates with additional therapeutic proteins reduces clinical risk, as we are able to study the safety profile of each therapeutic protein that is intended to provide more potent anti-tumor immune effects.

We believe that our ability to incorporate multiple mechanisms of action into a practical "off-the-shelf", or a pre-manufactured drug product, approach to initiating or enhancing an anti-tumor immune response, including to neo-antigens, will offer significant advantages over the various approaches to immune activation that are currently in development, including personalized vaccine treatments. Tumor neo-antigens are uniquely present in tumors, rather than normal tissue, because they

result from the genetic changes that occur as cancer develops. Unlike the antigens present in normal tissue, the immune system identifies neo-antigens as foreign. As a result, the immune system is able to mount an immune response to tumor neo-antigens in the same way that it would to the antigens contained in disease-causing micro-organisms, which the immune system also identifies as foreign. Researchers believe immune responses to tumor neo-antigens are particularly important in the immune system's ability to combat cancer, and as a consequence various "personalized vaccine" approaches to generating immune responses to tumor neo-antigens are in development. These approaches are generally both expensive and time consuming because a vaccine cannot be designed and manufactured until a tumor biopsy is taken and analyzed in the laboratory to identify the mutated tumor antigens that will be targeted by the treatment. We also believe that our "off-the-shelf" approach may offer significant advantages over other approaches to anti-cancer immune activation that only target a single pathway of the immune system, as is the case with most of the other immuno-oncology therapies currently under development. Importantly, our product candidates are intended to maximally activate an immune response against cancer, which we believe is the missing element needed to allow anti-PD-1 or anti-PD(L)-1 therapy to treat more patients and tumor types, unlike some other therapies that are intended to act by blocking additional defense mechanisms against an anti-tumor immune response once it has been initiated.

Our Oncolytic Immunotherapy platform and product candidates

Our current product candidate pipeline is summarized in the table below:



Lead product candidate: RP1

Our lead product candidate, RP1, is a selectively replicating version of HSV-1 that expresses GALV-GP R(-) and human GM-CSF. RP1 has the following properties:

- we have deleted the ICP34.5-encoding gene, which enables tumor-selective virus replication;
- we have deleted the ICP47-encoding gene, which is intended to prevent the inhibition of the antigen presentation pathway otherwise caused by ICP47 binding to the transporter associated with antigen presentation. ICP47 deletion is also intended to result in the increased and earlier expression of the HSV-1 US11 gene by placing the HSV-1 US11 gene under the control of ICP47 promoter which we believe will increase virus replication in tumors without reducing tumor-selectivity; and
- we have inserted the sequences for GALV-GP R(-) and human GM-CSF, resulting in the expression of these therapeutic proteins with the intention of increasing both the direct tumor cell killing and the potency of the anti-tumor immune response that is induced.

We have developed RP1 as a monotherapy and for use in combination with immune checkpoint blockade therapy, particularly therapies targeting PD-1 or PD-(L)-1. We believe that the robust release of tumor antigens and the highly immunogenic tumor cell death intended to be caused by RP1 will further increase the previously observed synergy between oncolytic viruses and immune checkpoint blockade therapy.

RP1 Leading Indications

Our lead indication for our lead product candidate, RP1, is the potential treatment of advanced melanoma, which is currently under BLA review with the FDA. Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease and occurs when cancer spreads beyond the surface of the skin to other organs. The incidence of melanoma has been increasing steadily for the last 30 years. Globally, the World Health Organization estimates that by 2035, melanoma incidence will reach 424,102, with 94,308 related deaths. We anticipate the commercial opportunity for RP1 to help improve the lives of patients with advanced melanoma is significant.

We estimate approximately 13,000 patients progress on or after PD-1 treatment annually in the U.S. with approximately 80% of these patients eligible for treatment with RP1 in combination with nivolumab, if approved. Importantly, we believe these treatments will take place in the outpatient setting, not require hospitalization and that nearly all of these patients are being treated in healthcare settings that have interventional radiology onsite or readily accessible, further supporting the anticipated rapid adoption of RP1.

Our following indications with our lead product candidate, RP1, include patients that develop skin cancers following a solid organ transplant. Individuals who receive an organ transplant face a significantly higher risk, greater than 50 times higher, of developing skin cancer following the transplant. These individuals are also on chronic immuno-suppressive treatments to reduce the risk of transplant rejection by their immune system. Adding to this risk for these individuals, anti-PD-1/L1 based cancer treatment options, which are approved and/or used in other skin cancer settings carry a high risk of transplant rejection, potentially leaving these patients without many treatment options.

We are also investigating RP1 as a potential product candidate for the treatment of non-melanoma skin cancers, or NMSC, which is a collection of common cancer types which occurs mainly in fair-skinned populations. About 80% of all NMSC are basal cell carcinomas, squamous cell carcinomas represent about 20%, with other diagnoses representing around 1% or less.

Pipeline product candidates: RP2 and RP3

We have designed our RP2 product candidate to express an anti-CTLA-4 antibody-like protein intended to block the inhibition of the immune response otherwise caused by CTLA-4. We believe that RP2 may offer advantages compared with current CTLA-4 approaches, including ipilimumab. By expressing anti-CTLA-4 only locally in the tumor and draining lymph nodes, we believe that activity will be retained, but that toxicity will be reduced. We expect that our RP2 product candidate will be used as monotherapy and/or in combination with other treatment approaches, including anti-PD-1 therapy, which, when used in combination, we believe will result in both synergy with the oncolytic immunotherapy and the expression of anti-CTLA-4 in the tumor.

RP2 Leading Indication

Uveal melanoma, or mUM, represents the predominant primary intraocular malignancy among adults, comprising over 95% of cases. Globally, the estimated annual incidence of mUM is approximately 4,800 individuals, with an estimated 1,700 new diagnoses occurring in the U.S. each year. Risk factors for developing mUM include fair skin, light-colored eyes, congenital ocular melanocytosis, melanocytoma, and the BAP1-tumour predisposition syndrome. It is estimated that greater than about 90% of mUM cases develop metastatic liver tumors. Historically, one-year survival rate of patients with distant metastases (such as liver metastases) is 15%, while reported median survival time is less than 1 year ranging from four to fifteen months. RP2 is currently being investigated in a randomized , phase 2/3 open label study to investigate the efficacy and safety of RP2 in combination with nivolunab vs. ipilimumab in combination with nivolunab in immune checkpoint inhibitor naive adult patients with metastatic uveal melanoma.

We have another product candidate in the portfolio as well and have designed our RP3 product candidate to express further immune-activating proteins that stimulate T cells, in addition to anti-CTLA-4 and GALV-GP R(-). These immune activating proteins are the ligands for two immune co-stimulatory pathways responsible for T cell proliferation and/or activation, the CD40L and 4-1BBL pathways. Due to program prioritization we are currently not pursuing further development of RP3 at this time.

Intellectual property

We believe our rights under our issued patents and, anticipated future patents from our patent applications, will provide a competitive advantage. Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from

infringing upon our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

For the core technology in our RPx platform and each of our product candidates, we initially filed six patent applications under the Patent Cooperation Treaty, or PCT. All six of these PCT applications have entered the national phase and are in different stages of pending and/or issued in a range of countries. Patent examination has started and continues in these national phase applications. Six U.S. patents have been granted by the applicable authorities in the U.S. Four patents have been granted by the applicable authorities in each of the European Union and Japan. Three patents have been granted by the applicable authorities in Hong Kong, two patents have been granted by the applicable authorities in each of China and Israel and one patent has been granted by the applicable authorities in each of Singapore, India, Mexico and Australia. The granted U.S. patents include US patent numbers 10,570,377; 10,612,005; 10,626,377; 10,947,513; 11,427,810; 11,473,063; 12,024,724; 12,049,647; and 12,059,444 and include description and claims directed to oncolytic virus compositions of matter, pharmaceutical compositions encompassing an oncolytic virus and methods of use in treating cancer with oncolytic virus compositions. We have successfully defended all oppositions that have been brought by third-parties against our issued patents to-date and have maintained our proprietary position. We continue to vigorously pursue advancement and defense of our patents and patent applications through the respective patent offices in which they are granted or pending throughout the world. See "*Risk factors - Risks Related to intellectual property.*"

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In many countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a portion of the patent term lost during the U.S. clinical development and FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under clinical development in the United States and the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, and if and when patents grant, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors, as well as physical security of our premises and our information technology systems.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We compete in the highly competitive markets that address cancer and face significant competition from many sources, including pharmaceutical, biopharmaceutical and biotechnology companies, as well as universities and private and public research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large biopharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs and biologicals. These companies also have significantly greater research capabilities than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or universities and research institutions.

Our competitors fall primarily into the following groups of treatment:

- traditional cancer therapies, including chemotherapy, surgery, radiation and targeted therapies;
- approved immunotherapy antibodies and immunotherapy antibodies in clinical trials;
- oncolytic immunotherapies, including T-Vec and other oncolytic immunotherapies in clinical trials;
- therapies aimed at activating innate immunity such as those targeting STING and TLRs;
- cancer vaccines including personalized vaccines and those targeting tumor neo-antigens; and

- cell-based therapies, such as TILs, CAR-T, T cell receptor-based, and natural killer cell therapies.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies, especially if these get to market sooner than our products. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Our oncolytic product candidates, if and when marketed, will compete with a number of drugs that are currently marketed or in development that also target cancer but that utilize a different mechanism of action. To compete effectively with these agents, our product candidates will need to demonstrate advantages that lead to improved clinical efficacy and safety compared with these competitors. At the same time, however, we believe that our oncolytic product candidates, if and when ultimately marketed, would likely be used principally in combination with checkpoint blockade therapies in addition to existing cancer therapies, including surgery, chemotherapy, radiation therapy and other biological therapies such as antibodies targeting particular surface receptors. We therefore believe that our product candidates, if and when marketed, would largely complement rather than compete directly with some of these existing treatment options.

We do, however, expect to face direct and increasing competition from a number of companies that are also seeking to develop cancer therapies based on oncolytic viruses and other ways to prime the immune system, including neo-antigen vaccination, TILs or the like. We believe that our ability to successfully compete will depend, among other things, on our ability to:

- expeditiously advance the development of our product candidates;
- design, enroll patients in and successfully complete appropriate clinical trials in a timely fashion;
- gain regulatory approval for our product candidates in their first indications as well as further indications;
- establish collaborations and partnerships for the development and marketing of our product candidates;
- commercialize our product candidates successfully, including demonstrating the safety and efficacy of our product candidates over currently approved therapies to physicians, insurers and third-party payors;
- secure sufficient coverage from insurers and other payors;
- secure, maintain and protect intellectual property rights based on our innovations; and
- manufacture or otherwise obtain and sell commercial quantities of future products to the market.

Manufacturing and suppliers

We have established an operations leadership team that we believe has extensive experience in manufacturing biologics based on viruses, including oncolytic products and gene therapy products and we operate our own in-house, approximately 63,000 square foot, U.S. based manufacturing facility in Framingham, Massachusetts. We operate our in-house manufacturing facility in order to secure our product candidates for our ongoing and planned clinical studies and, if approved, commercial launch and supply. The facility has been designed to allow us to produce enough material to cover full global commercialization of all our product candidates that are currently in development. The facility is intended to give us control over key aspects of the supply chain for our products and product candidates.

By controlling our own manufacturing facility, we aim to minimize or eliminate reliance on contract manufacturing organizations, which typically have limited capacity at commercial scale and long-lead time to conduct manufacturing campaigns. We believe that having control over the whole manufacturing process, in the U.S., will allow us to reduce cycle times, cost of goods for commercial production, other potential political or territorial cost efficiencies, and to shorten overall timelines for new product candidates in our development pipeline, as well as help us to develop drug formulations or presentations to simplify distribution and/or administration of future oncolytic immunotherapies. We also believe that having a dedicated manufacturing facility will allow us to optimize commercial-scale processes and to enhance security of supply to support market launch and commercialization of our product candidates, if approved. While we do control our own manufacturing facility, we rely on industry suppliers for raw materials and other process supplies, such as single-use manufacturing components, formulation components, sterile filters, bioreactors and other consumable components.

Sales and marketing

None of our product candidates have been approved for sale. If and when our product candidates advance closer to marketing approval, we intend to commercialize them on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. We may take different approaches to commercialization in different geographies. We continue to build our in-house sales, marketing and commercialization capabilities with the addition of sales, marketing, trade and distribution, as well as other related expertise. Clinical data, the size of the opportunity for our product candidates, and the size of the commercial infrastructure required will influence our commercialization plans and decision making.

Collaborations

BMS

In February 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with BMS. Pursuant to the agreement, BMS is providing to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at no cost to us, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us. In January 2020, the agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 failed melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (x) in the event of an uncured material breach by the other party, (y) in the event the other party is insolvent or in bankruptcy proceedings or (z) for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

In April 2019, we entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide, at no cost to us, nivolumab for use in our Phase 1 clinical trial of RP2 in combination with nivolumab.

Roche

In December 2022, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Roche in relation to our RP2 and RP3 programs in colorectal cancer, or CRC, and HCC. Under the agreement, the companies intended to collaborate in 30 patient cohort signal finding studies in third-line, or 3L, CRC and in first- and second-line, or 1L and 2L, respectively, HCC. Following our re-prioritization of our product development portfolio in December 2023, we have agreed with Roche to terminate the CRC collaboration and pursue the 2L cohort in HCC with RP2 only. Roche has continued to supply its currently approved drugs, atezolizumab and bevacizumab for the 2L cohort in HCC but is not sharing costs following our re-prioritization. Under the terms of the initial agreement we retained the responsibility of operating the clinical trials as well as retaining all the rights to the development and commercialization of our product candidates. The agreement may be terminated by either party upon sixty days prior written notice to the other party.

Regulatory matters

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import, and export of biopharmaceutical products such as those we are developing. In addition, manufacturers of biopharmaceutical products participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, and rebate requirements. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. Regulatory requirements are also continually evolving. By example, the FDA and governmental authorities in other countries have issued a growing body of guidance documents on various regulatory matters, including those specific to cell and gene therapy development. While FDA's guidance is not binding, it does provide FDA's current interpretation and approach.

FDA and EU regulation

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Services Act, or PHSA, and their implementing regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an institutional review board, or IRB, for each clinical site, or centrally, before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity, and potency of the proposed product candidate for its intended use, performed in accordance with good clinical practices, or GCPs;
- development and maintenance of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- preparation and submission to the FDA of a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection or remote regulatory assessment of the manufacturing facility or facilities at which the products are produced to assess compliance with current good manufacturing practices, or cGMPs, and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection or remote regulatory assessment of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

The process in the European Union and other countries with developed regulatory regimes is broadly comparable save that there is no dedicated BLA route in Europe as a Marketing Authorisation, or MAA, covers both small molecules, and biologics and cell and gene therapies.

Preclinical studies and IND submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA's and other countries' regulatory authorities' pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with GLPs. Recently, however, in the U.S., new methods of non-animal preclinical testing are being explored. For instance, in 2025, FDA outlined a stepwise plan to reduce animal testing in preclinical safety studies with scientifically validated new approach methodologies, or NAMs, which may include organ-on-a-chip systems, computational modeling, and advanced in vitro assays, and other data.

Prior to commencing the first clinical trial at a United States or other country's investigational site under and IND with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND (or equivalent in other countries). Additional preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of

the study by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. Sponsors will also be required to provide FDA with diversity action plans. In addition, an IRB at each study site participating in the clinical trial or a central IRB must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Special clinical trial ethical considerations also must be taken into account if a study involves children. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be added to the IND for FDA review and sent to the IRB for approval. If a product candidate is being investigated for multiple intended indications, separate INDs may also be required. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee, or DMC, that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

Moreover, certain studies involving recombinant and synthetic nucleic acid molecules are subject to review by Institutional Biosafety Committees, or IBCs, under the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

The manufacture of investigational biologics for the conduct of human clinical trials is subject to cGMP requirements. Investigational biologics and active ingredients imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as United States export requirements under the FDCA.

In general, for purposes of BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap, be divided, or be combined.

- Phase 1 — Trials are initially conducted in healthy human volunteers or subjects with the target disease or condition and test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of the activity of the product candidate.
- Phase 2 — Trials are conducted in limited subject populations with a specified disease or condition to evaluate the effectiveness of the product candidate for a particular indication or indications, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.
- Phase 3 — These adequate and well controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product for approval, to establish the overall risk benefit profile of the product, and to provide adequate information for the labeling of the product. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, approval may be based upon a single adequate and

well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

Additional kinds of data may also help to support a BLA, such as patient experience data and real-world evidence. Real world evidence may also be used to assist in clinical trial design. For appropriate indications sought through supplemental BLAs, data summaries may provide marketing application support. For genetically targeted products and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application. More recently, a program was established whereby a platform technology that is incorporated within or utilized by an approved drug or biologic product may be designated as a platform technology, provided that certain conditions are met and provided that the technology is considered a platform technology under FDA's definition, in which case development and approval of subsequent products using such technology may be streamlined.

Further, under certain circumstances, manufacturers and sponsors of investigational biopharmaceutical product candidates can provide access to the product candidates to certain qualifying patients outside of clinical trials. For instance, under the FDA's expanded access program, with FDA approval and subject to certain requirements, sponsors may provide access to product candidates to patients with serious or immediately life threatening diseases or conditions for which there is no comparable or satisfactory alternative therapy, provided that the potential patient benefit justifies the risks, the risks are not unreasonable in the context of the disease or condition to be treated, and the provision of the product candidate for the requested use will not interfere with clinical investigations. The specific expanded access criteria and requirements depend on the number of expanded access patients. Sponsors and investigators of expanded access programs must still comply with the FDA's clinical trial guidelines and are subject to subject protection regulations. Federal and state laws in the United States, referred to as right to try laws, also establish a separate mechanism through which certain patients with life threatening diseases or conditions, who have exhausted all approved treatment options and are unable to participate in a clinical trial, may request access to investigational product candidates that have completed a Phase 1 clinical trial. While certain criteria must be met for a patient to be eligible for access to product candidates under right to try laws, these laws do not require the FDA to approve the use of the product candidate and do not require compliance with the majority of the FDA's clinical trial regulations.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved to further assess the product's safety and effectiveness, and to ensure that population representative data is collected. These so-called Phase 4 trials may be made a condition to be satisfied after approval. The results of Phase 4 trials can confirm or refute the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trial in the United Kingdom and in so far as trials will be conducted in other countries with a view to obtaining a marketing authorization from the Medicines and Healthcare products Regulatory Agency, or MHRA, and the European Medicines Agency, there are broadly equivalent GLP, GCP, cGMP and ethical approval requirements. In the European Union, these rules are memorialized in the form of Regulations, which are directly enforceable in all European Union member states or Directives, which must be implemented nationally. However, enforcement of such rules is conducted by the regulatory authority in which the trial is carried out, which is the MHRA in the United Kingdom. With the full departure of the United Kingdom from the European Union in January 2021, the United Kingdom is not covered by the European Union Clinical Trial Regulation, in force since January 2022, which *inter alia* introduced a portal to streamline cross-border trial applications, and is instead subject to rules equivalent to the previous 2001 EU Clinical Trials Directive.

Combination products

Biologic products may be regulated as combination products if they are intended for use in conjunction with medical devices, such as a delivery device. In such cases, the use of the two products together (i.e., the biological product and the device) must be shown to be safe and effective for the proposed intended use, and, the labeling of the two products must reflect their combined use. In some cases, the device component may require a separate premarket submission; for example, when the device component is intended for use with multiple therapeutics. Sponsors of clinical studies using investigational devices are

required to comply with FDA's investigational device exemption regulations. Once approved or cleared, the sponsor of the device component submission (or the combination product submission, if both components are covered by one premarket submission) would need to comply with FDA's post-market device requirements, including establishment registration, device listing, device labeling, unique device identifier, quality system regulations, medical device reporting, and reporting of corrections and removals. In the European Union there are specific quality requirements for drug-device combinations.

BLA submission, review by the FDA, and marketing approval

Assuming successful completion of the required clinical and preclinical testing, the results of product development, including chemistry, manufacture, and controls, non-clinical studies, and clinical trial results, including negative or ambiguous results as well as positive findings, are all submitted to the FDA, along with the proposed labeling, as part of a BLA requesting approval to market the product for one or more indications. In most cases, the submission of a BLA is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness 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. Also, under the FDA Reauthorization Act of 2017, for applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a REMS to ensure that the benefits of the biologic outweigh the risks. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the biologic outweigh the risks.

Once the FDA receives an application, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review before it accepts the application for filing. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA has set the review goal of completing its review of 90% of all applications within ten months from the 60-day filing date for its initial review of a BLA. The FDA does not always meet its PDUFA goal dates for BLA submissions, and the review process may be extended if the FDA requests or the sponsor otherwise provides additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts, and may at times includes patients, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe, pure and potent and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, potency, and purity. Before approving a BLA, the FDA typically will inspect or conduct a remote regulatory assessment of the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA the FDA will inspect or conduct a remote regulatory assessment of one or more clinical trial sites to assure compliance with GCPs.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or CRL. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval, and describes all of the specific deficiencies that the FDA identified in the BLA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the BLA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. If a CRL is issued, the applicant may either: resubmit the BLA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with the pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

While there is no direct equivalent to the separate route for biologics, broadly equivalent requirements and controls similarly apply to the submission of pediatric testing and marketing authorization applications to the European Medicines Agency in the European Union and, post-approval, to the holding of such marketing authorizations, including conditionality.

Additional FDA expedited review and approval programs

FDA's fast track, priority review, accelerated approval, and breakthrough therapy programs are special programs and pathways at the agency that are intended to facilitate and expedite product development and approval. Product candidates 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 an unmet medical need. If a sponsor applies for and receives fast track designation, the designated product candidate may be eligible for more frequent FDA interactions as well as rolling review of sections of an application before the application is complete. To qualify for rolling review, the applicant must provide and FDA must approve a schedule for the submission of the full application. User fees must also be paid before FDA will commence its review of an application submitted on a rolling basis.

Priority review may be available to product candidates that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious condition. If a product receives priority review, FDA's PDUFA review goal is shortened to six months following FDA acceptance of a BLA, rather than the standard review of ten months.

Product candidates eligible for FDA's accelerated approval pathway are those that are intended to treat serious or life-threatening illnesses that provide meaningful therapeutic benefit to patients over existing treatments. Under this pathway, FDA may approve a marketing application based upon adequate and well-controlled clinical trials that evaluate a product candidate's effect on a surrogate endpoint, which is an endpoint that is reasonably likely to predict clinical benefit, or a product's effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality, taking into account the severity, rarity, or prevalence of the condition and availability or lack of alternative treatments. Products approved under the accelerated approval pathway must complete Phase 4 clinical trials to demonstrate the product's clinical benefit. By the date of approval of an accelerated approval product, FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. FDA may also, and frequently does, require that the confirmatory Phase 4 studies be commenced prior to FDA granting a product accelerated approval. If a Phase 4 study is not sufficiently advanced at the time of a marketing application, FDA can issue a complete response letter rather than approve the product. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to FDA every 180 days after approval. If the confirmatory Phase 4 studies fail

to verify the clinical benefit of the product, the FDA may withdraw approval of the application through a statutorily defined streamlined process. Failure to conduct the required Phase 4 confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject a sponsor to penalties. Promotional materials for a drug or biologic approved under the accelerated approval pathway are subject to FDA prior review.

A third program that may be available is the breakthrough therapy program, which is for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Breakthrough therapy products may be eligible for intensive FDA guidance on development programs as early as Phase 1 clinical trials, FDA organization commitment to involve senior managers and experienced review and regulatory management staff in a proactive collaborative, proactive, and cross-disciplinary reviews, and marketing application rolling review.

FDA designations may be rescinded if the applicable qualifying criteria are no longer met.

Biosimilars and exclusivity

The Biologic Product Competition and Innovation Act, or BPCIA, created an abbreviated approval pathway for biological products shown to be "biosimilar to" or "interchangeable with" an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires a high similarity to the reference product notwithstanding minor differences in clinically inactive components, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the FDA. There must be no difference between the reference product and a biosimilar in mechanism of action, conditions of use (though a biosimilar may be licensed for fewer indications than that of its reference product), route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The FDA has issued a number of guidance documents outlining its approach for review and approval of biosimilars, including guidance documents on the demonstration of interchangeability and the licensure of biosimilar and interchangeable products for fewer than all of the reference product’s licensed conditions of use.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product and not approved for another 8 years from the date of licensure of the reference product. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the twelve-year exclusivity period. The PHSA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

The FDA maintains a publicly-available online database of licensed biological products, which is commonly referred to as the “Purple Book”. The Purple Book lists product names, dates of licensure, and applicable periods of exclusivity. Further, pursuant to a statute to enable biological product patent transparency, the reference product sponsor must provide patent information and patent expiry dates to the FDA following the exchange of patent information between biosimilar and reference product sponsors. This information is then published in the Purple Book.

In the European Union there is a period of 10 years (or 11 years for significant new indications) of data exclusivity so that those seeking to market biosimilars cannot apply on an abridged basis for a marketing authorization for eight years from when the product was first marketed in the European Union and cannot place it on the market for 10 or 11 years from such first marketing although the European Union has proposed legislation reducing these exclusivity periods.

If approved, biologics may also be eligible for periods of United States patent term restoration. If a timely application is made and if granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life with the extension also cannot exceed fourteen years from the product’s approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a full marketing application, and all of the time between the submission of the full marketing application and its approval. This period may also be reduced by any time that the applicant did not act with due diligence.

In the European Union, a supplementary protection certificate, or SPC, can similarly extend a patent term for a maximum of five years. A further six-month additional extension is available if the SPC relates to a medicinal product for which data has been submitted according to a Pediatric Investigation Plan.

In an effort to increase competition in the biologic product marketplace, Congress, the executive branch, and FDA have taken certain legislative and regulatory steps. By way of example, measures have been proposed and implemented to facilitate product importation. Moreover, the 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved biologic products, including those subject to REMS, provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market-based terms. Failure to do so can subject the approved product sponsor to civil actions, penalties, and responsibility for attorney's fees and costs of the civil action. More recently, the U.S. President issued an Executive Order to require FDA to provide administrative and legislative recommendations to accelerate approval of biosimilar products.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, deviation reporting, shortage reporting, risk management plans, supply chain security, and periodic reporting, product distribution, advertising, marketing, promotion, certain electronic records and signatures, and post-approval obligations imposed as a condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA notice or review and approval. There also are continuing annual program user fee requirements for approved products. In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections or remote regulatory assessment by the FDA and these state agencies for compliance with cGMP and other requirements, which impose certain procedural and documentation requirements upon sponsors and third-party manufacturers. The information that must be submitted to FDA regarding manufactured products was expanded through the Coronavirus Aid, Relief, and Economic Security, or CARES, Act to include the volume of drugs produced during the prior year. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, require label modifications or request product recalls, among other actions, if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. Many states also regulate the distribution of drug product samples and commercial product.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to safety and efficacy, purity, and potency that are consistent with the FDA approved label. All promotional and advertising statements must further be truthful and non-misleading, adequately substantiated, and must contain a fair balance between product benefit and risk information. Recently, FDA has taken a few actions in the advertising and promotional spaces, including issuing a final rule and a guidance on risk and efficacy disclosures in direct to consumer advertising, and a guidance on communication of off-label scientific information about approved products. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Biopharmaceutical companies, however, are required to promote their products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, suspension and debarment from government procurement and non-procurement programs, and refusal of orders under existing government contracts.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the products to individuals and entities to which product ownership is transferred, are required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners must be transferred electronically. FDA is also phasing in requirements with respect to the interoperable exchange of electronic product tracing at the package level. Manufacturers must further verify that purchasers of the manufacturers' products are appropriately licensed. Additionally, under this legislation, manufactures have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements additionally are imposed through this legislation on other companies within the biopharmaceutical product supply chain, such as distributors and dispensers.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of a BLA. 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 significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, civil penalties, criminal fines and imprisonment, and result in adverse publicity, among other adverse consequences.

The FDA post-approval requirements are continually evolving. For example, in March 2020, the U.S. Congress passed the CARES Act, which includes various provisions regarding FDA drug shortage and manufacturing volume reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. As part of the CARES Act implementation, the FDA issued guidance on the reporting of the volume of drugs produced, which reporting will require additional administrative efforts by drug manufacturers. In recent years, both the U.S. Congress and the President have taken actions to encourage the use of domestic pharmaceutical suppliers.

Broadly equivalent requirements, controls and sanctions similarly apply to supply, QA, manufacture, labelling, advertising, pharmacovigilance and tracing of medicinal products as imposed by European Union laws and enforced by European Union national regulatory authorities.

Additional controls for biologics and oncology programs

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. There are also a number of additional standards that apply to oncolytic virus products. The FDA has issued various applicable guidance documents on factors that the agency considers during product development including, but not limited to, preclinical assessments; chemistry manufacturing and controls; and long-term patient and clinical study subject follow up and regulatory reporting. In the European Union, while there is no direct equivalent to the separate route for biologics, the EMA issues scientific guidelines on biological medicinal products and the standard Common Technical Document structure is modified for biologicals and plasma-derived products.

With respect to oncology product candidates, FDA has also established a number of different projects, intended to address different aspects of oncology development. For instance, FDA's Project Optimus is an initiative at FDA to reform dose optimization and selection. Project FrontRunner is aimed at encouraging drug sponsors to potentially pursue the development of products for earlier clinical settings, rather than for the treatment of patients who have received a number of different prior therapies. Project Confirm is a third FDA initiative, which aims to promote transparency regarding the outcomes related to accelerated approval products.

Other regulatory agencies may also regulate our use of biological materials, which may necessitate that we, our manufacturers, or other third parties with whom we work obtain permits and otherwise comply with regulatory requirements.

Fraud and abuse, data privacy and security, and transparency laws and regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare & Medicaid Services, or CMS and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws.

The federal Anti-Kickback Statute, which regulates, among other things, marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order, or the referral to another for the furnishing or arranging for the furnishing of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers, on the other, as well as to free trial and starter prescriptions provided through pharmacies. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Health and Human Services, or HHS, recently promulgated a regulation that is effective in two phases. First, the regulation excludes from the definition of "remuneration" limited categories of (a) PBM rebates or other reductions in price to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of sale reductions in price and (b) PBM service fees. Second, the regulation expressly provides that rebates to plan sponsors under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager will not be protected under the anti-kickback discount safe harbor. Recent legislation has delayed implementation of the aforementioned regulation until January 1, 2032. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the 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 of the facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, including purchases of products paid by federal healthcare programs, the statute has been violated. The ACA modified the intent requirement under the Anti-Kickback Statute to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, 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, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product's label, failure to comply with cGMP requirements, and allegations as to misrepresentations with respect to products, contract requirements and services

rendered. In addition, private payers have filed follow-on lawsuits alleging fraudulent misrepresentation. Intent to deceive is not required to establish liability under the civil False Claims Act. Civil False Claims Act actions may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into hundreds of millions of dollars. For these reasons, since 2004, civil False Claims Act lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as $3.0 billion, regarding certain sales practices and promoting off label uses. Civil False Claims Act liability may further be imposed for known Medicare or Medicaid overpayments that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, judgment for violating the civil False Claims Act may result in exclusion from participation in federal health care programs, suspension and debarment from government procurement and non-procurement programs, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent. Unlike the civil False Claims Act, the criminal False Claims Act requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes penalties against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Payment or reimbursement of prescription therapeutics, including, but not limited to, by Medicaid or Medicare requires manufacturers to submit certified pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for certain therapeutics. The Medicaid Drug Rebate statute also imposes inflation penalties, and recent legislative changes have removed the caps limiting the magnitude of these Medicaid penalties and the implementation of new inflation penalties applicable to the Medicare program. In addition to the Medicaid statutory rebate, states are authorized to negotiate supplemental rebates on pharmaceuticals included in their formularies. For therapeutics paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate. For products approved under a BLA (including biosimilars), or an NDA, the Veterans Health Care Act, or VHCA, requires manufacturers to calculate and report to the Department Veterans Affairs, or VA, a different price called the Non-Federal Average Manufacturer Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price, or FCP. Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense regulation requires manufacturers to provide this discount on therapeutics dispensed by retail pharmacies when paid by the TRICARE Program. All of these price reporting requirements create risk of inadvertently submitting false information to the government, and potential FCA liability.

The VHCA also requires manufacturers of covered therapeutics participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their covered therapeutics must be sold to certain federal agencies at FCP. This necessitates compliance with applicable federal procurement laws and regulations (e.g., Federal Acquisition Regulations), including submission of commercial sales and pricing information and certification of compliance with the Trade Agreements Act, and subjects us to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires manufacturers participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics under the 340B program based on the manufacturer's reported Medicaid pricing information. The 340B program has its own regulatory authority to impose sanctions for non-compliance and adjudicate overcharge claims against manufacturers by the purchasing entities.

The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to 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, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters.

Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Under the federal Physician Payments Sunshine Act and its implementing regulations, manufacturers of biologics for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) must make annual reports to CMS regarding payments and other transfers of value made to or at the request of covered recipients, such as, but not limited to, physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family. Certain research payments, including for clinical trials, are included within the ambit of this law. CMS makes the reported information publicly available.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economics and Clinical Health Act, or HITECH Act, and its respective implementing regulations imposes requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. Among other things, the HITECH Act, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. The HITECH Act also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, 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 attorney's fees and costs associated with pursuing federal civil actions. HIPAA imposes certain privacy requirements with respect to the use and disclosure of protected health information for research purposes, which will impact how we conduct our clinical trials. In addition, other federal and state laws, such as the California Consumer Privacy Act, may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts. For example, certain states, such as Washington, Nevada and Connecticut, have enacted new privacy laws with respect to consumer health data that is not protected health information governed by HIPAA.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require manufacturers to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to penalties or other enforcement actions, including significant civil monetary penalties, damages, criminal fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, non- and deferred prosecution agreements, suspension and debarment from government procurement and non-procurement programs, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

The European Union General Data Protection Regulation, the United Kingdom General Data Protection Regulation and related data protection, cybersecurity and e-privacy laws in the European Union, European Economic Area, or the EEA, and the United Kingdom, (collectively referred to herein as the "GDPR, and equivalent Swiss laws may apply to some or all of the clinical or other personal data obtained, transmitted, stored or otherwise processed by us (or on our behalf) from those jurisdictions. The GDPR contains potentially strict requirements with respect to lawfully processing personal data in connection with clinical trials and other business activities in Europe (including with respect to obtaining consents, securing personal data, notifying personal data breaches to supervisory authorities and affected data subjects, and transferring personal data outside

Europe). The GDPR and Swiss law allow supervisory authorities to potentially impose high regulatory fines (among other enforcement tools) in the event of violations, for example, under the GDPR up to 4% of global annual group turnover or EUR 20 million (whichever is the higher amount). Supervisory authorities in the European Union and EEA, Switzerland and the United Kingdom may potentially levy such fines directly upon on the non-compliant entity and/or on the parent company (so-called "undertaking") of the non-compliant entity. Separate from regulatory enforcement actions, individuals may bring private actions (including potentially group or representative actions). There is no statutory cap in the GDPR on the amount of compensation or the damages which individuals may recover.

Overall, the significant costs of GDPR and Swiss law compliance, risk of regulatory enforcement actions and private litigation under, and other burdens imposed by these laws as well as under other regulatory schemes throughout the world related to privacy and security of health information and other personal and private data could have an adverse impact on our business, reputation, financial condition, and results of operations. We may also be subject to additional industry-specific privacy, cybersecurity, data protection, operational and information systems resilience, and artificial intelligence-related laws in Europe which may subject us to additional similar risks and impacts.

Coverage and reimbursement generally

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including, but not limited to, Medicare and Medicaid, private health insurers, and other third-party payors, provide coverage for and establish adequate reimbursement levels for our product candidates. Government authorities, private health insurers, and other organizations generally decide which therapeutics they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program managed by CMS through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program, including supplemental rebate programs that restrict coverage to therapeutics on the state Preferred Drug List. Similarly, government laws and regulations establish the parameters for coverage of prescription therapeutics by health plans participating in state exchanges and Tricare, the health care program for military personnel, retirees, and related beneficiaries. Some states have also created pharmacy assistance programs for individuals who do not qualify for federal programs. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through, amongst others, the Medicare or Medicaid programs for such products and services.

In the United States, the European Union, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be and sometimes at or below the provider's acquisition cost. In the United States, it is also common for government and private health plans to use coverage determinations to leverage rebates from manufacturers in order to reduce the plans' net costs. These restrictions and limitations influence the purchase of healthcare services and products and lower the realization on manufacturers' sales of prescription therapeutics. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other dispensing restrictions, such as, but not limited to step edits, before covering certain products and by broadening therapeutic classes to increase competition. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Absent clinical differentiators, third-party payors may treat products as therapeutically equivalent and base formulary decisions on net cost. To lower the prescription cost, manufacturers frequently rebate a portion of the prescription price to the third-party payors. Recently, purchasers and third-party payors have begun to focus on value of new therapeutics and sought agreements in which price is based on achievement of performance metrics.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation over the lifecycle of a product. All of these conditions can affect realization and return on investment.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. In addition, many government programs as a condition of participation mandate fixed discounts or rebates from manufacturers regardless of formulary position or utilization, and then rely on competition in the market to attain further price reductions, which can greatly reduce realization on the sale.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, judicial decisions and governmental laws and regulations related to, amongst others, Medicare, Medicaid, and healthcare reform, biopharmaceutical coverage and reimbursement policies, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as, but not limited to, Medicare and Medicaid, private health insurers, and other third-party payors.

As a result of the above, we may need to conduct expensive pharmacoeconomic and/or health technology assessment studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA and EMA approvals. Our product candidates may not be considered medically necessary or cost-effective, or the rebate percentages required to secure coverage may not yield an adequate margin over cost.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in therapeutic development. Legislative or regulatory proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

The absence in Europe of any substantive harmonization of pricing and reimbursement regimes, including health technology assessment, means that separate negotiations will need to take place with the relevant authorities in each member state and may include a variety of risk share agreements with payors.

Healthcare reform measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and expanding access. In the United States, the biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, such as, but not limited to, the Inflation Reduction Act, or IRA, and the Bayh-Dole Act march-in rights expansion.

For example, on November 27, 2020, CMS issued an interim final rule implementing a Most Favored Nation payment model under which reimbursement for certain Medicare Part B drugs and biologicals would have been based on a price that reflected the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organization for Economic Co-operation and Development (OECD) with a GDP per capita that was at least sixty percent of the U.S. GDP per capita. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. This rule has now been rescinded, but similar programs have been described in recent legislative proposals. Our results of operations could be adversely affected by current and future healthcare legislation and reforms.

Moreover, the ACA broadened access to health insurance, attempts to reduce or constrain the growth of healthcare spending, enhanced remedies against fraud and abuse, added new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on the health care industry, and imposed additional health policy reforms. The law expanded the eligibility criteria and mandatory eligibility categories for Medicaid programs, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability. The law also expanded the 340B discount program that mandates discounts to certain hospitals, community centers, and other qualifying providers, by expanding the categories of entities eligible to purchase under the program. In addition, the ACA authorized civil monetary penalties for violating 340B

pricing requirements, and regulations implementing this authority became effective on January 1, 2019. The ACA revised the definition of "average manufacturer price", or AMP, for reporting purposes, which generally increased the amount of Medicaid rebates to states and created a separate AMP for certain categories of administered therapeutics provided in non-retail outpatient settings. The law additionally extended manufacturer's Medicaid rebate liability to covered therapeutics dispensed to patients enrolled in Medicaid managed care organizations and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate program. The revisions to the AMP definition and Medicaid rebate formula can have the further effect of increasing the required 340B discounts. Further, the ACA required manufacturers of covered therapeutics to pay mandatory Medicare Part D coverage gap rebates, and the Bipartisan Budget Act of 2018, increased the required percentage to 70% of the pharmacy charge to Medicare Part D patients while they are in the coverage gap. Finally, the ACA imposes a significant annual fee on companies that manufacture or import branded prescription therapeutic products. Substantial new provisions affecting compliance have also been enacted through the ACA and otherwise, including the reporting of therapeutic sample distribution, which may require us to modify our business practices with healthcare practitioners. Although the ACA was later amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law may continue, it is likely that pressure on biopharmaceutical pricing, especially under the Medicare program, will continue, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

Most recently, on April 15, 2025, the U.S. Administration released Executive Order entitled *Lowering Drug Prices by Once Again Putting Americans First*. Amongst other agencies, it directs the Secretary of HHS to take wide-ranging steps aimed to lower U.S. drug prices, including prices for biologic products. Solely by example, the Executive Order requires the Secretary to propose and seek comment and guidance on the differential treatment of small and large molecule drug products under the IRA's Medicare Drug Price Negotiation Program. Depending on the ultimate outcome of these steps, the pricing and reimbursement rates for any of our approved drug products, and our ultimate revenue realization could be adversely impacted.

The cost of biopharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the biopharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, as amended, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget "sequestration" Medicare payment reductions of 2%, at present that reduction has been extended through 2030. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. 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 products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our product candidates if approved and commercialized. The Bipartisan Budget Act also extended Manufacturer responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate or representatives of international organizations for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business or obtaining an improper advantage. The FCPA also obligates companies whose securities are listed in the United States to comply with books and records and accounting control provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in

criminal and civil fines, imprisonment, disgorgement, oversight by compliance monitors, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Other foreign anti-corruption regimes are arguably of wider application. For instance, the U.K. Bribery Act 2010 applies to dealings with any decision maker whether in the private or public sector in a position of trust.

Human capital

As of March 31, 2025, we employed 479 employees, all of which are full-time employees. Of the 479 employees, 347 are in research and development and 132 are in selling, general and administrative functions. We have never had a work stoppage, and none of our employees are represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

We believe that developing an inclusive culture with talent reflecting a diverse range of backgrounds, experiences, and perspectives is important to attracting and retaining the top talent necessary to deliver on our growth strategy. As such, we strive for, and are investing in, a work environment where our employees feel inspired and included.

We focus on identifying, attracting, retaining and developing highly talented and motivated employees. Our equity and cash incentive plans are aligned to attract, retain and reward our employees through the granting of stock-based and cash-based compensation awards. We conduct annual internal and external pay reviews to ensure fair and equitable pay for our employees, which includes an internal pay equity analysis, as well as the use of an external compensation analysis expert for the review of our employees' pay against external market data. We believe motivating our employees to perform at their highest level and take pride in achieving company goals increases stockholder value.

We are committed to our employees’ health, safety and well-being. Our work paradigm is flexible and designed to accommodate a range of work profiles. Our workforce is a combination of full-time on-site, hybrid, and fully remote employees, including both at our manufacturing facility as well as in our offices in Woburn and the United Kingdom. We offer a wide variety of competitive benefits to support our employees' physical, mental and financial well-being. Our benefits package is comprehensive in coverage and offers options to support all employees in staying healthy, planning for their future and developing their careers. Our management continues to assess and respond to the evolving needs of our workforce.

Corporate information

We are a Delaware corporation organized in July 2017. Our principal executive offices are located at 500 Unicorn Park Drive, Suite 303, Woburn, MA 01801, and our telephone number is (781) 222-9600. Our website is www.replimune.com. Information that is contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Available information

We make available free of charge on the investor relations portion of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements for our annual meetings of stockholders, and amendments to those reports, as soon as reasonably practicable after we file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. These filings are available for download free of charge on the investor relations portion of our website located at https://ir.replimune.com. The SEC also maintains a website that contains reports, proxy and information statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is https://www.sec.gov.

Item 1A. Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes and “Management’s discussion and analysis of results of operations and financial condition.” If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Summary of risk factors

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- the timing, progress, and results of our preclinical studies and clinical trials for our product candidates, and the timing, scope or likelihood of regulatory filings and approvals for any of our product candidates;
- our ability to develop and advance any future product candidates based on our novel and proprietary RPx platform and successfully complete clinical trials and prepare for and successfully complete inspections, submissions and reviews of licensing applications;
- our ability to develop our product candidates for use in combination with other checkpoint blockade therapies, including anti-PD-1;
- our ability to successfully commercialize any product candidate for which we receive regulatory approval and our expectations regarding the size of the patient populations or the market acceptance of our product candidates if approved for commercial use;
- our ability to compete with other biopharmaceutical companies, biotechnology companies and other third parties and risks associated with such third parties developing or commercializing products more quickly or marketing them more successfully than us;
- negative developments in the field of immuno-oncology including clinical or commercial developments that may be attributed to our product candidates;
- our history of losses, the likelihood that we will continue to incur substantial and increasing net losses in the future, and/or the likelihood that we will require additional financing to achieve our goals;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation or alleged violation of any third-party intellectual property rights;
- our ability to successfully qualify, obtain approval for, and maintain successful operation, approval and qualification of our in-house manufacturing operations;
- our ability to obtain and maintain sufficient quantities of raw material supplies to build or maintain our product candidate supplies or otherwise operate our in-house manufacturing facility;
- our ability to obtain and maintain sufficient quantities of materials and supplies to conduct our clinical trials, such as comparative, control and/or standard of care therapies including chemotherapeutic agents that are currently in short supply in the industry;
- the costs of operating our in-house manufacturing facility and our reliance on third-party collaborators and clinical trial service providers, which may be single or of limited source;
- our compliance with domestic and foreign laws, rules and regulations and the consequences in the event that we fail to comply with such laws, rules and regulations;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our competitive position, and developments and projections relating to our competitors and our industry;
- the potential increased costs associated with tariffs imposed or threatened by the new U.S. administration on pharmaceuticals and pharmaceutical ingredients where there is no available exception;
- the ongoing trade and military conflicts between Russia-Ukraine and Israel-Hamas and U.S.-China, including imposed and threatened tariffs, and other international hostilities and conflicts, and their impact on the global economy and related governmental imposed sanctions and potential material supplies and supply chain disruptions and global or national economic impacts such as inflation.

Risks related to product development

Our product candidates are in various stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We have never generated any revenue from product sales and may never be profitable.

All of our product candidates are in research or development. We have not generated any revenues from the sale of any product. Although the FDA recently accepted and granted priority review for our BLA for our lead product candidate, RP1, and any other product candidates will require extensive preclinical and/or clinical testing and regulatory approval prior to commercial use. Our research and development efforts may not be successful. Furthermore, even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect in humans, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage, the data is being reviewed or during the license application process.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- regulators or IRBs may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or contract research organizations, or CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes in manufacturing facilities or the manufacturing process for our product candidates may impact how our product candidates perform in clinical trials;

- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a BLA or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain them on favorable terms due to reasons, such as international trade policies and supply chain disruptions, including the imposition of tariffs;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs. For example, the FDA may determine that larger trials, Phase 3 trials, randomized and controlled clinical trials, or clinical trials designed to replicate results found in our registrational or pivotal trials are required before we may file a BLA or before the FDA will approve or maintain a marketing application;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs or study data analysis that may make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries or may find that such data is not sufficiently representative;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing, testing, comparability or quality processes or our manufacturing facilities for clinical and future commercial supplies and may delay approval, refuse to approve or rescind approval of a product candidate;
- the data collected from clinical trials of our product candidates, including our registration directed or registration intended trials may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA may decide that our intended pathways, including accelerated approval, are not appropriate for our product candidates, requiring that we conduct additional studies. For example, in recent years the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, depending on the results of our studies, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed. For instance, our confirmatory studies may not confirm a product's clinical benefit, in which case, the FDA could withdraw the product from the market, we may choose to voluntarily withdraw the product from the market, or we may need to conduct further studies to determine whether the product has a clinical benefit. Even if accelerated approval is granted, payors, including governmental payors, may be less welling to provide sufficient reimbursement for products approved via accelerated approval;

- we may not be able to obtain or maintain any special designations that our product candidates have received, including breakthrough designation. For instance, the FDA may find that, following designation, our product candidates no longer qualify for the designation due to changed circumstances or study results. This may result in the FDA rescinding a designation that we previously received. Any such designation also may not expedite or otherwise facilitate product development;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates or necessary inspections before an approval can be issued may be delayed;
- there may be events outside of our control, including, with respect to the budget, staffing, and funding of the U.S. Federal government, the FDA's ability to hire and retain key personnel, the FDA's ability to accept user fees, and other regulatory and policy changes. Disruptions at the FDA may slow the time to approval of a new drug or may otherwise impact our ability to obtain guidance from and interact with the agency. For instance, in recent years, the U.S. Federal government has experienced shutdowns. Should there be a prolonged government shutdown, it could significantly impact the ability of the FDA to review or slow the FDA in its review of any of our submissions or applications, which could have a materially adverse impact on our business; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Our 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 any of our product candidates. We will be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Topline data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data. As topline or interim data, 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 and interim 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 and interim data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimations, 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 drug candidate or drug and our company in general. In addition, the information we may 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 and interim data that we report differ from a future analysis of results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

We anticipate that our product candidates will be used in combination with third-party drugs, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Our product candidates may be administered in combination with checkpoint blockade drugs, a class of drugs that are intended to stop tumor cells from "switching off" an immune system attack against themselves. We have entered into agreements with BMS for the supply of nivolumab, its anti-PD-1 therapy, for use in connection with our ongoing IGNYTE Phase 1/2 trials with RP1, our Phase 1/2 clinical trial with RP2 and our Phase 1 and Phase 2 clinical trials with RP3 where we decide to use nivolumab. We have also entered into a clinical collaboration agreement with Regeneron, which includes the supply of cemiplimab, its anti-PD-1 therapy, for clinical trials conducted thereunder. Additionally, our signal finding study in

HCC is being developed in combination with atezolizumab and bevacizumab under a supply and clinical collaboration arrangement with Roche. We may enter into additional agreements for the supply of anti-PD-1 products for use in combination with and for the continued development of one or more of our product candidates. Although we have entered into such collaboration and supply agreements, and may continue to do so, our partners may remain in control of the supply and other decisions relating to their products or product candidates and we rely on their adherence to the terms of such agreements for the proper execution of their obligations. Our ability to develop and ultimately commercialize our product candidates used in combination with nivolumab, cemiplimab, atezolizumab, bevacizumab or any other checkpoint blockade therapy will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the availability and expense of purchasing checkpoint blockade therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of our product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. While we have opened a clinical trial for use of RP1 as a monotherapy, we are generally developing RP1 and our other product candidates for use in combination with anti-PD-1 or potentially anti-PD(L)-1 therapies and may develop RP1 or our other product candidates for use with other therapies. Although we intend for some of our trials to support registrational filings, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the therapy with which our products were combined and not our product candidates. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross-labeled for combined use or the FDA may pull back a previously granted marketing license if a confirmational trial does not result in data supporting an earlier approval. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Developments related to the other product may further impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that BMS or Roche or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms or at all, we would need to identify alternatives for accessing an anti-PD-1 therapy. Additionally, should the supply of products from BMS or Roche or any of our other current or future collaborators or suppliers be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed, interrupted or halted. In the event we are unable to source a supply of an acceptable alternative anti-PD-1 therapy, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

An underlying problem with our proprietary RPx platform would adversely affect our business and may require us to discontinue development of product candidates based on the same or similar therapeutic approaches.

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our RPx platform. Our ability to generate any revenues from the sale of our product candidates will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates using our RPx platform. Since all of the product candidates in our current pipeline are based on our proprietary RPx platform, if any of our product candidates fail in development as a result of any underlying problem with our proprietary RPx platform, then we may be required to discontinue development of all product candidates that are based on our RPx platform. If we were required to discontinue development of our product candidates that are based on our RPx platform, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach from our RPx platform.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

While our lead product candidate is RP1, we intend to continue to pursue clinical development of additional product candidates, including RP2 and, in the future potentially reinitiating development plans with RP3. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure our shareholders that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of solid tumors, we cannot assure our shareholders that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Risks related to regulatory approval

Even if our development efforts are successful, we may not obtain regulatory approval for any of our product candidates in the United States or other jurisdictions, which would prevent us from commercializing our product candidates. Even if we obtain regulatory approval for our product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize our product candidates.

We are not permitted to market or promote or sell any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection or remote regulatory assessment of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdiction, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings, contraindications, and precautions;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS to monitor the safety or efficacy of the products.

We previously submitted a BLA to the FDA for our lead product candidate, RP1. Earlier this year, the FDA accepted our BLA and granted priority review with a PDUFA action date of July 22, 2025. However, priority review for RP1 may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval. In addition, we have not previously submitted similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or at all.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. These regulatory requirements may require us to amend our clinical trial protocols, conduct additional preclinical studies or clinical trials that may require regulatory or IRB approval, or otherwise cause delays in the approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

The FDA or a comparable foreign regulatory authority may determine that our product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

There can be no assurance that undesirable side effects or serious adverse events will not be caused by or associated with RP1 or our other product candidates as they continue through or enter clinical development. Serious adverse events or undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities 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 comparable foreign regulatory authorities. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. The FDA or comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our product candidates.

Undesirable side effects caused by any of our product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our product candidates. Undesirable side effects may limit the potential market for any approved products or could result in the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post approval study requirements, or other testing and surveillance.

If any of our product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, facilities, equipment and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, penalties, injunctions, or other enforcement actions, including criminal actions, if we are determined to be promoting the use of our products for unapproved or "off label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign

regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off label uses, and our business, financial condition, results of operations, stock price and prospects may be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off label use.

If we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. 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. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of our products, following approval, for off label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil penalties, and criminal fines and agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements and non- or deferred prosecution agreements and could lead to exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claims action, pay civil penalties, criminal fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post approval clinical data, labeling, packaging, distribution, adverse event reporting, shortage reporting, risk management plans, supply chain security, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control,

quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections or remote regulatory assessments by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA preapproval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government procurement and non-procurement programs, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, corporate integrity agreements, or non- or deferred prosecution agreements; or
- injunctions, the imposition of civil penalties, criminal fines, or imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other

material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, 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 be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

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

We currently conduct clinical trials outside the United States. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the United States or another jurisdiction 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 basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. 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. Even if the foregoing is complied with, 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 would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of RP1 or any of our other product candidates, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from and, in some cases, greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Additionally, with the full departure of the United Kingdom from the European Union in January 2021, commonly referred to as Brexit, there is continuing regulatory uncertainty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, and the degree to which the United Kingdom and European Union regulatory regimes align or diverge could materially impact the execution of our clinical trials or approval of our product candidates in the United Kingdom or the European Union.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing 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. If we fail to comply with the regulatory requirements in international markets and/or 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. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Risks related to commercialization

If we are unable to successfully commercialize RP1 or any of our other product candidates for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for RP1 or any of our other product candidates, our ability to generate revenues from our product candidates will depend on our success in:

- launching commercial sales of our product candidates, whether alone or in collaboration with others;
- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market the product candidates;
- creating market demand for our product candidates through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize product candidates in the United States;
- manufacturing product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;
- maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation or alleged violation of any third-party intellectual property rights;
- achieving market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieving appropriate coverage and reimbursement for our product candidates;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety and efficacy profile of our product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including oncolytic immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While our product candidates are intended to be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also

target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Further, depending on the specific competing product, earlier approval of a competitor's products could block us from receiving approval and could require that we change our development strategy. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions or third-party intellectual property rights that another may allege are violated by our product candidates.

Certain of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must continue to build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. We have incurred and we expect we will continue to incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building, managing, growing and operating a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop is, and will continue to be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We have and will continue to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop an effective marketing and sales infrastructure, we may not be able to commercialize our product candidates in the United States or elsewhere in an effective manner, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidates;

- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- third-party intellectual property rights that another may allege are violated by our product candidates;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

As we continue to evolve from a company primarily involved in research and development to a company also expected to be involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

We anticipate that, as our operations expand and, assuming that our development, testing, studies and trials are successful, we will need to expand our internal manufacturing, marketing and sales capabilities. Managing our future growth will impose significant added responsibilities on members of our management team and will be time consuming and costly. We must be able to manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; and improve managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of oncolytic immunotherapies. Limited immunotherapies have received FDA approval to date. Any product candidates that are approved may be subject to extensive post approval regulatory requirements, including requirements pertaining to manufacturing, distribution, and promotion. We may need to devote significant time and resources to compliance with these requirements.

If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability.

Additionally, efforts to educate the medical community and third party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are out of our control, including the following:

- the efficacy of our product candidates in combination with marketed checkpoint blockade drugs;
- the commercial success of the checkpoint blockade drugs with which our products are co-administered;
- the prevalence and severity of adverse events associated with our product candidates or those products with which they are co-administered;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product candidates by direct injection into tumors, a less common method for the administration of oncology therapies than systemic administration, which may result in slower adoption of our therapies;
- the relative convenience and ease of administration of any products with which our product candidates are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the price concessions required by third party payors to obtain coverage;
- the extent and strength of our marketing and distribution of our product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product candidates, as well as competitive products;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our manufacturing operations and our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our product candidates are co-administered;
- the approval of other new products;
- adverse publicity about our product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies.

Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including, but not limited to, Medicare and Medicaid, private health

insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer adequate formulary coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly-approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm our business and reduce our revenue.

In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. For example, the Inflation Reduction Act of 2022, or IRA, includes several measures intended to lower the cost of prescription drugs and related healthcare reforms, including limits on price increases, inflation and non-compliance penalties, and subjecting an escalating number of drugs to annual maximum fair price negotiations with CMS. We cannot be sure whether additional legislation related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. Similarly, several states have established prescription drug affordability boards that set upper payment limits (maximum prices that can be charged for specific drugs) for select high-cost drugs. We cannot be sure whether additional state legislation related to price caps will be enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

If future reimbursement for approved product candidates, if any, is substantially less than we project, or rebate and/or discount, or fees and obligations associated with them are substantially greater than we expect, our future net revenue and profitability could be materially diminished.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for oncolytic immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved oncolytic immunotherapy, T-Vec, which has yet to enjoy broad market acceptance. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and surveys of clinics. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

Negative developments in the field of immuno-oncology could damage public perception of our product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for our product candidates. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of a modified virus, adverse developments in antiviral vaccines or clinical trials of other oncolytic immunotherapy products based on viruses may result in a disproportionately negative effect for our product candidates as compared to other products in the field of immuno-oncology that are not based on viruses. Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental

regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

Risks related to our financial position and need for additional capital

We are a clinical stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history, and we are still relatively early in our development efforts. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain marketing approval and become commercially viable. We have financed our operations to date primarily through the sale of equity securities, including the sale of our common stock and pre-funded warrants in public and private offerings. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our proprietary RPx platform, including our lead product candidate, RP1, and our other product candidates. We expect to spend substantial funds to continue the research, development and testing of our products that are in the preclinical and clinical testing stages of development and to prepare to commercialize products in anticipation of FDA approval. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.

We are not profitable and have incurred losses in each period since our inception. For the years ended March 31, 2025 and 2024, we reported a net loss of $247.3 million and $215.8 million, respectively. At March 31, 2025, we had an accumulated deficit of $948.6 million. We expect to continue to incur significant losses for the foreseeable future, and, notwithstanding our discontinuation of certain development efforts, as previously announced, we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, RP1, our other product candidates and any additional product candidates we may develop.

Even if we succeed in receiving marketing approval for and commercialize RP1 or our other product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional potential products, including if and when appropriate, sales and marketing costs associated with preparing for commercialization of RP1 or our other product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals.

We have no products approved for commercial sale and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, RP1 and our other product candidates;
- obtaining marketing approvals for RP1 and our other product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for RP1 and our other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing RP1 and our other product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of RP1 and our other product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and

- attracting, hiring, and retaining qualified personnel.

Even if our product candidates or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market RP1 or our other product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. At March 31, 2025, our cash and cash equivalents and short-term investments were $483.8 million. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of RP1 and our other product candidates. Accordingly, we will need to obtain additional funds to achieve our business objectives. If we are able to gain marketing approval of any product candidate, we will require significant additional amounts of cash in order to launch and commercialize such product. In addition, other unanticipated costs may arise.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing RP1 and our other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for RP1 and our other product candidates if clinical trials are successful;
- the success of any collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of operating our manufacturing facility;
- the cost of manufacturing RP1 and our other product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of March 31, 2025 will enable us to fund operations into the fourth quarter of 2026 which includes scale up for the potential commercialization of RP1 in skin cancers and for working capital and general corporate purposes and excludes any potential revenue. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RP1 or our other product candidates.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

Most of our cash, cash equivalents and short-term investments are held in accounts with banking institutions. The balances of some of these accounts have in the past, and may in the future, exceed the Federal Deposit Insurance Corporation, or the FDIC, insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. In March 2023, the FDIC took control of Silicon Valley Bank, or SVB, where we previously held a portion of our cash. The Federal Reserve subsequently announced that account holders would be made whole and we were able to access all of our cash held at SVB. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash, short-term investments and cash equivalents could have an adverse effect on our ability to pay our operational expenses, fund our operations or make other payments, which could adversely affect our business.

Risks related to intellectual property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology and proprietary RPx platform, including our lead product candidate, RP1, and our other product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation and subject to change with regulatory agencies and court decisions. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own in the future are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information, use by third parties of our products or infringement of our intellectual property rights, both inside and outside of the United States.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our issued patents and issued patents that we license from third parties or that we may own in the future may be challenged in the courts or patent offices inside or outside of the United States. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be interpreted or reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. In addition, defending against challenges in respect of the inventorship, scope, validity or enforceability of our patents may be expensive, time consuming, difficult and in some cases may not be possible. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, the patent prosecution process is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. If we are unable to obtain and maintain patent protection for our technology or inventions, or for RP1 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our ability to successfully commercialize RP1 or our other product candidates and future technologies or inventions may be adversely affected.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated. Given the amount of time required for the development, testing and regulatory review of our product candidates, such as RP1 and our other product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

Filing, prosecuting and defending patents on our technology or inventions in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries or religions outside the United States can be less protective of our products than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Changes to the patent law in

the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect RP1 and our other product candidates. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies or inventions in jurisdictions where we have not obtained patent protection to develop and/or manufacture their own products and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement or misappropriation may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. Although we enter into confidentiality agreements with our employees, consultants, collaborators, suppliers, manufacturers and other third parties who have access to our trade secrets, and our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms or may have conflicting agreements with third parties. In addition, in the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. If any of our trade secrets, know-how or confidential or proprietary information were to be lawfully obtained, patented or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and may be blocked from using such trade secrets, know-how or confidential or proprietary information ourselves. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may in the future initiate legal proceedings alleging that we are infringing their intellectual property rights, and we may become involved in lawsuits or other administrative procedures to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Our commercial success depends on our ability and the ability of our current or future collaborators to develop, manufacture, market and sell RP1 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates. For example, we are aware of U.S. Patent 10,034,938 (the '938 Patent) held by Amgen Inc., which includes claims purported to cover methods and kits for treating stage IIIb to IV melanoma by the administration of (i) an effective amount of an anti-PD-1 antibody or anti-CTLA-4 antibody; and (ii) a herpes simplex virus, wherein the herpes simplex virus lacks a functional ICP34.5 encoding gene and a functional ICP47 encoding gene, and comprises a gene encoding human GM-CSF. In November 2022, we filed a petition for inter partes review with the Patent Trial and Appeal Board, or PTAB, of the United States Patent and Trademark Office, or USPTO, seeking to invalidate certain claims of United States Patent 10,034,938, or the ‘938 Patent. In August 2023 we entered into a Settlement Agreement with Amgen and mutually agreed to terminate our challenges to their patents. In connection with the Settlement Agreement, we entered into a License and Covenant Agreement with Amgen in which we agreed to pay Amgen low single-digit royalty payments on net sales of our products that, but for the license, could be found to infringe a valid Amgen patent on a country-by-country and product-by-product basis.

Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be filed and/or granted in the future. At times we may attempt to initiate litigation or other administrative procedures to invalidate or otherwise limit the scope of a third party’s intellectual property and these attempts may not be successful. If we are found to infringe a third party’s intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid, unenforceable or otherwise not infringed, we could be required to obtain a license from such third-

party to continue developing, manufacturing and commercializing RP1 and our other product candidates. Such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies and inventions licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing RP1 or our other product candidates or we could be found liable for significant monetary damages if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their know-how, confidential or proprietary information or trade secrets could have a similar material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology or inventions, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on RP1 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, stock price and prospects.

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we take steps to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, confidential or proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets, know-how or other confidential or proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all.

In addition, we are developing certain of our product candidates in combination with products, which are or may be covered by patents or licenses held by third parties, and to which we do not have a license other than for use in connection with the applicable clinical trial. We also may develop our product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with RP1 or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which license may not be available on commercially reasonable terms, or at all.

Competitors may infringe any future licensed patents or any patent we own in the future or misappropriate or otherwise violate our intellectual property rights. We may also be required to defend against claims of infringement and our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others.

These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our trade secrets, know-how, or proprietary or confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Risks related to manufacturing and our reliance on third parties

We have agreements with BMS and Regeneron, and in the future may have agreements with other companies, to obtain the supply of anti-PD-1 therapies for the development of our product candidates. If our relationships with BMS or any future collaborator or supplier are not successful, we may be delayed in completing the development of our product candidates.

We have entered into arrangements with BMS and Regeneron as part of our clinical development programs where nivolumab or cemiplimab, respectively, are intended to be used for these clinical programs. BMS is providing nivolumab, its anti-PD-1 therapy, for use in the IGNYTE trial with RP1, our Phase 1/2 clinical trial with RP2 and our Phase 1 and Phase 2 clinical trials with RP3 where we intend to use nivolumab and may potentially do so for other clinical trials in the future; Regeneron provided cemiplimab, its anti-PD-1 therapy, for use in our CERPASS Phase 2 clinical trial and may potentially do so for other clinical trials in the future. We may also enter into agreements with additional companies for the supply of anti-PD-1 therapies for use in the development of RP1 and our other product candidates, similar to our agreement with Roche. The outcome of these clinical trials is dependent, in part, both on the performance of our partners' products and product candidates and also on our partners' ability to deliver sufficient quantities of adequately produced product. Should any of our partners' products or product candidates fail to produce the results that we anticipate, we may have to re-run clinical trials or may otherwise be delayed in the commercialization of RP1 or our other product candidates. Similarly, should any partner fail to provide us with a product or product candidate that suits our requirements, we may have to re-run clinical trials for RP1 or our other product candidates or may be otherwise delayed in the commercialization of RP1 or our other product candidates. Additionally, we are subject to specific risks associated with our collaboration partners, including possible discrepancies as to the timing, nature and the extent of development plans, contract interpretations, and the costs and allocation of costs related to the conduct of our clinical trials. If we and any collaboration partner are unable to agree or fail to perform our respective obligations or effectively manage our relationship, our clinical trials performed under such collaboration could incur additional costs, be delayed or could result in costly or time-consuming legal proceedings that could have an adverse effect on a collaboration or on our business.

Our collaboration agreements with any future partners may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may in the future seek collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future clinical trial materials supply, research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate development or commercialization of any product candidate it licenses to us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely on third-party CROs, study sites, and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and

protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with GLP regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections or remote regulatory assessment of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs, the applicable study protocols and plans, or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations or use of product that does not meet the applicable quality requirements in clinical trials may compromise the resulting trial data and may require us to repeat clinical trials, which would delay the regulatory approval process.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and may result in delays that could compromise our ability to meet our desired development timelines.

We also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

If the manufacturers upon which we rely fail to produce our raw materials or product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

We continue to rely on third-party contract manufacturers to manufacture our raw materials and certain clinical trial product supplies. As a result, there can be no assurance that our clinical development or commercial supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices.

We currently have only one in-house manufacturing site for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of raw materials or clinical trial material or guaranteed prices for our product candidates or their components. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers of raw materials or our product candidates, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. Any replacement of our contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our raw materials or product candidates that meet the necessary quality standards may delay our development or commercialization.

If our manufacturers of raw materials, equipment or process consumables do not perform as agreed or encounter difficulties in production costs and yields, quality control, shortages of qualified personnel or key raw materials, compliance with strictly enforced federal, state, and foreign regulations, or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

In addition, if our Framingham manufacturing site cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure or

maintain regulatory approval for our manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining raw materials, products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization.

We are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, but, other than through our contractual arrangements, we have little control over our raw materials or process consumables manufacturers' compliance with these regulations and standards.

In order to use our in-house Framingham manufacturing site or any third party manufacturing site for the production of product for commercialization, the sites must pass an FDA pre-approval inspection. FDA will not approve a BLA until such inspection demonstrates that product can be adequately and reliably produced. If the FDA or a comparable foreign regulatory authority does not approve these facilities for manufacturing or supply, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. We must also receive FDA approval for the use of any new manufacturers for clinical or commercial supply, including our own manufacturing facility.

A failure to comply with the applicable regulatory requirements, including inspections or remote regulatory assessments, may result in regulatory enforcement actions against our manufacturers or us (including criminal fines, civil penalties, or imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, non- or deferred prosecution agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our or our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Operating our own manufacturing facility may result in unanticipated delays or expenses and we may not experience the anticipated operating efficiencies we intended.

Our approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts is fully operational. The Framingham facility is intended to give us control over key aspects of the supply chain for our products and product candidates. However, we may not experience the anticipated operating efficiencies as we commence manufacturing operations at our in-house facility. Any such delays may disrupt or delay the supply of our product candidates if we have not maintained a sufficient backup supply of our product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the facility, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable state and foreign regulatory authorities' cGMP requirements for the production of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable state and foreign regulatory authority licensing requirements and inspections. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. If we are not able to comply with the applicable regulatory requirements or produce product that meets our requirements and specifications, we will be subject to the same risks that we would be subject to should third party manufacturers be unable to comply with the applicable regulatory requirements or produce product meeting our requirements or specifications, as described above. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.

In operating our own manufacturing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, raw material supply, regulatory, facilities and information technology. Further, should corrective or preventative actions be required, we will be fully responsible for these. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from our in-house facility, which may negatively affect our product development timeline, product candidate supplies and, if approved, our commercial product supplies. If we experience any unanticipated shortages of key raw materials, or other difficulties related to our raw material supply, we may not be able to effectively manage our ongoing manufacturing timelines and costs which may negatively affect our product development schedule and our ability to provide clinical trial supplies to patients in our clinical trials, and if approved, commercial product supplies.

Any problems or delays we experience in preparing for commercial scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Any such problems could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates, if approved, and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks related to legal and compliance matters

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. 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 or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anticorruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anticorruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or the Bribery Act, and other anticorruption laws that apply in countries where we do business. We also may participate in collaborations and relationships with third parties whose actions, if noncompliant, could potentially subject us to liability under the FCPA, Bribery Act or local anticorruption laws.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and the United Kingdom and authorities in the European Union, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anticorruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anticorruption laws or trade control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, HIPAA, the FCPA, the ACA, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to our business. We will be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business.

As noted above, the significant costs of GDPR and Swiss law compliance, risk of regulatory enforcement actions and private litigation under, and other burdens imposed by these laws as well as under other regulatory schemes throughout the world related to privacy and security of health information and other personal and private data could have an adverse impact on our business, reputation, financial condition, and results of operations. We may also be subject to additional industry-specific privacy, cybersecurity, data protection, operational and information systems resilience, and artificial intelligence-related laws in Europe which may subject us to additional similar risks and impacts.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other laws or regulations that apply to us, we may be subject to sanctions, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products, which could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

Compliance with the Drug Supply Chain Security Act, or DSCSA requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, either in the present or future, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs 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 of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. 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, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other 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, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third party claims. 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 costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

We are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities 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, numerous federal, state, and local governments have enacted numerous data privacy and security laws and regulations, including personal data privacy laws, health information privacy laws, data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Additionally, the California Consumer Privacy Act, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA also allows for statutory fines for noncompliance (up to $7,500 per violation) and includes a private right of action for certain data breaches. Although there are some exemptions for clinical trial data and health information, the CCPA may impact our business activities and increase our compliance costs and potential liability. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, GDPR contains potentially strict requirements with respect to lawfully processing personal data in connection with clinical trials and other business activities in Europe (including with respect to obtaining consents, securing personal data, notifying personal data breaches to supervisory authorities and affected data subjects, and transferring personal data outside Europe). The GDPR and Swiss law allow supervisory authorities to potentially impose high regulatory fines (among other enforcement tools) in the event of violations, for example, under the GDPR up to 4% of global annual group turnover or EUR 20 million (whichever is the higher amount). Supervisory authorities in the European Union and EEA, Switzerland and the United Kingdom may potentially levy such fines directly upon on the non-compliant entity and/or on the parent company (so-called “undertaking”) of the non-compliant entity. Separate from regulatory enforcement actions, individuals may bring private actions (including potentially group or representative actions). There is no statutory cap in the GDPR on the amount of compensation or the damages which individuals may recover.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the European Union or in other jurisdictions outside of the United States). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the European Union GDPR generally restricts the transfer of personal data to countries outside of the EEA that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of “Standard Contractual Clauses,” or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. The SCCs, though approved by the European Commission as a suitable alternative, have faced challenges in European courts, and may be further challenged, suspended or invalidated. Other countries in Europe, such as the United Kingdom, similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

See Part I, Item 1C, *Cybersecurity*, in this Annual Report on Form 10-K for more information regarding our cybersecurity risk management, strategy, and governance.

Risks related to our operations

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

As our clinical development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Our future financial performance and our ability to commercialize RP1 and our other product candidates will depend, in part, on our ability to effectively manage any future growth, which would impose significant additional responsibilities on members of management and may divert their attention away from day-to-day activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing, as well as support for our financial reporting and accounting functions. If the services of independent organizations, advisors and consultants become unavailable to us or we are unable to effectively manage our outsourced activities, or if the quality or accuracy of such services is compromised for any reason, our clinical trials may be extended, delayed or terminated, we may not comply with our financial reporting and accounting obligations on a timely basis

and we may not be able to obtain marketing approval of RP1 and our other product candidates or otherwise advance our business.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize RP1 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain our key employees and consultants, and to attract and motivate highly qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our executive leadership team, as well as our other scientific, manufacturing, quality and medical personnel. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, without our inability to find suitable replacements, could result in delays in product development and harm our business.

Changes in our management team resulting from the hiring or departure of executives and key employees from time to time could disrupt our business. Any future significant leadership changes or senior management transitions involve inherent risk. Any failure to ensure an effective transition, including the effective onboarding, assimilation, and retention of our management team and key employees, could hinder our strategic planning, business execution and future performance. In addition, executive leadership transition periods, including the transition we currently effected, can be disruptive and may result in a loss of personnel with deep technical knowledge, or result in changes to business strategy or objectives, and may negatively impact our operations and relationships with employees and third-parties due to increased or unanticipated expenses, operational inefficiencies, uncertainty regarding changes in strategy, decreased employee morale and productivity, and increased turnover.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option and restricted stock unit grants that vest over time and, in some instances, based on performance metrics. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements generally provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice.

If we fail to establish and maintain proper and effective internal control over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal control over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to incur substantial professional fees and internal costs for our accounting and finance functions, expend significant management efforts, continue to implement plans developed to address areas that we have identified as requiring improvement, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.

We believe that any internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of 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 an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate the material weaknesses in a timely manner or otherwise fail to maintain effective internal control over financial reporting, which may result in material misstatements of our interim and annual consolidated financial statements, our ability to comply with applicable laws and regulations could be impaired which could harm our business and negatively impact the value of our common stock.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of the consolidated financial statements for this Annual Report on Form 10-K, we identified material weaknesses in our internal control over financial reporting whereby we did not design and maintain effective information technology ("IT") general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain effective: (i) program change management controls to ensure that information technology program and data changes are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel; (iii) computer operations controls to ensure that processing and transfer of data, and data backups and recovery are monitored; and (iv) program development controls to ensure that new software development is tested, authorized and implemented appropriately.

The material weaknesses described above did not result in a misstatement to our annual or interim consolidated financial statements. However, these material weaknesses could result in a misstatement of substantially all account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

We have performed extensive work with personnel responsible for the design and operating effectiveness of internal control over financial reporting in our efforts to ensure that appropriate controls are in place and appropriate evidence is maintained. We are continuing to implement comprehensive control protocols for our enterprise resource planning environment in order to implement restrictions on user and privileged access to certain applications, implementing controls to review the activities for those users who have privileged access and program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately.

The design and implementation of these remediation efforts is in progress, may require additional expenditures to implement, and will require validation and testing of the design and operating effectiveness of internal control over financial reporting over a sustained period of financial reporting cycles, and as a result, the timing of when we will be able to fully remediate the material weaknesses described above is uncertain. We can give no assurance that our efforts will remediate the material weaknesses in our internal control over financial reporting, or that any additional material weaknesses will not be identified in the future. If the steps we take do not remediate the material weaknesses we have identified in a timely manner, or if our internal control over financial reporting is not effective, there could be a material misstatement in our interim or annual consolidated financial statements that could result in a restatement of our financial statements, and could cause us to fail to meet our reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock.

Additionally, ineffective internal control over financial reporting could expose us to an increased risk of financial reporting fraud and the misappropriation of assets and subject us to potential delisting from the stock exchange on which we list or to other regulatory investigations and civil or criminal sanctions. If we are unable to remediate the material weaknesses we have identified in a timely manner, or if additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weaknesses, our reputation, results of operations and financial condition could suffer. For more information see "Item 9A. Controls and Procedures"

Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. The secure maintenance of this information is critical to our

operations and business strategy. Some of this information could be an attractive target of criminal attack or unauthorized access and use by third parties with a wide range of motives and expertise, including organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. There can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Our internal computer systems and those of our contractors and consultants are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, pandemics, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of pre-clinical trial data or data from clinical trials for our product candidates could result in delays in our regulatory filings and development efforts, as well as delays in the commercialization of our products, and significantly increase our costs. To the extent that any disruption, security breach or unauthorized or inappropriate use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, including but not limited to patient, employee or vendor information, we could incur notification obligations to affected individuals and government agencies, liability, including potential lawsuits from patients, collaborators, employees, stockholders or other third parties and liability under foreign, federal and state laws that protect the privacy and security of personal information, and the development and potential commercialization of our product candidates could be delayed. For additional information, see the Risk Factor captioned, "*We are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business*."

Risks related to our common stock and general risks

An active trading market for our common stock may not be sustained.

Our common stock began trading on the Nasdaq Global Select Market on July 20, 2018 and we can provide no assurances that we will be able to continue to maintain an active trading market on the Nasdaq Global Select Market or any other exchange in the future. In the absence of an active trading market for shares of our common stock, our stockholders may not be able to sell their common stock at or above the price at which such stockholder acquired our common stock or at the time that they would like to sell. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to use our shares as consideration in commercial transactions.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which it was acquired. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of RP1 and our other product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of RP1 and our other product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- political and economic instability, the possibility of an economic recession, international hostilities, governmental restrictions and sanctions, inflation, global supply chain disruptions, trade relationships and military and political alliances; and
- the other factors described in this "Risk factors" section.

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 our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- the total expenses we incur in connection with equipping and operating our manufacturing facility;
- our ability to engage clinical trial sites in the U.S. and in foreign territories, obtain the approval for conducing our clinical trials in foreign territories from their regulatory authorities, as well as our ability to enroll the number of patients necessary in our clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on the FDA's and comparable foreign regulatory authorities' guidelines and requirements, the quantity of production and the terms of any agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical and preclinical studies for RP1 and our other product candidates or competing product candidates;
- competition from existing and potential future products that compete with RP1 and our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of RP1 or our other product candidates;
- the level of demand for RP1 and our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with RP1 and our other product candidates;
- our ability to commercialize RP1 and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- the success of and our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- natural disasters, public health crises, political crises, negative global climate patterns, or other catastrophic events, the possibility of an economic recession, international hostilities and trade disruptions, including, but not limited to, those resulting from the recent U.S. presidential election, ongoing military conflicts between Russia-Ukraine and Israel-

Hamas, the ongoing trade conflict between US-China, acts of terrorism, governmental restrictions and sanctions, inflation, global supply chain disruptions, increased costs from tariffs, trade relationships and military and political alliances;

- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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 and/or earnings guidance we may provide.

We have broad discretion in how we use our cash, cash equivalents and investments, and may not use these resources effectively, which could affect our results of operations and cause our stock price to decline.

Our management has considerable discretion in the application of our cash, cash equivalents and investments. We intend to use our resources to fund our preclinical and clinical development programs as well as for general corporate purposes, including working capital requirements and other operating expenses. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of our resources. We may use our resources for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration of contractual or legal restrictions on resale lapse, the market price of our common stock could decline. These sales may make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisition.

In addition, a significant number of shares of common stock that are either subject to outstanding options and restricted stock units, reserved for future issuance under our equity incentive plans or subject to outstanding warrants are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act, including our ESPP if activated. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Certain holders of shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of shares of our common stock pursuant to the amended and restated investors' rights agreement by and among us and certain of our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

We may sell up to $89.0 million of shares of our common stock in "at-the-market" offerings pursuant to a Sales Agreement entered into on August 3, 2023 as amended, with Leerink Partners LLC, or the 2023 Sales Agreement. The sale of a substantial number of shares of our common stock pursuant to the 2023 Sales Agreement, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. In addition, issuances of any shares of our common stock sold pursuant to the 2023 Sales Agreement will have a dilutive effect on our existing stockholders.

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

To the extent that we raise additional capital through the sale of common stock or securities convertible, exercisable or exchangeable into common stock, our existing stockholders' interest will be diluted. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market one or more of our product candidates or technologies that we would otherwise prefer to develop and market ourselves.

If we engage in future acquisitions or strategic partnerships, this 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 evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- 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, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, 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 or intangible asset impairment charges. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely impact our business.

Global financial markets have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices. We are unable to predict the likely duration and severity of the current disruptions in financial markets and adverse economic conditions throughout the world. These economic developments affect businesses such as ours and those of third parties on which we rely in a number of ways that could result in unfavorable consequences to us. Current economic conditions or a deepening economic downturn in the United States and elsewhere may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

Although we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments, we cannot assure you that deterioration of the global credit and financial markets

would not negatively impact our current portfolio of cash equivalents or short-term investments, or our ability to meet our financing objectives. Furthermore, our stock price may decline due, in part, to the volatility of the stock market and general economic downturns.

Exchange rate fluctuations may materially affect our results of operations and financial conditions.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the British pound and the euro, may adversely affect us. Although we are based in the United States, we have significant research and development operations in the United Kingdom, and source consulting and other services in the United Kingdom and the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Unfavorable global economic conditions and geopolitical events could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military and trade conflicts, including the ongoing military conflicts between Russia-Ukraine and Israel-Hamas and the ongoing trade conflict between U.S.-China, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also adversely impact our clinical trials, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. A weak or declining economy or political disruption, including any international trade disputes, economic instability, changes in tax laws and regulations and additional tariffs, including based on the recent U.S. presidential election, export controls, and increased interest rates could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Although we do not currently operate in Russia, Ukraine, Israel, or China, those conflicts may impact, and if any of those conflicts broaden it may further impact, the markets, countries or territories in which we do operate or intend to operate, which could have a negative impact on our ability to achieve our objectives or timelines.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, customers, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have a materially adverse impact on our business and financial condition. In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

The Hercules Loan and Security Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.

On October 6, 2022 we and certain of our subsidiaries entered into a Loan and Security Agreement, or the Hercules Loan Agreement with Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent and as a lender, which such agreement was subsequently amended in June 2023 and December 2023. The Hercules Loan Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. The Hercules Loan Agreement also contains customary affirmative and negative covenants that, among other things, may limit our ability, subject to certain exceptions, to incur indebtedness, grant liens, enter into a merger or consolidation, enter into transactions with affiliates, or sell all or a portion of our property, business or assets. The Hercules Loan Agreement contains customary events of default. Upon the occurrence and continuation of an event of default, all amounts due under the Hercules Loan Agreement become (in the case of an insolvency or bankruptcy event), or may become (in the case of all other events of default and at the option of Hercules), immediately due and payable. If an event of default under the Hercules Loan Agreement should occur, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Hercules Loan Agreement. Even if we are able to repay any indebtedness on an

event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned.

Item 1B. Unresolved staff comments

None.

Item 1C. Cybersecurity

We have policies, procedures, and processes for assessing, identifying, and managing cybersecurity risks, which are built into our overall information technology function and information about cybersecurity risks and our risk management processes is collected, analyzed and considered as part of our overall risk management program. Such policies, procedures, and processes are designed to help protect our information assets and operations from internal and external cyber threats as well as secure our networks and systems. Such processes include procedural and technical safeguards, response plans, regular vulnerability and penetration tests on our systems and product applications, incident simulations, and routine review of our policies and procedures to identify risks and improve our practices. Our security incident response plan is designed to help coordinate our response to, and recovery from, cybersecurity incidents, and includes processes to assess the severity of, escalate, contain, investigate, and remediate incidents as well as to comply with applicable legal obligations. We maintain cyber insurance coverage; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks, and other related breaches.

We engage certain external parties, including cybersecurity assessors, consultants and auditors, to enhance our cybersecurity processes and strategies. In addition, depending on the nature of the services provided, the sensitivity and quantity of information processed, and the identity of the service provider, we evaluate the security and risk posture with respect to our third party service providers according to the perceived level of risk and in accordance based on industry standard best practices.

Our audit committee of the Board of Directors provides direct oversight over cybersecurity risk and provides applicable updates to the Board of Directors regarding such oversight. Members of management responsible for data privacy, technology, and information security risks join our audit committee meetings from time to time to discuss these risks, risk management activities, incident response plans, best practices, the effectiveness of our security measures, and other related matters.

Our Chief Information Officer, who reports to our Chief Financial Officer, leads the operational oversight of company-wide cybersecurity strategy, policy, standards, and processes and works across relevant departments to assess and help prepare us and our employees to address cybersecurity risks. Specific cybersecurity related responsibilities include overseeing our processes and strategies for the detection, mitigation, and remediation of cybersecurity incidents. Our Chief Information Officer has extensive experience assessing and managing cybersecurity and risk programs having served in relevant positions of increasing responsibility for over 25 years at several private and public companies.

In an effort to deter and detect cyber threats, we provide all employees with routine response and prevention training, which covers timely and relevant topics, including social engineering, phishing, password protection, confidential data protection, asset use, and mobile security, and educates employees on the importance of reporting all incidents promptly. We also use technology-based tools to mitigate cybersecurity threats and risks and to bolster our employee-based cybersecurity programs.

At this time, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face certain ongoing risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. Despite our cybersecurity efforts, we may not be successful in preventing or mitigating a cybersecurity incident that could materially affect us. See Part I, Item 1A, Risk Factors, in this Annual Report for a discussion of cybersecurity risks.

Item 2. Properties

Our corporate headquarters is located in Woburn, Massachusetts, where we occupy approximately 18,712 square feet pursuant to a lease expiring in 2029, with an option to extend by an additional five years. We also lease an approximately 12,000 square-foot facility in Oxfordshire, United Kingdom, containing research and development, laboratory and office space. This lease expires in April 2031 and we have the right to terminate it in April 2026. In October 2021 and March 2023, the Company entered into additional agreements to lease approximately 2,951 and 2,058 square feet, respectively, of research and development, office and laboratory space in Abingdon, Oxfordshire, United Kingdom. These lease agreements are both for five years and expire in October 2026 and March 2028, respectively, with no right to renewal.

In June 2018, we entered into an agreement to lease approximately 63,000 square feet of office, manufacturing and laboratory space in Framingham, Massachusetts. Pursuant to the lease agreement, the lease term commenced in December 2018 and the rent commenced in August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions.

We believe that our current facilities are suitable and adequate to meet our current and planned needs. Our leases can be renewed, and we believe that suitable alternative spaces will be available as needed in the future, on commercially reasonable terms. We do not own any real property.

Item 3. Legal proceedings

We are not currently a party to any material legal proceedings.

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

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "REPL" since July 20, 2018. Prior to that date, there was no public trading market for our common stock.

Holders of common stock

As of the close of business on May 19, 2025, there were approximately 7 holders of record of our common stock. This number does not reflect beneficial owners whose shares are held in street name.

Dividend policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, contractual restrictions, business prospects, general business conditions and other factors that our board of directors may deem relevant.

Securities authorized for issuance under equity compensation plans

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth herein under Part III, Item 12 below.

Recent sales of unregistered securities

There have been no unregistered sales of securities other than previously disclosed by us in our Current Report on Form 8-K, as filed with the SEC on June 13, 2024.

Purchases of equity securities by the Issuer and affiliated purchasers

None.

Performance Graph

Not required.

Item 6. Reserved

Item 7. Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and related notes and other financial information included elsewhere in this Annual Report on Form 10-K. In addition to historical information, some of the statements contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have based these forward-looking statements on our current expectations and projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Annual Report on Form 10-K, particularly including those risks identified in Part I, Item 1A "Risk factors" and our other filings with the SEC.

We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report on Form 10-K. Statements made herein are as of the date of the filing of this Annual Report on Form 10-K with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report on Form 10-K, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients through our novel oncolytic immunotherapies. Our proprietary oncolytic immunotherapy product candidates are designed and intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy is an emerging drug class, which we intend to establish as the second cornerstone of immune-based cancer treatments, alongside checkpoint blockade. Oncolytic immunotherapy exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Our product candidates incorporate multiple mechanisms into a practical "off-the-shelf" approach that is intended to maximize the immune response against a patient's cancer and to offer significant advantages over other approaches of inducing anti-tumor immunity, including personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will increase clinical efficacy and simplify the development path of our product candidates, while also improving patient outcome.

Financial

Since our inception, we have devoted substantially all of our resources to developing our proprietary RPx platform, building our intellectual property portfolio, conducting research and development of our product candidates, business planning, raising capital and providing selling, general and administrative support for our operations. To date, we have incurred significant operating losses and we have financed our operations primarily with proceeds from the sale of equity securities and to a lesser extent the proceeds from the issuance of debt securities. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales.

Since our initial public offering, or IPO, on July 20, 2018, we have raised an aggregate of approximately $1,101.8 million in net proceeds to fund our operations, of which $101.2 million was from our IPO, $862.0 million was from five separate follow-on offerings, or the Public Offerings, that we closed in November 2019, June 2020, October 2020, December 2022, and November 2024, respectively, $96.7 million was from our private placement transaction in June 2024, and $41.9 million was from at-the-market offerings.

Our net losses were $247.3 million and $215.8 million for the years ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $948.6 million. These losses have resulted primarily from costs incurred in connection with research and development activities and selling, general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We anticipate that our expenses and capital requirements will fluctuate from period to period depending upon the Company's development programs and priorities. We expect to continue to incur costs in connection with our ongoing development activities, including further advancement of any preclinical activities and clinical trials of our product candidates across our platform, and if and as we:

- conduct our current and future clinical trials;
- further preclinical development of our platform;
- operate our in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- until our manufacturing facility is fully validated, continued limited manufacturing by third parties for clinical development;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional clinical, quality control, scientific and selling, general and administration personnel;
- acquire or in-license other drugs, technologies or intellectual property rights; and

- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and operations as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2025, we had cash and cash equivalents and short-term investments of $483.8 million. Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 10-K.

See "*Results of Operations — Liquidity and capital resources*" and "*Risk factors — Risks related to our financial position and need for additional capital*."

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales as we do not have any approved products and we can not be certain we will generate any revenue from the sale of products in the future. If our development efforts for RP1 or any other product candidates that we may develop in the future are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from those collaborations or license agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- expenses incurred under agreements with third parties, including clinical research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs that manufacture our product candidates for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants engaged in research and development functions, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements in connection with the development of our product candidates; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. 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 consolidated financial statements as prepaid or accrued research and development expenses.

Direct research and development costs, consisting of costs, such as fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development activities, are tracked by study. Additional costs, consisting primarily of our initial manufacturing costs, including materials, supplies, depreciation and facility costs, are allocated at a program level, based upon manufacturing runs, as the drug product can be utilized across multiple studies for any particular program. Additional costs to label, package and distribute the drug product is then directly allocated to the specific studies when

incurred, as that drug product has then been assigned to a particular study. In the event our additional future or ongoing study costs become meaningful to investors, we will present those costs by study.

We do not allocate personnel costs, costs associated with our discovery efforts, laboratory supplies or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue enrollment and initiate additional clinical trials and continue to discover and develop additional product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the scope, rate of progress, expense and results of our ongoing clinical trials, as well as future clinical trials or other product candidates and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- uncertainties in clinical trial design;
- the rate of enrollment in clinical trials;
- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities, if any, and our ability to maintain approval of any of our product candidates;
- our success in operating our manufacturing facility, or securing manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to maintain, expand and protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- our ability to successfully develop our product candidates for use in combination with third-party products or product candidates;
- negative developments in the field of immuno-oncology;
- competition with other products; and
- significant and changing government regulation and regulatory guidance.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we could be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in obtaining regulatory approval for any of our product candidates.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate, commercial, and business development and administrative functions. Selling, general and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, pre-commercial planning, travel expenses, and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our selling, general and administrative expenses will continue to increase in the future as we increase our selling, general and administrative headcount to support our continued operations and pre-launch activities to prepare for potential commercialization of our product candidates. We also expect to continue to incur increased expenses, including accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Other income (expense), net

Research and development incentives

Research and development incentives consists of reimbursements of research and development expenditures. We participate, through our subsidiary in the United Kingdom, in the research and development program provided by the United Kingdom tax relief program, such that a percentage of up to 16.2% of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as other income.

Investment income

Investment income consists of income earned on our cash and cash equivalents and short-term investments.

Interest expense on finance lease liability

Interest expense on finance lease liability consists of amortization of finance charges under our financing lease.

Interest expense on debt obligations

Interest expense on debt obligations consists of the amortization of debt discount and cash paid for interest under the Hercules Loan Agreement.

Other (expense) income, net

Other (expense) income, net consists primarily of realized and unrealized foreign currency transaction gains and losses.

Income taxes

During the year ended March 31, 2025 and 2024, the Company recorded an income tax provision of $0.5 million and $0.4 million, respectively, related to U.S. current taxes primarily due to the transfer pricing arrangement between the U.S. and the U.K., as well as unfavorable adjustments related to stock compensation, resulting in U.S. taxable income partially reduced by certain tax attributes and U.S. tax partially reduced by certain credits and U.S. tax partially reduced by certain credits.

Results of operations

Comparison of the years ended March 31, 2025 and 2024

The following table summarizes our results of operations for the years ended March 31, 2025 and 2024:

	Year Ended March 31,		Change	
	2025	2024	$	%
	(Amounts in thousands)			
Operating expenses:				
Research and development	$ 189,447	$ 174,963	$ 14,484	8 %
Selling, general and administrative	72,180	59,810	12,370	21 %
Total operating expenses	261,627	234,773	26,854	11 %
Loss from operations	(261,627)	(234,773)	(26,854)	11 %
Other income (expense):				
Research and development incentives	1,773	1,920	(147)	(8)%
Investment income	21,120	23,356	(2,236)	(10)%
Interest expense on finance lease liability	(2,118)	(2,163)	45	(2)%
Interest expense on debt obligations	(5,775)	(4,497)	(1,278)	28 %
Other (expense) income	(202)	771	(973)	(126)%
Total other income (expense), net	14,798	19,387	(4,589)	(24)%
Loss before income taxes	$ (246,829)	$ (215,386)	$ (31,443)	15 %
Income tax provision	468	408	60	15 %
Net loss	$ (247,297)	$ (215,794)	$ (31,503)	15 %

Research and development expenses

Research and development expenses for the year ended March 31, 2025 were $189.4 million, compared to $175.0 million for the year ended March 31, 2024. The following table summarizes our research and development expenses for the years ended March 31, 2025 and 2024:

	Year Ended March 31,		Change	
	2025	2024	$	%
Direct research and development expenses by program:				
RP1 program costs by study:				
IGNYTE	14,620	16,641	(2,021)	(12)%
ARTACUS	6,934	6,198	736	12 %
CERPASS	7,276	16,165	(8,889)	(55)%
IGNYTE-3	7,183	2,042	5,141	252 %
Other RP1 study costs	10,863	10,446	417	4 %
Total RP1 costs	46,876	51,492	(4,616)	(9)%
RP2	12,043	10,701	1,342	13 %
RP3	4,948	13,162	(8,214)	(62)%
Unallocated research and development expenses:				
Personnel related (including stock-based compensation)	91,578	80,395	11,183	14 %
Other	34,002	19,213	14,789	77 %
Total research and development expenses	$ 189,447	$ 174,963	$ 14,484	8 %

The total increase of $14.5 million in research and development expenses was driven by an increase of $26.0 million in unallocated expenses, partially offset by a decrease of $11.5 million in our direct research and development costs. The increase in unallocated expenses includes $14.8 million in other costs and $11.2 million in personnel-related costs. The increase in other costs is driven primarily by an increase in consulting costs, medical affairs and facility costs. The increase in personnel-related costs largely reflected the hiring of additional personnel in our research and development functions, most specifically within the manufacturing departments, as we prepared and scaled operations for commercial launch.

The decrease of approximately $11.5 million in our direct research and development costs primarily relates to a decrease of $8.2 million related to RP3 as a result of the deprioritization of development efforts on this product candidate, which began in

the second half of the prior fiscal year, as well as a decrease of $4.6 million in RP1 costs as a result of declining enrollment and the wind down of the CERPASS study and completion of enrollment in the IGNYTE advanced melanoma cohort. These decreases are slightly offset by an increase of approximately $1.3 million in RP2 costs as the Company began to ramp up costs for the MUM study, specifically with spending related to set up costs and Clinical Research Organization ("CRO") costs. In addition, in the prior year, the company incurred costs related to manufacturing batches for RP1, as well as significant costs related to the CERPASS trial in the areas of CROs, investigators and imaging costs in preparation of the primary data release, which did not recur in the current year.

Selling, general and administrative expenses

Selling, general and administrative expenses were $72.2 million for the year ended March 31, 2025, compared to $59.8 million for the year ended March 31, 2024. The increase of $12.4 million in sales, general and administrative costs is driven primarily by an increase of $9.3 million in sales and marketing costs related to promotional materials, market access and insights and analytics, as the Company prepares for a potential commercial launch of RP1. In addition, there is a year over year increase of $4.3 million in personnel related costs, comprised of an increase of $7.1 million in payroll and fringe benefits offset by a stock-based compensation decrease of $2.8 million. The increase in personnel related costs was driven by the continued hiring of additional personnel within our selling, general and administrative functions, specifically focusing on planning for a potential commercial launch. Personnel related costs for the year ended March 31, 2025 and 2024 included stock-based compensation expense of $16.6 million and $19.4 million, respectively.

Total other income (expense), net

Other income for the year ended March 31, 2025 was $14.8 million compared to $19.4 million for the year ended March 31, 2024. The net change of $4.6 million is primarily attributable to a decrease of $2.2 million in investment income in the current year as compared to the prior year as a result of the cash and investment balance being lower throughout the year as compared to the prior year due to normal cash burn, as well as an increase in interest expense on debt obligations in the amount of $1.3 million as a result of a higher debt balance during the current year vs. the prior year. In addition, there is a $1.0 million increase in expense due to the changes in foreign exchange rates of the Great British Pound to United States Dollar.

Income tax provision

Income tax provision for the year ended March 31, 2025 was $0.5 million compared to $0.4 million for the year ended March 31, 2024. The income tax provision for the current year is attributable to U.S. current taxes primarily due to the transfer pricing arrangement between the U.S. and the U.K., as well as unfavorable adjustments related to stock compensation, resulting in U.S. taxable income partially reduced by certain prior year available net operating losses and U.S. tax partially reduced by certain credits.

Liquidity and capital resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Until we are able to generate sufficient revenue from RP1 and our other product candidates that we develop, if at all, we anticipate that we will continue to incur significant operating losses and negative cash flows from our operations.

Sources of liquidity

To date, we have financed our operations primarily with proceeds from the sale of equity securities and, to a lesser extent, proceeds from borrowing under a secured loan facility. Through March 31, 2025, we had received net proceeds of $1,101.8 million through the sale of shares of common stock and pre-funded warrants exercisable for common stock in public offerings, a private placement transaction, and at-the-market offerings, as well as our incurrence of debt under the Hercules Loan Agreement. As of March 31, 2025, we had cash and cash equivalents and short-term investments of $483.8 million.

Cash flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended March 31,	
	2025	2024
	(Amounts in thousands)	
Net cash used in operating activities	$ (192,250)	$ (185,467)
Net cash (used in) provided by investing activities	(23,796)	97,201
Net cash provided by financing activities	252,396	16,283
Effect of exchange rate changes on cash and cash equivalents	315	(86)
Net increase (decrease) in cash and cash equivalents	$ 36,665	$ (72,069)

Operating activities

During the year ended March 31, 2025, net cash used in operating activities was $192.3 million, primarily resulting from our net loss of $247.3 million, which was partially offset by non-cash charges of $31.0 million, consisting primarily of stock-based compensation expense of $35.0 million and depreciation expense of $3.5 million, somewhat offset by $8.9 million related to the net amortization of premiums and discounts on short-term investments. Additionally, there was an increase in cash of $24.1 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the year ended March 31, 2025 consisted primarily of a $11.7 million increase in accrued expenses and other current liabilities, a $9.9 million increase in accounts payable, and a net $2.4 million change in operating and financing right-of-use assets and lease liabilities.

During the year ended March 31, 2024, net cash used in operating activities was $185.5 million, primarily resulting from our net loss of $215.8 million, which was partially offset by non-cash charges of $24.8 million, consisting primarily of stock-based compensation expense of $34.1 million offset by $12.3 million related to the net amortization of premiums and discounts on short-term investments. Additionally, there was an increase in cash of $5.5 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the year ended March 31, 2024 consisted primarily of a $9.2 million increase in accrued expenses and other current liabilities, a $2.8 million decrease in accounts payable, and a net $2.4 million change in operating and financing right-of-use assets and lease liabilities.

Investing activities

During the year ended March 31, 2025, net cash used in investing activities was $23.8 million, consisting of $403.6 million in purchases of available for sale securities and $6.7 million in purchases of property, plant and equipment, partially offset by $386.5 million in proceeds from sales and maturities of short-term investments.

During the year ended March 31, 2024, net cash provided by investing activities was $97.2 million, consisting of $592.4 million in proceeds from sales and maturities of short-term investments, partially offset by $489.5 million in purchases of available for sale securities and $5.7 million in purchases of property, plant and equipment.

Financing Activities

During the year ended March 31, 2025, net cash provided by financing activities was $252.4 million, consisting primarily of $252.7 million in proceeds from the Company's private placement transaction in June 2024 as well as the Company's November 2024 public offering.

During the year ended March 31, 2024, net cash provided by financing activities was $16.3 million, consisting primarily of $15.0 million in proceeds from the incurrence of debt under the Hercules Loan Agreement, as well as approximately $1.8 million in proceeds from the exercise of stock options.

Funding requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of RP1 and our other product candidates and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates, and potential commercialization of RP1 and if and as we:

- conduct our current and future clinical trials with RP1, RP2 and RP3;
- further preclinical development of our RPx platform;

- operate, qualify and maintain our in-house manufacturing facility and qualify and maintain our product candidates made therein for use in our clinical trials;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- until our planned manufacturing facility is fully validated, continued limited manufacturing by third parties for clinical development;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs, technologies or third-party intellectual property; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and operations as a public company.

As of March 31, 2025, we had cash and cash equivalents and short-term investments of $483.8 million and $46.4 million in long term debt. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of March 31, 2025, will enable us to fund operations into the calendar fourth quarter of 2026 which includes scale up for the potential commercialization of RP1 in skin cancers and for working capital and general corporate purposes and excludes any potential revenue. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the development of RP1 and other product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development and potential commercialization of our product candidates. Our future capital requirements will depend on many factors, including those described in this section and above under "— Operating expenses — Research and development expenses."

Developing novel biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of therapies that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of our equity or convertible debt securities, our shareholders' interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Our contractual obligations include those related to our operating and financing leases, long-term debt,

as well as costs associated with contracts entered into in the normal course of business with CROs, CMOs and other third parties for clinical trials and preclinical research studies and testing.

Lease Commitments

As of March 31, 2025, the aggregate amount of future lease payments is approximately $49.1 million, with $4.0 million due within one year. For additional information on our leases and timing of future payments, see Note 13 *Commitments and contingencies,* of the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K.

Loan Agreement

Our commitments due for our term loan under our arrangement with Hercules include principal payments of $45.0 million as of March 31, 2025. Borrowings under the term loan agreement are repayable in monthly interest-only payments through September 2026, and the agreement has a maturity date of October 2027. Our remaining commitments, based on our current draws, are due through October 2027, and include principal and interest payments of $58.3 million, and an additional fee upon maturity of the loan of $2.2 million. See Note 7, *Long term debt*, of the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K for further discussion of the Hercules term loan.

Other Obligations

Manufacturing and research commitments include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. As of March 31, 2025, the aggregate amount of non-cancelable purchase obligations related to such manufacturing commitments are approximately $0.8 million and all of this balance is due within one year.

Collaborations

BMS

In February 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb Company, or BMS. Pursuant to the agreement, BMS is providing to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at no cost to us, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us. In January 2020, this agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 failed melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (x) in the event of an uncured material breach by the other party, (y) in the event the other party is insolvent or in bankruptcy proceedings or (z) for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

In April 2019, we entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide, at no cost to us, nivolumab for use in our Phase 1 clinical trial of RP2 in combination with nivolumab.

Roche

In December 2022, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Roche in relation to our RP2 and RP3 programs in colorectal cancer, or CRC, and hepatocellular carcinoma, or HCC. Under the agreement, the companies intended to collaborate in 30 patient cohort signal finding studies in third-line, or 3L, CRC and in first- and second-line, or 1L and 2L, respectively, HCC. Following our re-prioritization of our product development portfolio in December 2023, we have agreed with Roche to terminate the CRC collaboration and pursue the 2L cohort in HCC with RP2 only. Roche has continued to supply its currently approved drugs, atezolizumab and bevacizumab for the 2L cohort in HCC but is not sharing costs following our re-prioritization. Under the terms of the initial agreement we retained the responsibility of operating the

clinical trials as well as retaining all the rights to the development and commercialization of our product candidates. The agreement may be terminated by either party upon sixty days prior written notice to the other party.

Critical accounting policies and estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities and conducting preclinical studies and clinical trials on our behalf;
- CMOs in connection with the production of preclinical and clinical trial materials;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed and/or timing of receiving invoices for actual services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We issue stock-based awards to employees, directors, consultants and non-employees in the form of stock options, restricted stock units, or RSUs, and performance-based restricted stock units, or PSUs. We measure such stock-based awards in accordance with ASC 718, *Compensation — Stock Compensation*, which requires all stock-based awards to be recognized in the consolidated statements of operations and comprehensive loss based on their fair value on the date of the grant and the related compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of

the respective award. We have, to date, issued stock-based awards with service-based and performance-based vesting conditions. Expense for stock-based awards with service-based vesting conditions is recorded using the straight-line method and for PSUs with performance-based vesting conditions, the expense is recorded using the graded vesting method. The fair value of each stock option grant is estimated on the date of grant 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 our expected dividend yield. See Note 10 of the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K for more information. Forfeitures are accounted for as they occur. The fair value of each RSU and PSU is estimated on the date of grant based on the fair value of our common stock on that same date.

We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Recently issued accounting pronouncements

Refer to Note 2, Summary of significant accounting policies of the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements that are applicable to our business and may potentially have an impact on our financial position and results of operations.

Item 7A. Quantitative and qualitative disclosures about market risks

Interest rate sensitivity

As of March 31, 2025, we had cash and cash equivalents and short-term investments of $483.8 million, which consisted of cash equivalents, U.S. Treasury securities and U.S. government agency securities. Our primary exposure to market risk relates to fluctuations in interest rates, which are affected by changes in the general level of U.S. interest rates. Given the short-term nature of our cash, cash equivalents and marketable securities, we do not expect that a sudden change in market interest rates would have a material impact on our financial condition and/or results of operations.

Foreign currency exchange risk

Our headquarters are located in the United States, where the majority of our selling, general and administrative expenses are incurred in U.S. dollars. The majority of our research and development costs are incurred by our subsidiary in Oxfordshire, United Kingdom, whose functional currency is the British pound. We are exposed to foreign exchange rate risk. During the year ended March 31, 2025, we recorded net foreign currency transaction gains of $0.2 million whereas for the year ended March 31, 2024, we recognized a net foreign currency transaction loss of $0.8 million. These gains and losses are primarily related to unrealized and realized foreign currency gains and losses as a result of transactions entered into by our United Kingdom subsidiary in currencies other than the British pound, primarily the euro. These foreign currency transaction gains and losses were recorded as a component of other income (expense), net in our consolidated statements of operations. We believe that a 10% change in the exchange rate between the British pound and the euro would not have a material impact on our financial position or results of operations.

As we continue to grow our business, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Item 8. Financial statements and supplementary data

See the consolidated financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below.

Item 9. Changes in and disagreements with accountants on accounting and financial disclosures

None.

Item 9A. Controls and procedures

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report, as required by

Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2025, our disclosure controls and procedures were ineffective due to material weaknesses in internal control over financial reporting as described below.

Our management concluded that the consolidated financial statements included in this Annual Report on Form 10-K,present fairly, in all material respects, our financial position, results of operations, and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. Our Principal Executive Officer and Principal Financial Officer have certified that, based on each such officer's knowledge, the financial statements, as well as the other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this Annual Report.

Management's report on internal control over financial reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has assessed the effectiveness of our internal control over financial reporting as of March 31, 2025. Our management's assessment was based on the framework in "Internal Control — Integrated Framework (2013)" ("2013 framework"), issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, our management concluded that, as of March 31, 2025, our internal control over financial reporting was ineffective based on the criteria in the 2013 framework issued by the COSO due to the existence of the material weaknesses described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis. In connection with the preparation of the consolidated financial statements for this Annual Report on Form 10-K, we identified material weaknesses in our internal control over financial reporting whereby we did not design and maintain effective information technology ("IT") general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain effective: (i) program change management controls to ensure that information technology program and data changes are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel; (iii) computer operations controls to ensure that processing and transfer of data, and data backups and recovery are monitored; and (iv) program development controls to ensure that new software development is tested, authorized and implemented appropriately.

The material weaknesses identified above did not result in any material misstatements in our interim or annual consolidated financial statements or disclosures; however, they could result in misstatements impacting substantially all accounts or disclosures in the annual or interim consolidated financial statements that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Our management concluded that the consolidated financial statements included in this Annual Report on Form 10-K, present fairly, in all material respects, our financial position, results of operations, and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Management's Plan for Remediation of the Material Weakness

Management, with the oversight of the audit committee of the board of directors, is committed to maintaining a strong internal control environment. In response to the material weaknesses identified above, we have begun to develop remediation actions which include:

- Designing and implementing controls over program change management and the review and update of user access rights and privileges.
- Designing and implementing controls to formalize roles and review responsibilities in order to formalize and implement controls over segregation of duties across key financial systems.
- Designing and implementing computer operation and program development controls to ensure data integrity and that new software development is tested, authorized and implemented appropriately.

We believe that these actions, when fully designed and implemented, will remediate the material weaknesses. However, the material weaknesses will not be considered fully remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. As we

continue to evaluate operating effectiveness and monitor improvements to our internal control over financial reporting, we may take additional measures to address control deficiencies or modify the remediation plan described above.

Changes in internal control over financial reporting

There have been no changes in our internal control over financial reporting during the fourth quarter of the fiscal year ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Plan Trading Arrangements

None of our directors or officers adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," in each case as defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, executive officers and corporate governance

The text of our Code of Business Conduct and Ethics, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the "Corporate Governance" section of our website, www.replimune.com. A copy of the Code of Business Conduct and Ethics can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and Nasdaq. The information contained on our website is not considered part of, or incorporated by reference into, this Annual Report on Form 10-K or any other filing that we make with the Securities and Exchange Commission.

In addition, we have adopted an insider trading policy and procedures governing the purchase, sale, and/or other dispositions of our securities (the "Insider Trading Policy") that applies to all directors, officers, and employees of the Company and its subsidiaries. With regard to the Company's trading in its own securities, it is the Company's policy to comply with the federal securities laws and the applicable exchange listing requirements. We believe that the Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations with respect to the purchase, sale and/or other dispositions of the Company's securities, as well as any listing standards, rules and regulations applicable to us. A copy of the Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Information about our executive officers, directors, and all other remaining matters required to be disclosed in Item 10 "Directors, executive officers and corporate governance" appears under the "Executive Officers," "Proposal No. 1 – Election of Directors," "Board of Directors," "Corporate Governance," "Anti-Hedging and Pledging Policy," and "Audit Committee Report" sections of our proxy statement for our 2025 annual meeting of stockholders, or our 2025 Proxy Statement, and is hereby incorporated by reference. We will file our 2025 Proxy Statement with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the close of our fiscal year ended March 31, 2025.

Item 11. Executive compensation

Information about compensation of our named executive officers appears under the "Corporate Governance," "Director Compensation," "Executive Compensation," and the "Pay versus Performance" sections of our 2025 Proxy Statement and is hereby incorporated by reference. Information about compensation of the Board appears under the "Director Compensation" section of our 2025 Proxy Statement and is hereby incorporated by reference. We will file our 2025 Proxy Statement with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the close of our fiscal year ended March 31, 2025.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters

Securities authorized for issuance under equity compensation plans

The following table provides information as of March 31, 2025, regarding our common stock that may be issued under (1) the 2017 Equity Compensation Plan, or the 2017 Plan; (2) the 2018 Omnibus Incentive Compensation Plan, or the 2018 Plan; or (3) the Employee Stock Purchase Plan, or the ESPP.

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Plan Category:			
Equity compensation plans approved by stockholders			
2017 Plan	1,054,999	3.13	—
2018 Plan[(1)]	8,561,114	16.36	2,119,283
ESPP	—	—	3,405,175
Equity compensation plans not approved by stockholders	—	—	—
Total	**9,616,113**		**5,524,458**

(1) Includes 3,098,797 shares of common stock subject to outstanding restricted and performance stock units.

Information about security ownership of certain beneficial owners and management appears under the "Security Ownership of Certain Owners and Management" section of our 2025 Proxy Statement and is hereby incorporated by reference. We will file our 2025 Proxy Statement with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the close of our fiscal year ended March 31, 2025.

Item 13. Certain relationships and related transactions, and director independence

Information about certain relationships and related transactions, and director independence appears under “Certain Relationships and Related Party Transactions” and “Corporate Governance” sections of our 2025 Proxy Statement and are hereby incorporated by reference. We will file our 2025 Proxy Statement with the Securities and Exchange Commission
pursuant to Regulation 14A not later than 120 days after the close of our fiscal year ended March 31, 2025.

Item 14. Principal accountant fees and services

Information about the fees and services of our principal accountant, PricewaterhouseCoopers LLP, appears under the “Proposal No. 2 — Ratification of Selection of Independent Registered Public Accounting Firm” section of our 2025 Proxy Statement and is hereby incorporated by reference. We will file our 2025 Proxy Statement with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the close of our fiscal year ended March 31, 2025.

PART IV

Item 15. Exhibits and financial statement schedules

(a) 1. Consolidated financial statements.

For a list of the consolidated financial statements included herein, see Index on page F-1 of this report.

2. Financial statement schedules.

All required information is included in the financial statements or notes thereto.

3. List of exhibits.

The documents listed in the exhibit index immediately preceding the signature page of this Annual Report on Form 10-K are incorporated by reference or are filed or furnished with this Annual Report on Form 10-K, in each case as indicated therein.

Item 16. 10-K summary

None.

REPLIMUNE GROUP, INC.

Index to Consolidated Financial Statements

For the Years Ended March 31, 2025 and 2024

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Replimune Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Replimune Group, Inc. and its subsidiaries (the "Company") as of March 31, 2025 and 2024, and the related consolidated statements of operations, of comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including 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 as of March 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Research and Development Costs

As described in Notes 2 and 6 to the consolidated financial statements, the Company has entered into various research and development-related contracts with companies both inside and outside of the United States. When billing terms under these contracts do not coincide with the timing of when the work is performed, management is required to make estimates of outstanding obligations to those third parties as of the end of the reporting period. The Company records accruals for estimated ongoing research costs. Within accrued expenses and other current liabilities, total accrued research and development costs amounted to $19.6 million as of March 31, 2025. Accrual estimates are based on a number of factors, including management's assessment of progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research organization or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates are made by management in determining the accrued balances at the end of any reporting period.

The principal considerations for our determination that performing procedures relating to accrued research and development costs is a critical audit matter are (i) the significant judgment by management in developing the estimate of the accrued research and development costs and (ii) a high degree of auditor judgment and effort in performing procedures related to the accrued research and development costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) testing management's process for developing the estimate of accrued research and development costs; (ii) evaluating the appropriateness of the methodology used by management to develop the estimate; (iii) evaluating the reasonableness of management's estimate of accrued external research and development costs by (a) testing the completeness and accuracy of costs incurred, on a sample basis, by tracing information to the underlying contracts, purchase orders, invoices and information received from the research organization or other companies, as applicable, and (b) evaluating the reasonableness of the estimated costs incurred for the services that have not been invoiced, on a sample basis, by tracing to underlying supporting documentation, such as underlying contracts, purchase orders and information received from research organizations or other companies, as applicable.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
May 22, 2025

We have served as the Company's auditor since 2018.

REPLIMUNE GROUP, INC.

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)

	March 31, 2025	March 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 111,119	$ 74,457
Short-term investments	372,685	346,211
Research and development incentives receivable	3,725	4,922
Prepaid expenses and other current assets	8,351	8,077
Total current assets	495,880	433,667
Property, plant and equipment, net	13,739	10,483
Restricted cash	1,703	1,700
Other non-current assets	1,200	—
Right-to-use asset – operating leases	3,998	4,635
Right-to-use asset – financing leases	34,808	37,237
Total assets	$ 551,328	$ 487,722
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,463	$ 2,578
Accrued expenses and other current liabilities	45,916	33,981
Operating lease liabilities, current	1,184	1,161
Financing lease liabilities, current	2,799	2,718
Total current liabilities	62,362	40,438
Operating lease liabilities, non-current	3,076	3,771
Financing lease liabilities, non-current	22,729	23,410
Long term debt, net of discount	46,377	44,809
Other liabilities, non-current	941	786
Total liabilities	$ 135,485	$ 113,214
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized as of March 31, 2025 and March 31, 2024; 77,085,024 and 61,415,105 shares issued and outstanding as of March 31, 2025 and March 31, 2024, respectively	77	61
Additional paid-in capital	1,358,897	1,070,874
Accumulated deficit	(948,579)	(701,282)
Accumulated other comprehensive income	5,448	4,855
Total stockholders' equity	415,843	374,508
Total liabilities and stockholders' equity	$ 551,328	$ 487,722

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

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)

	Year Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 189,447	$ 174,963
Selling, general and administrative	72,180	59,810
Total operating expenses	261,627	234,773
Loss from operations	(261,627)	(234,773)
Other income (expense):		
Research and development incentives	1,773	1,920
Investment income	21,120	23,356
Interest expense on finance lease liability	(2,118)	(2,163)
Interest expense on debt obligations	(5,775)	(4,497)
Other (expense) income	(202)	771
Total other income, net	14,798	19,387
Loss before income taxes	$ (246,829)	$ (215,386)
Income tax provision	468	408
Net loss	$ (247,297)	$ (215,794)
Net loss per common share, basic and diluted	$ (3.07)	$ (3.24)
Weighted average common shares outstanding, basic and diluted	80,564,147	66,569,894

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

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Amounts in thousands)

	Year Ended March 31,	
	2025	2024
Net loss	$ (247,297)	$ (215,794)
Other comprehensive loss:		
Foreign currency translation gain (loss)	174	(826)
Net unrealized gain (loss) on short-term investments, net of tax of $0	419	(48)
Comprehensive loss	$ (246,704)	$ (216,668)

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

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Total stockholders' equity
	Shares	Amount				
Balances as of March 31, 2023	56,676,313	$ 57	$ 1,034,994	$ (485,488)	$ 5,729	$ 555,292
Foreign currency translation adjustment	—	—	—	—	(826)	(826)
Unrealized gain on short-term investments	—	—	—	—	(48)	(48)
Exercise of pre-funded warrants	4,202,622	4	(4)	—	—	—
Exercise of stock options	164,221	—	1,759	—	—	1,759
Vesting of RSUs	371,949	—	—	—	—	—
Stock-based compensation expense	—	—	34,125	—	—	34,125
Net loss	—	—	—	(215,794)	—	(215,794)
Balances as of March 31, 2024	61,415,105	$ 61	$ 1,070,874	$ (701,282)	$ 4,855	$ 374,508
Issuance of prefunded warrants to purchase common stock, net of issuance costs	—	—	97,000	—	—	97,000
Issuance of common stock, net of issuance costs and underwriter fees	14,207,314	14	155,714	—	—	155,728
Foreign currency translation adjustment	—	—	—	—	174	174
Unrealized gain on short-term investments	—	—	—	—	419	419
Exercise of pre-funded warrants	739,225	1	(1)	—	—	—
Exercise of stock options	84,261	—	267	—	—	267
Vesting of RSUs	639,119	1	(1)	—	—	—
Stock-based compensation expense	—	—	35,044	—	—	35,044
Net loss	—	—	—	(247,297)	—	(247,297)
Balances as of March 31, 2025	77,085,024	$ 77	$ 1,358,897	$ (948,579)	$ 5,448	$ 415,843

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

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (247,297)	$ (215,794)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	35,044	34,125
Depreciation and amortization	3,502	2,655
Net amortization of premiums and discounts on short-term investments	(8,947)	(12,326)
Noncash interest expense	1,568	1,161
Unrealized foreign currency transaction losses	(201)	(771)
Changes in operating assets and liabilities:		
Research and development incentives receivable	1,303	(1,916)
Prepaid expenses and other current assets	(252)	(1,778)
Operating lease, right-of-use-asset	683	615
Finance lease, right-of-use-asset	2,428	2,428
Other non-current assets	(1,200)	—
Accounts payable	9,941	(2,794)
Accrued expenses and other current liabilities	11,743	9,234
Operating lease liabilities	(720)	(620)
Other non-current liabilities	155	314
Net cash used in operating activities	(192,250)	(185,467)
Cash flows from investing activities:		
Purchases of property, plant and equipment and software capitalization	(6,687)	(5,662)
Purchase of short-term investments	(403,586)	(489,516)
Proceeds from sales and maturities of short-term investments	386,477	592,379
Net cash (used in) provided by investing activities	(23,796)	97,201
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of underwriting fees and offering costs	155,728	—
Proceeds from issuance of prefunded warrants to purchase common stock, net of underwriting fees and offering costs	97,000	—
Proceeds from long-term debt	—	15,000
Principal payment of finance lease obligation	(599)	(476)
Proceeds from exercise of stock options	267	1,759
Net cash provided by financing activities	252,396	16,283
Effect of exchange rate changes on cash, cash equivalents and restricted cash	315	(86)
Net increase (decrease) in cash, cash equivalents and restricted cash	36,665	(72,069)
Cash, cash equivalents and restricted cash at beginning of period	76,157	148,226
Cash, cash equivalents and restricted cash at end of period	$ 112,822	$ 76,157
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	4,198	$ 3,044
Cash paid for income taxes	105	300
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable	$ 171	$ 101

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

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

1. Nature of the business

Replimune Group, Inc. (the "Company") is a clinical-stage biotechnology company focused on the development of oncolytic immunotherapies to treat cancer. Replimune Group, Inc., whose predecessor was founded in 2015, is the parent company of its wholly owned, direct and indirect subsidiaries: Replimune Limited ("Replimune UK"); Replimune, Inc. ("Replimune US"); Replimune Securities Corporation; and Replimune (Ireland) Limited.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Basis of presentation

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since its inception, including net losses of $247.3 million and $215.8 million for the years ended March 31, 2025 and 2024, respectively. In addition, as of March 31, 2025, the Company had an accumulated deficit of $948.6 million. The Company expects to continue to generate operating losses for the foreseeable future and to finance its future cash needs through a combination of equity offerings, debt financings, collaborations, strategic partnerships and alliances or licensing arrangements. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate some or all of its research and development programs, preclinical and clinical testing or commercialization efforts, which could adversely affect its business prospects. As of the issuance date of these consolidated financial statements, the Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements.

2. Summary of significant accounting policies

Principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and include the accounts of the Company and its direct and indirect wholly owned subsidiaries, Replimune UK, Replimune US, Replimune Securities Corporation and Replimune (Ireland) Limited after elimination of all intercompany accounts and transactions.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances.

Foreign currency and currency translation

The functional currency for the Company's wholly owned foreign subsidiary, Replimune UK, is the British pound. Assets and liabilities of Replimune UK are translated into United States dollars at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of stockholders' equity as a component of accumulated other comprehensive income (loss). Adjustments that arise from exchange rate changes

on transactions denominated in a currency other than the local currency are included in other income (expense), net in the consolidated statements of operations as incurred.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents as well as short-term investments. The Company deposits its cash in financial institutions in amounts that may exceed federally insured limits. We limit our exposure to credit risk by placing investments with high credit quality financial institutions, diversifying our investment portfolio and placing investments with maturities that maintain safety and liquidity. To date, the Company has not experienced any losses on such accounts.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture and supply raw materials and supply services for its development programs. These programs could be adversely affected by a significant interruption in these services or the availability of raw materials.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. Cash equivalents consisted of money market funds as of March 31, 2025 and 2024, respectively. As of March 31, 2025 and 2024, the amount of cash equivalents included in cash and cash equivalents totaled $89.9 million and $41.1 million, respectively.

Restricted cash

The Company holds restricted cash in segregated bank accounts in connection with a letter of credit. As of March 31, 2025 and 2024, restricted cash consisted of $1.7 million, respectively, held for the benefit of the landlords in connection with our leases and for the Company's credit card program in the United Kingdom. These amounts have been classified as non-current assets on the Company’s consolidated balance sheets.

Short-term investments

The Company’s short-term debt security investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and non-credit related losses reported as a component of accumulated other comprehensive income (loss) and included in stockholders’ equity. Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

For available-for-sale debt securities in an unrealized loss position, we first assess whether we intend to sell, or if it is more likely than not that we will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security’s amortized cost basis is written down to fair value through a charge to interest income. For available-for-sale debt securities that do not meet the aforementioned criteria, we evaluate whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers such factors as, among other things, the severity of the impairment, any changes in interest rates, how long the market value of the investment has been less than its original cost, the Company’s ability and intent to retain the short-term debt security investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive loss on the statements of comprehensive loss.

No credit-related losses or impairments have been recognized on the Company's investments in available-for-sale debt securities during the years ended March 31, 2025 or 2024.

The Company’s short-term investments as of March 31, 2025 and 2024 had maturities of less than two years. The Company has classified its investments with maturities beyond one year as short term, based on their highly liquid nature and because they represent the investment of cash that is available for current operations.

Property, plant and equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful life
Office equipment	5 years
Computer equipment and software	3 years
Plant, manufacturing and laboratory equipment	5 years
Capitalized software	3 to 5 years
Leasehold improvements	Lesser of lease term or 10 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Capitalized software as a service costs represent implementation costs incurred during the application development stage and are included in "property, plant and equipment, net" on the Company's consolidated balance sheet. Such costs are amortized on a straight-line basis over the term of the associated arrangement plus any reasonably certain renewal period. Costs incurred during the preliminary project stage and the post-implementation-operation stage are expensed as incurred.

Inventory

Prior to the regulatory approval of the Company’s product candidates, the Company incurs expenses for the manufacture of drug product that could potentially be available to support the commercial launch of those products. Until the date at which regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expenses. There were no capitalized inventory costs recorded as of March 31, 2025 and 2024.

Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment, right-to-use-asset - operating leases, and right-to-use-asset - financing leases. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. 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 that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's short-term investments and cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of research and development incentives receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities. Furthermore, the carrying value of the Company's long-term debt approximates its fair value at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

Debt issuance costs

Debt issuance costs consist of payments made to secure commitments under certain debt financing arrangements. These amounts are recognized as interest expense over the period of the financing arrangement using the effective interest method. If the financing arrangement is canceled or forfeited, or if the utility of the arrangement to the Company is otherwise compromised, these costs are recognized as interest expense immediately. The Company's consolidated financial statements present debt issuance costs related to a recognized debt liability as a direct reduction from the carrying amount of that debt liability.

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's current focus is on developing oncolytic immunotherapies for the treatment of cancer.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, depreciation and external costs of outside vendors engaged to conduct preclinical development, clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. 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. Upfront payments for materials and supplies acquired for particular research and development activities that have no alternative future use in other research and development projects or otherwise, and therefore have no separate economic value, are expensed as research and development costs at the time the costs are incurred.

Research contract costs and accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. These agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. Accrual estimates are based on a number of factors, including management's assessment of progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research organization or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. When billing terms under these contracts do not coincide with the timing of when the work is performed, management is required to make estimates of outstanding obligations to those third parties as of the end of the reporting period. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as selling, general and administrative expenses.

Stock-based compensation

The Company accounts for share-based payment awards granted to employees, consultants, and non-employees and directors using the fair value of the Company's common stock on the grant date and compensation expense is recognized for those awards over the requisite service period, which is generally the vesting period of the respective award. The grant date fair value is utilized for restricted stock units, or RSUs and performance stock units, or PSUs and is based on the closing price of the Company's common stock on the date of grant. For PSUs, the cost is measured at the grant date based on the fair value of the award and is recognized over any relevant service period as expense when the achievement of the performance condition is probable. The fair value of each stock option grant is estimated on the date of grant 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 (see Note 10). Forfeitures are accounted for as they occur. To date, the Company has issued stock-based awards with service-based vesting conditions and records the related expense for these awards using the straight-line method. The Company has also issued PSUs with performance-based vesting conditions and records the expense for these awards using the graded vesting method.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Research and development incentives and receivable

The Company, through its subsidiary in the United Kingdom, receives reimbursements of certain research and development expenditures as part of a United Kingdom government's research and development tax reliefs program. Under the program, a percentage of qualifying research and development expenses incurred by the Company's subsidiary in the United Kingdom are reimbursed up to 16.2%.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

The Company recognizes income from the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. The Company records these research and development incentives as other income. The research and development incentives receivable represents an amount due in connection with the above program. The Company recorded other income from research and development incentives of $1.8 million and $1.9 million during the years ended March 31, 2025 and 2024, respectively, in the consolidated statements of operations and a research and development incentives receivable of $3.7 million and $4.9 million as of March 31, 2025 and 2024, respectively, on the consolidated balance sheets.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the year ended March 31, 2025, comprehensive loss included $0.4 million of unrealized gains on short-term investments, net of tax, as well as $0.2 million of foreign currency translation gains. For the year ended March 31, 2024, comprehensive loss included $0.8 million of foreign currency translation losses.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated

financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax provision. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net income (loss) per share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing the diluted net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures" which expands the disclosure requirements around significant expenses and other segment items, for entities with a single reportable segment, on an interim and annual basis. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 during the year ended March 31, 2025. See Note 17 Segment Information in the accompanying notes to the consolidated financial statements for further detail.

Recently Issued Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This ASU updates income tax disclosure requirements primarily by requiring specific categories and greater disaggregation within the rate reconciliation and disaggregation of income taxes paid by jurisdiction. This ASU is effective for annual periods beginning after December 15, 2024 and is applicable to the Company's fiscal year beginning April 1, 2025, with early application permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU-2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Topic 220): Disaggregation of Income Statement Expenses. The ASU requires additional disclosures of the nature of the expenses included in the income statement, including disaggregation of the expense captions presented on the Consolidated Statements of Operations into specific categories. ASU No. 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the impact of the ASU on the Consolidated Financial Statement disclosures.

3. Fair value of financial assets and liabilities

(Amounts in thousands, except share and per share amounts)

3. Fair value of financial assets and liabilities (Continued)

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Fair Value Measurements as of March 31, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 89,879	$ —	$ 89,879
Short-term investments:				
US Government Agency bonds	—	84,804	—	84,804
US Treasury bonds	—	287,881	—	287,881
	$ —	$ 462,564	$ —	$ 462,564

	Fair Value Measurements as of March 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 41,077	$ —	$ 41,077
Short-term investments:				
US Government Agency bonds	—	199,821	—	199,821
US Treasury bonds	—	146,390	—	146,390
	$ —	$ 387,288	$ —	$ 387,288

The underlying securities held in the money market funds held by the Company are all government backed securities. During the years ended March 31, 2025 and 2024, there were no transfers between levels.

Valuation of cash equivalents and short-term investments

Money market funds, U.S. Treasury bonds and U.S. Government Agency bonds were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. Cash equivalents consisted of money market funds at March 31, 2025 and March 31, 2024.

4. Short-term investments

As of March 31, 2025 and 2024, the Company's available-for-sale investments by type, consisted of the following:

	March 31, 2025				
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Credit Losses	Fair value
US Government agency bonds	$ 84,807	$ 15	$ (18)	$ —	$ 84,804
US Treasury bonds	287,570	334	(23)	$ —	287,881
	$ 372,377	$ 349	$ (41)	$ —	$ 372,685

	March 31, 2024				
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Credit Losses	Fair value
US Government agency bonds	$ 199,905	$ 33	$ (117)	$ —	$ 199,821
US Treasury bonds	146,417	11	(38)	—	146,390
	$ 346,322	$ 44	$ (155)	$ —	$ 346,211

As of March 31, 2025, available-for-sale securities consisted of investments that mature within one year, with the exception of certain U.S. Government agency bonds which had maturities between one and two years and an aggregate fair value of $24.8 million. As of March 31, 2024, available-for-sale securities consisted of investments that mature within one year.

(Amounts in thousands, except share and per share amounts)

5. Property, plant and equipment, net

Property, plant and equipment, net consisted of the following:

	March 31, 2025	March 31, 2024
Office equipment	$ 1,812	$ 1,464
Computer equipment	2,206	1,975
Plant and laboratory equipment	10,877	10,423
Leasehold improvements	2,504	1,886
Capitalized software	8,089	3,515
Construction in progress	1,650	1,117
	27,138	20,380
Less: Accumulated depreciation and amortization	(13,399)	(9,897)
	$ 13,739	$ 10,483

Depreciation and amortization expense was $3.5 million and $2.7 million for the years ended March 31, 2025 and 2024, respectively, and recorded within research and development and selling, general and administrative expenses in the consolidated statement of operations.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2025	March 31, 2024
Accrued research and development costs	$ 19,606	$ 16,376
Accrued compensation and benefits costs	20,080	13,906
Accrued professional fees	161	369
Other	6,069	3,330
	$ 45,916	$ 33,981

7. Long-term debt

Hercules Loan Agreement

On October 6, 2022, the Company entered into a Loan and Security Agreement (the “Loan Agreement”), with Hercules Capital, Inc., as administrative agent, collateral agent and as a lender (“Hercules”). Pursuant to the Loan Agreement, the Company can borrow term loans in an aggregate maximum principal amount of up to $200.0 million under multiple tranches (the “Term Loan Facility”). Under the Loan Agreement, the Company borrowed an initial amount of $30.0 million on the Closing Date, and at the Company's sole option, could have drawn, but did not draw, an additional $30.0 million on or prior to September 30, 2023. The Company can also draw as additional term loan advances in an aggregate principal amount of up to $115.0 million during the term of the Term Loan Facility subject to achievement of specified performance milestones, and two additional term loan advances up to an aggregate principal amount of $25.0 million subject to certain terms and conditions, on or prior to the end of the interest-only period. The Company intends to use the proceeds of the Term Loan Facility for working capital and general corporate purposes.

The Loan Agreement was subsequently amended (the "Amendment") on June 28, 2023 pursuant to which the Company agreed to draw an initial term loan advance in an aggregate principal amount not less than $30.0 million, provided that the aggregate amount of the term loan advances made under tranche 1 do not exceed $30.0 million, which reflects a decrease of $30.0 million from the $60.0 million in the original Loan Agreement for tranche 1. The total amount of the Loan Agreement, as

7. Long-term debt (Continued)

well as the outstanding balance of the loan, is unchanged, but the option to borrow additional funds were redistributed from tranche 1 to tranche 2. The impact of this amendment is not a modification, as it does not relate to outstanding debt, but is rather an amendment that provides for a future potential benefit. There was no material impact to the financial statements as a result of the Amendment.

A second amendment was made to the Loan Agreement (the "Second Amendment") on December 22, 2023 pursuant to which the Company agreed to draw a term loan advance in an aggregate principal amount not less than $15.0 million, provided that the aggregate amount of the term loan advances made under tranche 2 do not exceed $15.0 million on or prior to December 31, 2023. The Second Amendment re-allocated the total future consideration of the Loan Agreement to the future tranches extending through September 2026, subject to the terms and conditions of the Loan Agreement. The Second Amendment did not change the total aggregate maximum principal amount to be drawn under the Loan Agreement, which remains as up to $200.0 million. The Company evaluated the Second Amendment as a modification under relevant accounting guidance, and based on that analysis and the immaterial change in cash flows on current outstanding debt, it was determined that there was no material accounting impact. Upon closing of the Second Amendment, the Company drew down the tranche 2 amount of $15.0 million.

The Term Loan Facility will mature on October 1, 2027 (the “Maturity Date”). The outstanding principal balance of the Term Loan Facility bears interest payable in cash at a floating rate per annum equal to the greater of (i) 7.25% and (ii) the sum of the Prime Rate (which is capped at 7.25%) and 1.75%. Accrued interest is payable monthly following the funding of each term loan advance. In addition, the principal balance of the Term Loan Facility will bear “payment-in-kind” interest at the rate of 1.50% (“PIK Interest”), which PIK Interest will be added to the outstanding principal balance of the Term Loan Facility on each interest payment date.

Borrowings under the Loan Agreement are repayable in monthly interest-only payments through September 2026. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until October 2027. At the Company's option, the Company may prepay all or a portion of the outstanding borrowings, subject to a prepayment fee of 3.0% of the principal amount if prepayment occurs during the 12 months following the Closing Date, 2.0% after 12 months following the Closing Date but prior to 36 months following the Closing Date, and 1.0% thereafter.

The Loan Agreement contains customary facility fees, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain unrestricted cash in an amount not less than 35% of the aggregate outstanding secured obligations under the Loan Agreement in accounts subject to a control agreement in favor of the Agent (the “Unrestricted Cash”) at all times commencing on January 1, 2024. In addition, the Loan Agreement also contains a financial covenant that beginning on the later of (i) July 1, 2024 and (ii) the date on which the aggregate outstanding principal amount of the Term Loan Facility is equal to or greater than $100.0 million, the Company is required to satisfy one of the following requirements: (1) achieve a minimum amount of trailing three-month net product revenue tested on a monthly basis, (2) maintain a market capitalization in excess of $1.2 billion and Unrestricted Cash in an amount no less than 50% of the outstanding amount under the Term Loan Facility, or (3) maintain Unrestricted Cash in an amount no less than 85% of the outstanding amount under the Term Loan Facility.

The Company paid a $0.5 million facility charge and incurred debt issuance costs of $1.5 million upon closing of the Loan Agreement. The Loan Agreement also provides for a final payment, payable upon maturity or the repayment of the obligations in full or in part (on a pro rata basis), equal to 4.95% of the aggregate principal amount of Term Loans advanced to the Borrower and repaid on such date, which is being accrued on the Company's consolidated balance sheet. As of March 31, 2025 and 2024, the amount accrued for the final payment was $1.0 million and $0.5 million, respectively.

Unamortized debt issuance costs are recorded as a reduction of the carrying amount on the term loan and amortized as interest expense using the effective-interest method. In addition, unamortized deferred financing costs of $0.9 million and $1.2 million were recorded in other assets as of March 31, 2025 and 2024, respectively, related to the Company's right to borrow additional amounts from Hercules in the future and amortized to interest expense over the relevant draw period on a straight-line basis. Interest expense for the twelve months ended March 31, 2025 and 2024 was $5.8 million and $4.5 million, respectively.

The summary of obligations under the term loan as of March 31, 2025 and 2024 consisted of the following (in thousands):

(Amounts in thousands, except share and per share amounts)

7. Long-term debt (Continued)

	March 31, 2025	March 31, 2024
Principal loan balance	$ 46,450	$ 45,749
Facility charge and diligence fee	(201)	(266)
Unamortized issuance costs	(901)	(1,191)
Accumulated end of term fee	1,029	517
Long term debt, net	$ 46,377	$ 44,809

The annual principal payments by fiscal year due under the Loan Agreement as of March 31, 2025 were as follows:

	March 31, 2025
2026	—
2027	20,145
Thereafter	27,769
Total	$ 47,914

The table of future payments of long-term debt excludes the end of term charge of $2.2 million, which is due upon the maturity of the loan.

8. Stockholders' Equity

Common stock

As of March 31, 2025 and 2024, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 150,000,000 shares of common stock, par value $0.001 per share.

The Company had reserved for common stock for the exercise of outstanding stock options and the vesting of restricted share units, the number of shares remaining available for grant under the Company's 2018 Omnibus Incentive Compensation Plan and the Company's Employee Stock Purchase Plan (see Note 10) and the exercise of the outstanding warrants to purchase shares of common stock as follows:

	March 31, 2025	March 31, 2024
Stock options, issued and outstanding	10,214,878	8,652,256
Restricted and performance stock units	3,611,774	2,397,890
Stock options and restricted stock units, future issuance	2,119,283	2,284,141
Employee stock purchase plan, available for future grants	3,405,175	2,738,208
Pre-IPO warrants to purchase common stock	497,344	497,344
Pre-funded warrants	14,058,153	5,281,616
Total shares of common stock reserved for future issuance	**33,906,607**	**21,851,455**

Undesignated preferred stock

As of March 31, 2025 and 2024, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.001 per share. There were no undesignated preferred shares issued or outstanding as of March 31, 2025 and 2024.

ATM program

On August 3, 2023, the the Company and Leerink Partners LLC (the "Current Agent") entered into a sales agreement, which was subsequently amended on May 16, 2024, and on November 25, 2024 (as so amended, the "2023 Sales Agreement").

8. Stockholders' Equity (Continued)

Under the 2023 Sales Agreement, the Company may sell, from time to time, at its option, up to an aggregate of $89.0 million of share of the Company's common stock, $0.001 par value shares (the "Shares"), through the Current Agent, as the Company's sales agent.

Any Shares to be offered and sold under the 2023 Sales Agreement will be issued and sold (i) by methods deemed to be an "at the market offering" ("ATM") as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if authorized by the Company, in negotiated transactions or block trades, and (ii) pursuant to a registration statement on Form S-3 filed by the Company with the Securities and Exchange Commission on August 3, 2023, as amended for an offering of various securities, including shares of the Company's common stock, preferred stock, debt securities, warrants and/or units for sale to the public in one or more public offerings.

Subject to the terms of the 2023 Sales Agreement, the Current Agent will use reasonable efforts to sell the Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay the Current Agent a commission of up to 3.0% of the gross proceeds from the sale of the Shares. The Company has also agreed to provide the Current Agent with customary indemnification rights.

During the years ended March 31, 2025 and 2024, the Company did not issue or sell any shares under the 2023 Sales Agreement. The Company cannot provide any assurances that it will issue any additional Shares pursuant to the 2023 Sales Agreement.

Equity offerings

On June 14, 2024, the Company completed a private placement transaction (the "Private Placement") pursuant to which the Company sold (a) 5,668,937 shares of the Company's common stock, at an offering price of $8.82, and (b) in lieu of common stock to certain investors, pre-funded warrants to purchase 5,669,578 shares of the Company's common stock at an offering price of $8.819 per warrant (the "June 2024 Pre-Funded Warrants"). The Company received aggregate net proceeds in the Private Placement of approximately $96.7 million after deducting placement agent fees and other offering expenses payable by the Company of approximately $3.3 million.

On November 25, 2024, the Company completed a public offering of (a) 8,538,377 shares of the Company's common stock, inclusive of the Underwriters fully exercised 30-day option to purchase up to 1,615,377 additional shares of the Company's common stock at a public offering price of $13.00 per share, and (b) pre-funded warrants to purchase 3,846,184 shares of the Company's common stock at a public offering price of $12.9999 per warrant (the "December 2024 Pre-Funded Warrants"). The Company received aggregate net proceeds of approximately $156.0 million after deducting fees and expenses of approximately $5.0 million.

9. Pre-funded Warrants

The Company's pre-funded warrants are exercisable at any time after the date of issuance. Unless otherwise modified by a holder of a pre-funded warrant, no holder may exercise a pre-funded warrant (i) if such holder, together with its affiliates, would beneficially own more than 9.99% (or, in the case of the December 2024 Pre-Funded Warrants, 4.99%) of the number of shares of our common stock outstanding immediately after giving effect to such exercise, or (ii) if the combined voting power of our securities beneficially owned by such holder, together with its affiliates, would exceed 9.99% (or, in the case of the December 2024 Pre-Funded Warrants, 4.99%) of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise of such pre-funded warrants, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants.. A holder of the June 2024 Pre-funded Warrants may increase or decrease this percentage to any other percentage not in excess of 9.99%, whereas a holder of the Company's other Pre-funded Warrants, may increase or decrease this percentage up to 19.99%, in each case, by providing at least 61 days' prior notice to the Company.

The 14,058,153 shares of the Company's common stock underlying the pre-funded warrants issued by the Company are not included in the number of issued and outstanding shares of the Company's common stock outstanding as reported on the consolidated balance sheet, though they are included in the Company's annual pool increase calculation as well as the weighted average outstanding common stock in the calculation of basic and diluted net loss per share, as noted below in Note 11.

During the year ended March 31, 2025, a holder of the Company's pre-funded warrants exercised 739,225 of its pre-funded warrants for an exercise price of $0.0001 per pre-funded warrant and the Company issued 739,225 shares of Common Stock in exchange thereof.

10. Stock-based compensation

Stock-based compensation expense

The following table summarizes the classification of stock-based compensation expense in the consolidated statements of operations for the years ended March 31, 2025 and 2024 as follows:

	Year ended March 31,	
	2025	2024
Research and development	$ 18,439	$ 14,745
Selling, general and administrative	16,605	19,380
	$ 35,044	$ 34,125

The following table summarizes stock-based compensation expense by award type for the years ended March 31, 2025 and 2024 as follows:

	Year ended March 31,	
	2025	2024
Stock options	$ 19,885	$ 21,594
Restricted and performance stock units	15,159	12,531
	$ 35,044	$ 34,125

2015 Enterprise Management Incentive Share Option Plan

The 2015 Enterprise Management Incentive Share Option Plan of Replimune UK (the “2015 Plan”) provided for Replimune UK to grant incentive stock options, non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options are granted only to the Company’s employees, including officers and directors who are also employees. Non-statutory stock options are granted to employees, members of the board of directors, outside advisors and consultants of the Company.

2017 Equity Compensation Plan

In July 2017, in conjunction with reorganization by Replimune Limited, pursuant to which each shareholder thereof exchanged their outstanding shares in Replimune Limited for shares in Replimune Group, Inc., on a one-for-one basis (the "Reorganization"), the 2015 Plan was terminated, and all awards were cancelled with replacement awards issued under the 2017 Equity Compensation Plan (the “2017 Plan”). Subsequent to the Reorganization, no additional grants have been or will be made under the 2015 Plan and any outstanding awards under the 2015 Plan have continued, and will continue with their original terms. The Company concluded that the cancellation of the 2015 Plan and issuance of replacement awards under the 2017 Plan was a modification with no change in the material rights and preferences and therefore no recorded change in the fair value of each respective award.

The Company’s 2017 Plan provides for the Company to grant incentive stock options or non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options were granted under the 2017 Plan only to the Company’s employees, including officers and directors who were also employees. Restricted stock awards and non-statutory stock options were granted under the 2017 Plan to employees, officers, members of the board of directors, advisors and consultants of the Company. The maximum number of common shares that may be issued under the 2017 Plan was 2,659,885, of which none remained available for future grants as of March 31, 2025. Shares with respect to which awards have expired, terminated, surrendered or cancelled under the 2017 Plan without having been fully exercised will be available for future awards under the 2018 Plan referenced below. In addition, shares of common stock that are tendered to

10. Stock-based compensation (Continued)

the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

2018 Omnibus Incentive Compensation Plan

On July 9, 2018, the Company's board of directors adopted, and the Company's stockholders approved the 2018 Omnibus Incentive Compensation Plan (the "2018 Plan"), which became effective immediately prior to the effectiveness of the registration statement for the Company's initial public offering. The 2018 Plan provides for the issuance of incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. The number of shares initially reserved for issuance under the 2018 Plan is 3,617,968 shares. If any options or stock appreciation rights, including outstanding options and stock appreciation rights granted under the 2017 Plan (up to 2,520,247 shares), terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards, stock units or other stock-based awards, including outstanding awards granted under the 2017 Plan, are forfeited, terminated, or otherwise not paid in full in shares of common stock, the shares of the Company's common stock subject to such grants will be available for purposes of our 2018 Plan. The number of shares reserved for issuance under the 2018 Plan will increase automatically on the first day of each April equal to 4.0% of the total number of shares of Company stock outstanding on the last trading day in the immediately preceding fiscal year, which includes for these purposes, the 14,058,153 shares issuable upon exercise of those pre-funded warrants described in Note 9 to these consolidated financial statements, or such lesser amount as determined by the Board. On April 1, 2024, the number of shares reserved for issuance under the 2018 Plan automatically increased by 2,667,868 shares pursuant to the terms of the 2018 Plan and based on total number of shares of Company stock outstanding on March 31, 2024. As of March 31, 2025, 2,119,283 shares remained available for future grants under the 2018 Plan.

The 2015 Plan, the 2017 Plan and the 2018 Plan are administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. However, the board of directors shall administer and approve all grants made to non-employee directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (or 110% of fair value in the case of an award granted to employees who hold more than 10% of the total combined voting power of all classes of stock at the time of grant) and the term of stock options may not be greater than five years for an incentive stock option granted to a 10% stockholder and greater than ten years for all other options granted. Stock options awarded under both plans expire ten years after the grant date, unless the board of directors sets a shorter term. Vesting periods for both plans are determined at the discretion of the board of directors. Incentive stock options granted to employees and non-statutory options granted to employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over four years. In 2021 the board of directors initiated the award of RSUs, under the 2018 Plan in addition to stock option awards available as part of the Company's equity incentive for employees, officers, advisors and consultants of the Company. The RSUs typically vest over four approximately equal annual installments with the first such installment occurring on a designated vesting date that is approximately on the one year anniversary date of the date of grant and the subsequent installments occurring on the subsequent three annual anniversaries of the designated vesting date.

In January 2024, the Board of Directors approved the award of PSUs, under the 2018 Plan in addition to the aforementioned stock option awards and RSUs available as part of the Company's equity incentive for employees, officers, advisors and consultants of the Company. The PSUs will become vested upon the achievement of the approval of the Company's first Biologics Licnese Application ("BLA") for RP1 by the Food and Drug Administration ("FDA") no later than June 30, 2026, and the expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted. The timing of recognition of this stock-based compensation expense commences upon our determination that the related performance conditions are considered probable of being achieved. The Company granted 246,110 PSUs under the 2018 Plan during the year ended March 31, 2025. If the Company does not achieve the approval of the Company's first BLA for RP1 before the expiration of June 30, 2026 then no PSU will be earned or vested.

Employee Stock Purchase Plan

On July 9, 2018, the Company's board of directors adopted and the Company's stockholders approved the Employee Stock Purchase Plan (the "ESPP"), which became effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The total shares of common stock initially reserved for issuance under the ESPP is limited to 348,612 shares. In addition, as of the first trading day of each fiscal year during the term of the ESPP (excluding any extensions), an additional

(Amounts in thousands, except share and per share amounts)

10. Stock-based compensation (Continued)

number of shares of the Company's common stock equal to 1% of the total number of shares outstanding on the last trading day in the immediately preceding fiscal year, which includes for these purposes, the 14,058,153 shares issuable upon exercise of those pre-funded warrants described in Note 9 to these consolidated financial statements, or 697,224 shares, whichever is less (or such lesser amount as determined by the Company's board of directors) will be added to the number of shares authorized under the ESPP. In accordance with the terms of the ESPP, on April 1, 2024, the number of shares reserved for issuance under the ESPP automatically increased by 666,967, for a total of 3,405,175 shares reserved for the ESPP. If the total number of shares of common stock to be purchased pursuant to outstanding purchase rights on any particular date exceed the number of shares then available for issuance under the ESPP, then the plan administrator will allocate the available shares pro-rata and refund any excess payroll deductions or other contributions to participants. The Company's ESPP is not currently active.

Out-of-Plan Inducement Grant

From time to time, the Company grants equity awards to newly hired employees and executives as an inducement to enter into employment with the Company. The grants constitute "employment inducement grants" in accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules and was issued outside of the 2018 Plan and each of the other stock incentive plans described above. The inducement grants typically include nonqualified stock options to purchase shares of the Company's common stock, as well as restricted stock unit grants representing shares of the Company's common stock. These stock option and restricted stock unit inducement grants have terms and conditions consistent with those set forth under the 2018 Plan and vest under the same respective vesting schedules as stock option and restricted stock unit awards granted under the 2018 Plan. The inducement grants are included in the stock option and RSU award tables below. During the years ended March 31, 2025 and 2024, the Company granted 267,835 and 125,000 nonqualified stock options to purchase shares of the Company's common stock, respectively, and 404,030 and 83,330 restricted stock units, respectively, under employment inducement grants.

Stock option valuation

The fair value of stock option grants is estimated 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 determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for a period that approximates the expected term of the option, and our expected dividend yield. The expected stock volatility is based on Replimune's historical share price volatility. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options.

Forfeitures are accounted for as they occur. The fair value of each RSU and PSU is estimated on the date of grant based on the fair value of our common stock on that same date

The following table presents, on a weighted-average basis, the assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors:

	Year ended March 31,	
	2025	2024
Risk-free interest rate	4.35 %	3.75 %
Expected term (in years)	6.0	6.0
Expected volatility	76.3 %	74.2 %
Expected dividend yield	0 %	0 %

(Amounts in thousands, except share and per share amounts)

10. Stock-based compensation (Continued)

Stock options

A summary of stock option activity under the Company's equity incentive plans for the year ended March 31, 2025 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of March 31, 2024	8,652,256	$ 16.94	6.61	$ 5,748
Granted	2,191,911	8.51		
Exercised	(84,261)	3.17		
Cancelled	(545,028)	17.33		
Outstanding as of March 31, 2025	10,214,878	15.22	6.24	$ 10,652
Options exercisable as of March 31, 2025	6,704,895	$ 16.82	4.99	$ 7,059
Options vested and expected to vest as of March 31, 2025	10,214,878	$ 15.22	6.24	$ 10,652

As of March 31, 2025, there was $23.9 million of unrecognized compensation cost related to unvested common stock options, which is expected to be recognized over a weighted average period of 2.5 years.

The weighted average grant-date fair value of stock options granted during the years ended March 31, 2025 and 2024 was $5.91 and $11.41, respectively. The aggregate intrinsic value of stock options exercised during the years ended March 31, 2025 and 2024 was $0.5 million and $1.4 million, respectively.

Restricted and performance stock units

In January 2024, the Board approved a one-time PSU award under the 2018 Plan for all employees at the vice president level and below as of January 31, 2024, subject to non-market performance and service conditions. The grants will become vested upon the achievement of the approval of the Company's first Biologics License Application ("BLA") for RP1 by the Food and Drug Administration ("FDA") no later than June 30, 2026. If the Company does not achieve the approval of the Company's first BLA for RP1 before the expiration of June 30, 2026 then no PSU will be earned or vested. The grant date fair value for the PSUs is determined based on the market price of the Company's common stock on the grant date and is recognized over the requisite service period if and when the achievement of such performance condition is determined to be probable by the Company. The Company reassesses the probability of achieving the performance condition at each reporting period. As of March 31, 2025, the Company has not recognized any expense related to PSUs.

A summary of the changes in the Company's RSUs and PSUs during the year ended March 31, 2025 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of March 31, 2024	2,397,890	$ 17.97
Granted	2,153,237	8.83
Vested	(639,119)	21.07
Cancelled	(300,234)	12.84
Outstanding as of March 31, 2025	3,611,774	$ 12.40

As of March 31, 2025, there was $28.3 million of total unrecognized compensation cost related to unvested restricted stock units which vest over time, which primarily will be recognized over a weighted-average period of 2.3 years. In addition, the Company has unrecognized expense of approximately $4.5 million related to performance based awards with vesting tied to the achievement of a company milestone.

11. Net loss per share

11. Net loss per share (Continued)

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders (in thousands, except per share amounts):

	Year ended March 31,	
	2025	2024
Numerator:		
Net loss	$ (247,297)	$ (215,794)
Denominator:		
Weighted average common shares outstanding, basic and diluted	80,564,147	66,569,894
Net loss per share, basic and diluted	$ (3.07)	$ (3.24)

The 14,058,153 shares of the Company's common stock issuable upon exercise of Pre-Funded Warrants described in Note 9 to these consolidated financial statements are included as outstanding common stock in the calculation of basic and diluted net loss per share.

The Company's potentially dilutive securities, which include stock options, unvested restricted and performance stock units and warrants to purchase shares of common stock that resulted from the conversion of warrants to purchase shares of seed preferred stock existing before the Company's IPO, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Year ended March 31,	
	2025	2024
Options to purchase common stock	10,214,878	8,652,256
Unvested restricted and performance stock units	3,611,774	2,397,890
Warrants to purchase common stock	497,344	497,344
	14,323,996	11,547,490

12. Significant agreements

Agreement with Bristol-Myers Squibb Company

In February 2018, the Company entered into an agreement with Bristol-Myers Squibb Company ("BMS"). Pursuant to the agreement, BMS will provide to the Company, at no cost, nivolumab, its anti-PD-1 therapy, for use in the Company's ongoing clinical trial of RP1. Under the agreement, the Company will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted the Company a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and agreed to supply nivolumab, at no cost to the Company, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us. In January 2020, this agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 failed melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (x) in the event of an uncured material breach by the other party, (y) in the event the other party is insolvent or in bankruptcy proceedings or (z) for safety reasons. Upon termination, the licenses granted to the Company to use BMS's nivolumab in the clinical trial will terminate.

12. Significant agreements (Continued)

In April 2019, the Company entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide to the Company, at no cost, nivolumab for use in the Company's Phase 1 clinical trial of RP2 in combination with nivolumab.

Roche

In December 2022, the Company entered into a Master Clinical Trial Collaboration and Supply Agreement with Roche in relation to the Company's RP2 and RP3 programs in colorectal cancer, or CRC, and hepatocellular carcinoma, or HCC. Under the agreement, the companies intended to collaborate in 30 patient cohort signal finding studies in third-line, or 3L, CRC and in first- and second-line, or 1L and 2L, respectively, HCC. Following the Company's re-prioritization of its product development portfolio in December 2023, the Company has agreed with Roche to terminate the CRC collaboration and pursue the 2L cohort in HCC with RP2 only. Roche has continued to supply its currently approved drugs, atezolizumab and bevacizumab for the 2L cohort in HCC but is not sharing costs following the Company's re-prioritization. Under the terms of the initial agreement the Company retained the responsibility of operating the clinical trials as well as retaining all the rights to the development and commercialization of its product candidates. The agreement may be terminated by either party upon sixty days prior written notice to the other party.

The agreement with Roche is accounted for under ASC 808, *Collaborative Arrangements* ("ASC 808"), as both parties are active participants and each party pays its own compound costs and shares equally in development costs in accordance with and up to the amount in the agreed upon first study plan. The Company accounts for costs incurred as part of the study, including costs to supply compounds for use in the study, as research and development expenses within the consolidated statement of operations. The Company recognizes any amounts received from Roche in connection with this agreement as an offset to research and development expense within the consolidated statement of operations.

During the years ended March 31, 2025 and 2024, the Company did not make any payments to Roche under the terms of the agreement. The Company did not record any offset to research and development expenses during the year ended March 31, 2025, and the Company recorded $2.7 million as an offset to research and development expenses during the years ended March 31, 2024. During the years ended March 31, 2025 and 2024, the Company received payments under the terms of the agreement from Roche of $1.8 million and $1.7 million, respectively. As of March 31, 2025, the Company had no receivables recorded from Roche in connection with this agreement. As of March 31, 2024, the Company had $1.8 million in receivables recorded from Roche.

Amgen

In August 2023 the Company entered into a Settlement Agreement with Amgen and mutually agreed to terminate the Company's challenges to Amgen's patents. In connection with the Settlement Agreement, the Company entered into a License and Covenant Agreement with Amgen in which the Company agreed to pay Amgen low single-digit royalty payments on net sales of its products that, but for the license, could be found to infringe a valid Amgen patent on a country-by-country and product-by-product basis.

13. Commitments and contingencies

Leases

The Company leases real estate assets and equipment, and determination if an arrangement is a lease occurs at inception. For leases with terms greater than 12 months, the Company records a related right-of-use ("ROU") asset and lease liability at the present value of lease payments over the term. Many leases include fixed rental escalation clauses, renewal options and/or termination options that are factored into the determination of lease payments when appropriate. The Company's leases do not provide an implicit rate, and thus the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company has elected not to record a ROU asset and lease obligation for short-term leases (with terms less than 12 months) or separate non-lease components from associated lease components for its real estate lease assets. As a result, all contract consideration is allocated to the single lease component.

The Company's leases have remaining lease terms of five years to fifteen years. Some of the Company's leases include one or more options to renew with renewal terms that can extend the lease for additional years, or options to terminate the leases, both at the Company's discretion. The Company's lease terms include options to extend or terminate leases when the Company concludes it is reasonably certain that it would exercise those options. Lease expense for minimum lease payments is

(Amounts in thousands, except share and per share amounts)

13. Commitments and contingencies (Continued)

recognized on a straight-line basis based on the fixed components of a lease arrangement. The Company amortizes this expense over the term of the lease beginning with the date of initial possession, which is the date the Company can enter the leased space and begin to make improvements in preparation for its intended use. Variable lease components represent amounts that are not fixed in nature and are not tied to an index or rate, and are recognized as incurred.

The table below presents the lease-related costs which are included in the consolidated statements of operations for the years ended as of March 31, 2025 and 2024:

	Year ended March 31,	
	2025	2024
Lease cost		
Finance lease costs:		
Amortization of right-to-use asset	$ 2,428	$ 2,428
Interest on lease liabilities	2,118	2,163
Operating lease costs	1,129	1,122
Total lease cost	$ 5,675	$ 5,713

The following table summarizes the classification of lease costs in the consolidated statement of operations for the years ended March 31, 2025 and 2024 as follows:

	Year ended March 31,	
	2025	2024
Finance Lease Costs		
Research and development	$ 2,428	$ 2,428
Other income, net	2,118	2,163
Operating Lease Costs		
Research and development	877	911
Selling, general and administrative	252	211
Total lease cost	$ 5,675	$ 5,713

The following table summarizes the maturity of the Company's lease liabilities on an undiscounted cash flow basis and a reconciliation to the operating and financing lease liabilities recognized on our balance sheet as of March 31, 2025:

	March 31, 2025		
	Operating leases	Financing lease	Total
2026	$ 1,184	$ 2,799	$ 3,983
2027	1,149	2,883	4,032
2028	1,096	2,969	4,065
2029	1,013	3,058	4,071
2030	579	3,096	3,675
Thereafter	361	28,899	29,260
Total lease payments	5,382	43,704	49,086
Less: interest	1,122	18,176	19,298
Total lease liabilities	$ 4,260	$ 25,528	$ 29,788

(Amounts in thousands, except share and per share amounts)

13. Commitments and contingencies (Continued)

The following table provides lease disclosure as of and for the year ended March 31, 2025:

	March 31, 2025	March 31, 2024
Leases		
Right-to-use operating lease asset	$ 3,998	$ 4,635
Right-to-use finance lease asset	34,808	37,237
Total lease assets	$ 38,806	$ 41,872
Operating lease liabilities, current	$ 1,184	$ 1,161
Finance lease liabilities, current	2,799	2,718
Operating lease liabilities, non-current	3,076	3,771
Finance lease liabilities, non-current	22,729	23,410
Total lease liabilities	$ 29,788	$ 31,060
Other information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,167	$ 1,059
Operating cash flows from finance leases	$ 2,118	$ 2,163
Financing cash flows from finance leases	$ 599	$ 476
Right-to-use asset obtained in exchange for new operating lease liabilities	$ —	$ 0
Weighted-average remaining lease term – operating leases	4.7 years	5.6 years
Weighted-average remaining lease term – financing leases	14.3 years	15.3 years
Weighted-average discount rate – operating leases	10.4 %	10.3 %
Weighted-average discount rate – financing leases	8.3 %	8.3 %

The variable lease costs and short-term lease costs were insignificant for the years ended March 31, 2025 and 2024, respectively.

Manufacturing commitments

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of March 31, 2025 and 2024, the Company had committed to minimum payments under these arrangements totaling $0.8 million and $0.9 million.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its executive management team and its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and therefore it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2025 or 2024.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

14. Benefit plans

(Amounts in thousands, except share and per share amounts)

The Company established a defined-contribution savings plan under Section 401(k) of the Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the 401(k) Plan may be made at the discretion of the Company's board of directors. During the years ended March 31, 2025 and 2024, the Company made contributions totaling $2.4 million and $2.1 million, respectively, to the 401(k) Plan.

We provide a pension contribution plan for our employees in the United Kingdom, pursuant to which we match our employees' contributions each year in amounts up to 8% of their annual base salary.

15. Income taxes

Loss before income taxes for the years ended March 31, 2025 and 2024 were as follows:

	Year ended March 31,	
	2025	2024
United States	(25,870)	(19,367)
United Kingdom	(220,959)	(196,019)
Total	$ (246,829)	$ (215,386)

During the year ended March 31, 2025 and 2024, the Company recorded an income tax provision of $0.5 million and $0.4 million, respectively, related to U.S. current taxes primarily due to the transfer pricing arrangement between the U.S. and the U.K., as well as unfavorable adjustments related to stock compensation, resulting in U.S. taxable income partially reduced by certain prior year available net operating losses and U.S. tax partially reduced by certain credits.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of March 31, 2025 and 2024, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company's assessment is based on the weight of available evidence, including cumulative losses since inception and expected future losses and, as such, the Company does not believe it is more likely than not that the deferred tax assets will be realized. Accordingly, a full valuation allowance was maintained as of March 31, 2025 and 2024.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective tax rate for the years ended March 31, 2025 and 2024 is as follows:

	Year Ended March 31,	
	2025	2024
U.S. federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(0.5)%	(0.3)%
Research and development	(1.6)%	0.7 %
Stock compensation	1.2 %	3 %
Foreign tax rate differential	(3.6)%	(3.6)%
Change in tax rates	0.4 %	— %
Change in valuation allowance	24.3 %	21.4 %
Other	1.0 %	0.0 %
	0.2 %	0.2 %

(Amounts in thousands, except share and per share amounts)

15. Income taxes (Continued)

Components of the Company's deferred tax assets as of March 31, 2025 and 2024 were as follows:

	Year Ended March 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 192,909	$ 141,911
Research and development credits	2,676	—
Property, plant and equipment	4,596	4,706
Capitalized start-up costs	1,014	1,199
Stock compensation	16,478	13,798
Accrued expenses	6,397	3,221
Lease liability	7,318	7,938
Other	—	39
Total deferred tax assets	231,388	172,812
Valuation allowance	(221,629)	(161,890)
Net deferred tax assets	9,759	10,922
Deferred tax liabilities:		
Right of use asset	(9,698)	(10,922)
Other	(61)	—
Total deferred tax liabilities	(9,759)	(10,922)
Net deferred tax assets (liabilities)	$ —	$ —

As of March 31, 2025, the Company had U.S. federal operating loss carryforwards of approximately $15.9 million, which can be carried forward indefinitely subject to 80% limitation of taxable income when utilized. As of March 31, 2025, the Company had U.S. state net operating loss carryforwards of $54.4 million before gross unrecognized tax benefits from uncertain tax positions, which will begin to expire in 2040. As of March 31, 2025, the Company had U.K. net operating loss carryforwards of approximately $737.6 million, which can be carried forward indefinitely. Such U.S. federal and state, as well as U.K., net operating loss carryforwards are based on tax returns filed and does not reflect gross unrecognized tax benefits from uncertain tax positions in the U.S. and offsetting positions in the U.K. related to the transfer pricing arrangement between the U.S. and the U.K.

As of March 31, 2025, the Company had U.S. federal research and development credit carryforwards of approximately $5.4 million before gross unrecognized tax benefits from uncertain tax positions, which begin to expire in 2041. Additionally, the Company has state research and development credit carryforwards of approximately $1.5 million before gross unrecognized tax benefits from uncertain tax positions, which will begin to expire in 2036.

Utilization of the U.S. federal and state net operating loss as well as research and development credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss as well as research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has completed a study through March 31, 2025 and determined that an ownership change occurred on July 19, 2018. Due to the ownership change, the utilization of certain net operating loss as well as research and development credit carryforwards to offset future taxable income and tax are limited; however, none of the net operating loss as well as research and development credits are expected to expire unutilized.

(Amounts in thousands, except share and per share amounts)

15. Income taxes (Continued)

Changes in the valuation allowance for deferred tax assets during the years ended March 31, 2025 and 2024 related primarily to the increase in net operating loss carryforwards were as follows:

	Year Ended March 31,	
	2025	2024
Valuation allowance as of beginning of year	$ 161,890	$ 113,889
Increases recorded to income tax provision	59,848	45,941
(Decreases) increases recorded to equity	(109)	2,060
Valuation allowance as of end of year	$ 221,629	$ 161,890

Changes in the Company's gross unrecognized tax benefits from uncertain tax positions, excluding interest and penalties, consisted of the following:

	Year Ended March 31,	
	2025	2024
Unrecognized tax benefits - beginning of year	$ 8,667	$ 8,757
Increases for tax positions taken during current years	921	—
Increases (decreases) for tax positions taken during prior years	855	(90)
Unrecognized tax benefits - end of year	$ 10,443	$ 8,667

The Company's unrecognized tax benefits primarily relate to the Company's transfer pricing arrangement between the U.S. and the U.K. and the impacts to the Company’s net operating loss as well as research and development credit carryforwards.

The Company's unrecognized tax benefits, if recognized, would not have a material impact to the Company's effective tax rate and income tax provision due to the Company's full valuation allowance.

As of March 31, 2025 and 2024, the Company had not accrued interest or penalties related to uncertain income tax positions.

The Company files U.S. federal and state as well as U.K. income tax returns. In the normal course of business, the Company is subject to examination by U.S. federal and state as well as U.K. jurisdictions, where applicable. There are currently no pending income tax examinations. The Company is open to future U.S. federal income tax examination from 2021 to the present and in the U.K. from 2023 to the present. Although, carryforward attributes from earlier years may still be adjusted upon examination if they either have been used in an open year or will be used in a future period.

As of March 31, 2025 and 2024, income taxes on outside basis differences, primarily related to undistributed earnings, of the Company’s subsidiary have not been provided for as the Company intends to indefinitely reinvest its outside basis differences, and the undistributed earnings were in a cumulative and overall deficit.

16. Geographic information

The Company operates in two geographic regions: the United States (Massachusetts) and the United Kingdom (Oxfordshire). Information about the Company’s long-lived assets held in different geographic regions is presented in the tables below:

	March 31, 2025	March 31, 2024
United States	$ 12,820	$ 8,992
United Kingdom	919	1,491
	$ 13,739	$ 10,483

17. Segment Information

17. Segment information (Continued)

The Company manages its operations as a single operating and reportable segment with a focus on developing and commercializing novel oncolytic immunotherapies in order to treat cancer. The Company defines its segments on the basis of the way in which internally reported financial information is regularly reviewed to analyze financial performance and make operating decisions. The Company's Chief Operating Decision Maker ("CODM") is Sushil Patel, the Chief Executive Officer. The CODM reviews consolidated operating results, and uses the Company's consolidated net income (loss), in order to monitor actual results as compared to the budget, and to determine how best to allocate the Company's operating and capital resources, specifically as it relates to the Company's development programs.

The following table presents selected financial information with respect to the Company's single operating segment, including significant segment expenses by program, for the years ended March 31, 2025 and 2024:

	Year Ended March 31,	
	2025	**2024**
Operating expenses:	(Amounts in thousands)	
Direct research and development expenses by program:		
RP1 program costs by study:		
IGNYTE	14,620	16,641
ARTACUS	6,934	6,198
CERPASS	7,276	16,165
IGNYTE-3	7,183	2,042
Other RP1 study costs	10,863	10,446
RP2	12,043	10,701
RP3	4,948	13,162
Unallocated research and development expenses[1]:	125,580	99,608
Selling, general and administrative	72,180	59,810
Total operating expenses	261,627	234,773
Loss from operations	(261,627)	(234,773)
Other income (expense), net	14,798	$ 19,387
Loss before income taxes	$ (246,829)	$ (215,386)
Income tax provision	468	408
Net loss	(247,297)	(215,794)

[1]Includes personnel-related costs and other costs

1

Exhibit index

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant (conformed to include the Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on September 9, 2019).	10-K	June 3, 2020	3.1
3.2	Amended and Restated By-laws of the Registrant.	8-K	July 24, 2018	3.2
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	July 10, 2018	4.1
4.2	Amended and Restated Investors' Rights Agreement, dated July 10, 2017, by and among the Registrant and the investors set forth therein.	S-1	June 22, 2018	4.2
4.3*	Description of the Registrant's Securities registered pursuant to Section 12 of the Securities Exchange Act of 1934.			
4.4	Form of Pre-Funded Warrant (2019).	8-K	November 18, 2019	4.1
4.5	Form of Pre-Funded Warrant (2020).	8-K	June 10, 2020	4.1
4.6	Form of Pre-Funded Warrant (2022)	8-K	December 12, 2022	4.1
4.7	Form of Pre-Funded Warrant (June 2024)	8-K	June 13, 2024	4.1
4.8	Form of Pre-Funded Warrant (December 2024)	8-K/A	December 4, 2024	4.1
4.9	Form of Indenture to be entered into between the Registrant and a trustee acceptable to the Registrant.	S-3	August 3, 2023	4.7
10.1†	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	S-1/A	July 10, 2018	10.1
10.2†	2017 Equity Compensation Plan and Sub-Plan for U.K. Employees and forms of agreements thereunder.	S-1/A	June 26, 2018	10.2
10.3†	2018 Omnibus Incentive Compensation Plan and Sub-Plan for U.K. Employees and forms of agreements thereunder.	10-K	May 19, 2022	10.3
10.4†	Form of Performance Stock Unit Award Agreement under 2018 Omnibus Incentive Compensation Plan for U.S. Employees.	10-K	May 16, 2024	10.4
10.5†	Form of Performance Stock Unit Award Agreement under 2018 Omnibus Incentive Compensation Plan and Sub-Plan for U.K. Employees.	10-K	May 16, 2024	10.5
10.6†	Form of Inducement Stock Option Grant Agreement.	10-K	May 16, 2024	10.6
10.7†	Form of Inducement Restricted Stock Unit Grant Agreement.	10-K	May 16, 2024	10.7
10.8†	Employee Stock Purchase Plan.	S-1/A	July 10, 2018	10.4
10.16	Lease, dated as of April 1, 2016, by and between Cummings Properties, LLC and the Registrant.	S-1	June 22, 2018	10.8
10.17	Lease, dated as of April 4, 2016, by and between MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, and Replimune Limited.	S-1	June 22, 2018	10.9
10.18	Deed of Variation, dated June 29, 2020, by and among MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, and Replimune Limited.	10-Q	August 7, 2020	10.3
10.19‡	Clinical Trial Collaboration and Supply Agreement, dated as of February 26, 2018, by and between Bristol-Myers Squibb Company and the Registrant.	S-1/A	July 10, 2018	10.12

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
10.20‡	Master Clinical Trial Collaboration and Supply Agreement, dated as of May 29, 2018, by and between Regeneron Pharmaceuticals, Inc. and the Registrant.	S-1/A	July 17, 2018	10.13
10.21	Indenture of Lease, dated as of June 22, 2018, by and between CRP/King 33 NY Ave. Owner, L.L.C. and the Registrant.	S-1	June 22, 2018	10.12
10.22	Lease, dated as of June 7, 2019, by and between ND/CR Unicorn LLC and the Registrant.	8-K	June 13, 2019	10.1
10.24	Clinical Trial Collaboration and Supply Agreement (RP-2), dated as of April 12, 2019, by and between Bristol-Myers Squibb Company and Replimune, Inc.	10-K	June 3, 2020	10.22
10.25	Lease Agreement, dated as of October 29, 2021, by and among Replimune Limited, MEPC Milton Park No. 1 Limited, and MEPC Milton Park No. 2 Limited.	10-Q	February 3, 2022	10.3
10.26*	Lease Agreement, dated as of March 23, 2023, by and among Replimune Limited, MEPC Milton Park No. 1 Limited, and MEPC Milton Park No. 2 Limited.	10-K	May 18, 2023	10.34
10.28	Second Amendment to Loan and Security Agreement, dated as of December 22, 2023, by and among Replimune Group Inc., Replimune, Inc., Replimune Limited and Hercules	10-Q	February 8, 2024	10.1
10.29†	Employment Agreement, dated as of December 1, 2022, by and between Konstantinos Xynos and Replimune, Inc.	10-Q	February 9, 2023	10.2
10.30†	Amendment to Amended and Restated Employment Agreement, dated as of December 30, 2022, by and between Sushil Patel and Replimune, Inc.	10-Q	February 9, 2023	10.3
10.31†	Employment Agreement, dated as of December 30, 2022, by and between Christopher Sarchi and Replimune, Inc.	10-Q	February 9, 2023	10.4
10.32†	Employment Agreement, dated as of August 31, 2023, by and between Emily Hill and Replimune, Inc.	10-Q	November 7, 2023	10.1
10.33†	Second Amended and Restated Employment Agreement, dated as of March 25, 2024, by and between Replimune, Inc. and Sushil Patel.	10-K	May 16, 2024	10.33
10.34†	Second Amended and Restated Employment Agreement, dated as of March 25, 2024, by and between Replimune, Inc. and Philip Astley-Sparke.	10-K	May 16, 2024	10.34
10.35†	Separation and Transition Agreement, dated as of March 25, 2024, by and between Robert Coffin and Replimune, Inc.	10-K	May 16, 2024	10.35
10.36†	Consulting Agreement, dated as of March 25, 2024, by and between Robert Coffin and Replimune, Inc.	10-K	May 16, 2024	10.36
10.37†	Separation Agreement and Release, dated as of May 18, 2023 by and between Jean Franchi and Replimune, Inc.	10-Q	August 3, 2023	10.2
10.39†	Separation Agreement and Release, dated as of March 26, 2024, by and between Pamela Esposito and Replimune, Inc.	10-K	May 16, 2024	10.39
10.40†	Consulting Agreement, dated as of March 26, 2024, by and between Pamela Esposito and Replimune, Inc.	10-K	May 16, 2024	10.40
10.41†	Separation Agreement and Release, dated as of March 31, 2024, by and between Tanya Lewis and Replimune, Inc.	10-K	May 16, 2024	10.41
10.42†	Consulting Agreement, dated as of March 31, 2024, by and between Tanya Lewis and Replimune, Inc.	10-K	May 16, 2024	10.42
10.43†	Form of U.K. Inducement Stock Option Grant Agreement	10-Q	November 12, 2024	10.1
10.44†	Form of U.K. Inducement Restricted Stock Unit Grant Agreement	10-Q	November 12, 2024	10.2
10.45†	Executive Severance Plan for Chief-Level Executives	10-Q	November 12, 2024	10.3

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
10.46	Securities Purchase Agreement, dated June 12, 2024, by and among Replimune Group, Inc. and each of the investors as party thereto	8-K	June 13, 2024	10.1
10.47	Form of Registration Rights Agreement	8-K	June 13, 2024	10.2
10.48	Registration Rights Agreement, dated March 5, 2025, by and among Replimune Group, Inc. and 667, L.P. and Baker Brothers Life Sciences, L.P.	8-K	March 7, 2025	10.1
19.1*	Replimune Group, Inc. Amended and Restated Insider Trading Policy			
21.1*	Subsidiaries of the Registrant.			
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.			
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
31.2*	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.1**	Certification of the Chief Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.2**	Certification of the Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
97*	Replimune Group, Inc. Clawback Policy			
101.INS*	Inline XBRL Instance Document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.			
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			

* Filed herewith.

** Furnished and not filed herewith.

† Indicates management contract or compensatory plan.

‡ Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: May 22, 2025

By: /s/ SUSHIL PATEL
Sushil Patel
Chief Executive Officer and Director

POWER OF ATTORNEY

Each person whose individual signature appears below hereby constitutes and appoints Sushil Patel and Emily Hill, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place, and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ SUSHIL PATEL Sushil Patel	Chief Executive Officer and Director (Principal Executive Officer)	May 22, 2025
/s/ EMILY HILL Emily Hill	Chief Financial Officer, (Principal Financial Officer)	May 22, 2025
/s/ ANDREW SCHWENDENMAN Andrew Schwendenman	Chief Accounting Officer, (Principal Accounting Officer)	May 22, 2025
/s/ PHILIP ASTLEY-SPARKE Philip Astley-Sparke	Director	May 22, 2025
/s/ KAPIL DHINGRA Kapil Dhingra	Director	May 22, 2025
/s/ MADHAVAN BALACHANDRAN Madhavan Balachandran	Director	May 22, 2025
/s/ CHRISTY OLIGER Christy Oliger	Director	May 22, 2025
/s/ PAOLO PUCCI Paolo Pucci	Director	May 22, 2025
/s/ JOSEPH SLATTERY Joseph Slattery	Director	May 22, 2025
/s/ VELEKA PEEPLES-DYER Veleka Peeples-Dyer	Director	May 22, 2025
/s/ DIETER WEINAND Dieter Weinand	Director	May 22, 2025
/s/ MICHAEL GOLLER Michael Goller	Director	May 22, 2025

DESCRIPTION OF THE REGISTRANT'S SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE

SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of Replimune Group, Inc.'s ("we," "us," and "our") securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

DESCRIPTION OF CAPITAL STOCK

The following description is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, our Third Amended and Restated Certificate of Incorporation, as amended (our "Certificate of Incorporation"), and our Amended and Restated By-laws (our "Bylaws"), each of which are incorporated by reference or filed as an exhibit to our Annual Report on Form 10-K of which this Exhibit 4.3 is a part. The terms of these securities also may be affected by the Delaware General Corporation Law (the "DGCL").

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share.

Common Stock

Subject to any preferential rights that may be applicable to any outstanding shares of preferred stock from time to time, holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preferred Stock

Pursuant to our Certificate of Incorporation, our board of directors has the authority, without further action by our stockholders, to designate up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock.

The DGCL provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Pre-Funded Warrants

We have outstanding pre-funded warrants to purchase shares of our common stock consisting of pre-funded warrants to purchase:

- 217,391 shares of our common stock at an exercise price of $0.0001 per share, which were issued in June 2020 in an underwritten public offering;
- 125,000 shares of our common stock at an exercise price of $0.0001 per share, which were issued in October 2020 in an underwritten public offering;
- 4,200,000 shares of our common stock at an exercise price of $0.0001 per share, which were issued in December 2022 in an underwritten public offering;
- 5,669,578 shares of our common stock at an exercise price of $0.001 per share, which were issued in June 2024 in a private placement (the "June 2024 Pre-Funded Warrants"); and
- 3,846,184 shares of our common stock at an exercise price of $0.0001 per share, which were issued in December 2024 in an underwritten public offering (the "December 2024 Pre-Funded Warrants").

Each pre-funded warrant entitles the holder to purchase one share of our common stock at the applicable per share exercise price described above. The pre-funded warrants do not expire and may be exercised by the holder at any time after their original issuance. Unless otherwise modified by a holder of a pre-funded warrant, no holder may exercise a pre-funded warrant (i) if such holder, together with its affiliates, would beneficially own more than 9.99% (or, in the case of the December 2024 Pre-Funded Warrants, 4.99%) of the number of shares of our common stock outstanding immediately after giving effect to such exercise, or (ii) if the combined voting power of our securities beneficially owned by such holder, together with its affiliates, would exceed 9.99% (or, in the case of the December 2024 Pre-Funded Warrants, 4.99%) of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise of such pre-funded warrants, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, a holder of a pre-funded warrant may increase or decrease this percentage to any other percentage not in excess of 19.99% (or, in the case of the June 2024 Pre-Funded Warrants, 9.99%) by providing us with at least 61 days' prior notice. The exercise price of the pre-funded warrants and the number of shares of our common stock issuable upon exercise of the pre-funded warrants are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Anti-Takeover Effects of Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws

The provisions of Delaware law and of our Certificate of Incorporation and Bylaws may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a stockholder might consider favorable, including a proposal that might result in the payment of a premium over the market price for the shares held by stockholders. These provisions are summarized in the following paragraphs.

Classified Board of Directors. Our Certificate of Incorporation and Bylaws provide that our board of directors is divided into three classes of directors, with the directors in each class serving staggered three-year terms and with the number of directors in each class to be as nearly equal as possible. The classification of our board of directors has the effect of requiring at least two annual stockholder meetings, instead of one, to replace a majority of the members of our board of directors.

Authorized but Unissued or Undesignated Capital Stock. Our authorized capital stock consists of 150,000,000 shares of common stock and 10,000,000 shares of preferred stock. The authorized but unissued (and in the case of preferred stock, undesignated) stock may be issued by our board of directors in one or more transactions. In this regard, our Certificate of Incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued preferred stock. The issuance of shares of preferred stock pursuant to our board of directors' authority described above could decrease the amount of earnings and assets available for

distribution to holders of common stock and adversely affect the rights and powers, including voting rights, of such holders and may have the effect of delaying, deferring or preventing a change in control. Our board of directors does not currently intend to seek stockholder approval prior to any issuance of preferred stock, unless otherwise required by law.

Special Meetings of Stockholders. Our Certificate of Incorporation provides that special meetings of the stockholders may be called only by or at the direction of our board of directors. Our Bylaws prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors. In order for any matter to be "properly brought" before a meeting, a stockholder will have to comply with advance notice requirements and provide us with certain information. Additionally, vacancies and newly created directorships may be filled only by a vote of a majority of the directors then in office, even though less than a quorum, and not by the stockholders. Our Bylaws allow the presiding officer at a meeting of the stockholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Stockholder Action by Written Consent. Our Certificate of Incorporation prohibits the taking of any action of our stockholders by written consent without a meeting.

Amendments to Our Certificate of Incorporation and Bylaws. The DGCL provides that, unless a corporation's certificate of incorporation provides otherwise, the affirmative vote of holders of shares constituting a majority of the votes of all shares entitled to vote may approve amendments to the certificate of incorporation. Our Certificate of Incorporation and Bylaws provide that the affirmative vote of holders of at least 75% of the outstanding shares of capital stock, voting together as a single class, and entitled to vote in the election of directors, will be required to amend, alter, change or repeal our Certificate of Incorporation and Bylaws. This requirement of a
supermajority vote to approve amendments to our Certificate of Incorporation and Bylaws could enable a minority of our stockholders to exercise veto power over such amendments.

No Cumulative Voting. The DGCL provides that stockholders are not entitled to cumulate votes in the election of directors unless the corporation's certificate of incorporation provides otherwise. Our Certificate of Incorporation does not expressly provide for cumulative voting.

Delaware Anti-Takeover Statute. We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years of the date on which it is sought to be determined whether such person is an interested stockholder, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing a change in our control.

Registration Rights

Certain holders of our common stock, or their transferees, are entitled to registration rights with respect to registration of the resale of such shares under the Securities Act of 1933, as amended, pursuant to the amended and restated investors' rights agreement, by and among us and certain of our investors.

Stock Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “REPL.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

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REPLIMUNE GROUP, INC.
AMENDED AND RESTATED INSIDER TRADING POLICY

I. Introduction

The purpose of this insider trading policy (the "Policy") is to reduce the risk that any employee, executive officer or member of the Board of Directors (the "Board") of Replimune Group, Inc. or any of its subsidiaries or certain family members might be found to have engaged in insider trading in violation of securities laws. Insider trading may result in unfair manipulation of the market in the Company's stock and may adversely affect the value of its stock. It may also expose the Company to potential liability. This Policy sets parameters for when trading in the Company's stock, or other securities is not permitted or appropriate. However, it is not intended to be a comprehensive review of the laws of insider trading.

As used in this Policy:

the "Company" means Replimune Group, Inc.;

"Replimune Companies" means the Company and its subsidiaries, if any;

"Company Party" means any employee (including a temporary employee), executive officer or director of any Replimune Company, and consultants and contractors who have access to material nonpublic information as determined by the Chief Executive Officer; and

"Family Member" means (i) anyone who lives with you and any family members who do not live with you, but whose transactions in Company securities are directed by, or are subject to, your influence or control, such as parents or children, and (ii) entities controlled by you except that the definition of Family Member does not include an entity controlled by or affiliated with a person covered under this policy if the entity's principal business is the investment of securities (an investment fund or partnership) and the entity has established its own insider trading controls and procedures in compliance with applicable securities laws.

This Policy applies to all Company Parties and their Family Members. It is your obligation to make your Family Members aware of, and understand and comply with, the provisions and obligations of this Policy. Violation of this Policy is grounds for immediate disciplinary action, potentially including immediate dismissal from employment.

If you are a former or retired Company Party this policy will continue to apply to you and your Family Members until the later of (i) the first full trading day following the public release of earnings for the fiscal quarter in which you leave any Replimune Company, or (ii) the first full trading day after any material nonpublic information known to you has become public or is no longer material.

There are no exceptions to this Policy, even for situations that may seem necessary or justifiable (such as the need to raise money for an emergency expenditure) or small transactions. If material non-public information is inadvertently disclosed – no matter what the circumstances – the person making or discovering that disclosure should immediately report the disclosure to the Company's Chief Executive Officer, Chief Financial Officer or General Counsel.

II. Insider Trading Defined

As a general rule, it is against the law to buy, sell or otherwise trade any securities while in possession of material non-public information relevant to that security (sometimes called "inside information"), or to communicate such information to others (including family, friends and acquaintances) who trade on the basis of such information (with communication of such information commonly known as "tipping").

Information is "material" as to a security if a reasonable investor would consider the information significant in deciding whether to buy, hold or sell the security (i.e., any information that might affect the price of the security). Material information can be positive or negative and can relate to virtually any aspect of the Company's business. Examples of events or developments that should be presumed to be "material" with respect to the Company's securities include, but are not limited to:

- knowledge of a launch of a new product or clinical trial;
- results of preclinical tests or clinical trials;
- the occurrence of significant adverse events in any clinical trial;
- pending regulatory action (positive or negative) or approval or disapproval;
- knowledge about the Company's communications with government agencies;
- knowledge of a trend in the Company's revenues or earnings not yet fully disclosed to the public;
- knowledge of the Company's earnings results not yet disclosed to the public;
- acquisition or loss of a major contract or major license;
- a pending or proposed joint venture, collaboration or supply agreement;
- significant legal exposure due to actual, pending or threatened litigation or the resolution of such litigation;
- a purchase or sale of substantial assets (including licenses to intellectual property);
- changes in senior management or other major personnel changes;
- changes in dividend policy, declaration of a stock split or the offering of additional securities;
- significant expansion or curtailment of operations;
- extraordinary borrowing or changes in liquidity; and
- changes in the Company's auditors or a notification from its auditors that the Company may no longer rely on the auditor's audit report.

These examples are illustrative only and are not intended to be an exhaustive list; many other types of information may be considered "material," depending on the circumstances. The materiality of particular information is subject to reassessment on a regular basis.

Information is "non-public" as to a security until it has been effectively communicated to the marketplace through a filing with the Securities and Exchange Commission ("SEC"), a press release or other appropriate news media and enough time has elapsed to permit the market to absorb and evaluate the information. In many cases, this process may require the passage of at least one trading day after any initial disclosure. On the other hand, information disseminated solely through other methods, such as a posting on the Company's internal or external website or in a meeting, conference or presentation not open to the general public or major media, likely would not be deemed to have been disclosed to the public. If there can be any doubt whatsoever as to whether information has been effectively communicated to the marketplace, such information should be considered non-public until such time as there is no doubt.

Whether a particular item is "material" or "non-public" will be judged with hindsight. Accordingly, when in doubt as to a particular item of information, you should presume it is material and has not been disclosed to the public. Chances are, if you learn something that leads *you* to want to buy or sell securities, that information may be considered material. It is important to keep in mind that material information need not be *certain* information - information that something is likely to happen, or even just that it may happen, can affect the market price of the securities and therefore, in hindsight, may be determined to be material. Do not hesitate to contact the Company's General Counsel with any questions you may have. However, in all cases, the responsibility for determining whether an individual is in possession of material nonpublic information rests with the individual, and any action on the part of the Company, members of the Company's legal or finance departments or any other employee pursuant to this Policy does not in any way constitute legal advice or insulate an individual from liability under securities laws.

The Department of Justice ("DOJ") the SEC, the Financial Industry Regulatory Authority and Nasdaq are very effective at detecting and pursuing insider trading cases. The DOJ and SEC have aggressively prosecuted, and imposed severe consequences upon, insider traders and those who receive information from insiders also known as tippees. Any person who engages in insider trading or tipping can face a substantial jail term (up to 20 years), and criminal fines or significant civil penalties potentially up to three times the profit gained (or loss avoided) by that person and/or his or her tippees. If you tip information to a person who then trades, you can be subject to the same penalties as the tippee, even if you did not trade and did not profit from the trading made by the person who receives the tip. In addition, if it is found that the Company failed to take appropriate steps to prevent insider trading, the Company may be subject to significant penalties. Failure to comply with this Policy may also subject employees to Company-imposed disciplinary action up to and including dismissal for cause, whether or not the failure to comply with this Policy results in a violation of law.

Insider trading laws apply not only to trading in the Company's securities, but also apply to trading in the securities of other companies if you learn something in the course of your employment or relationship with a Replimune Company that might affect the value of such securities. Such other companies include, but are not limited to, our business partners, collaborators, vendors, licensors, suppliers and customers. You should treat material non-public information about such companies with the same care required with respect to information related directly to a Replimune Company. You must not trade in the securities of such companies when you possesses material non-public information, and must not communicate such information to any third party, except persons who have a legitimate "need to know" and understand their obligation not to trade on it.

III. General Policy Against Insider Trading

A Company Party must not trade in any Replimune Company securities, or the securities of other companies as discussed above, when the Company Party possesses inside information (i.e., material non-public information) with respect to the Company or such other company, as applicable, and must not communicate such information to any third party, except persons who have a legitimate "need to know" and understand their obligation not to trade on it. Because of the inevitable appearance of impropriety if Family Members either (i) trade in any such securities at a time when material information has not been disclosed, or (ii) communicate inside information (i.e. material non-public information) with respect to such securities to any third party, this policy also applies to Family Members of Company Parties to the same extent as it applies to such Company Parties. For purposes of this Policy, "trading" includes not only purchases and sales of Company stock, but also purchases and sales of options, warrants, pre-funded warrants, puts and calls, and other derivative securities related to Company stock.

IV. Specific Restrictions on Trading in Company Securities

To facilitate compliance with the Company's general policy against insider trading, the Company has established the following specific restrictions on trading securities of the Company.

1. Blackout Period

No Company Party or Family Member shall engage in any transaction involving any Replimune Company securities (including a sale, a purchase, a gift, a loan or pledge or hedge, a contribution to a trust or any other transfer) during the following periods (each, a "Blackout Period"):

the period beginning at the end of the 15th calendar day of the last month of each fiscal quarter and ending at the close of trading one full trading day after the release of the Company's quarterly or annual earnings results following that quarter; and

any other period designated by the Chief Executive Officer, Chief Financial Officer or General Counsel as a period during which no Company Party or Family Member shall engage in any transaction involving Company securities.

For purposes of determining the Blackout Period, a "trading day" is any day when Nasdaq is open for trading.

2. Prior Clearance

Each member of the Board, each person holding a title of Vice President or other title higher than Vice President of the Company and any employee holding a position identified by the Chief Executive Officer, Chief Financial Officer or General Counsel as subject to this prior clearance requirement (each, a "Designated Corporate Person" and collectively, the "Designated Corporate Persons") must obtain prior clearance from the Chief Executive Officer or their designee (any such designee, a "Permitted Designee"), at least two business days (or such other time determined by the Company's Chief Executive Officer or their Permitted Designee) before such member of the Board or Designated Corporate Person or his or her Family Member engages in any transaction involving any Replimune Company securities (the "Transaction Notice Period") (including certain stock plan transactions such as an option exercise, a gift, a loan (other than loans made from time to time without the knowledge of the member of the Board, Designated Corporate Person or Family Member under the general terms and conditions of a brokerage account owned by such member of the Board, Designated Corporate Person or Family Member), a contribution to a trust or any other transfer). In addition, each entry into a Planned Sale Program (as later defined) and any modifications or terminations of such Planned Sale Programs require pre-clearance. The Permitted Designee may at any time during such Transaction Notice Period disapprove such transaction if he or she in good faith believes that it is reasonably likely to result in a violation of this Policy.

Each proposed transaction will be evaluated to determine if it raises insider trading concerns or other concerns under federal or state securities laws and regulations. Any advice provided by the Company to the member of the Board, Designated Corporate Person or Family Member will relate solely to the restraints imposed by law and will not constitute advice regarding the investment aspects of any transaction. Clearance of a transaction is valid only for a period of two trading days unless the Permitted Designee has specified in writing an alternate period of validity, not to exceed five trading days. If the transaction order is not placed within that two trading day period (or other period designated in writing by the Permitted Designee), clearance of the transaction must be re-requested. If clearance is denied, the fact of such denial must be kept confidential by the person requesting such clearance. Any prior clearance

granted by the Permitted Designee may be withdrawn at any time upon notice to the member of the Board, Designated Corporate Person or Family Member.

Therefore, each member of the Board, Designated Corporate Person and Family Member must obtain prior clearance from the Permitted Designee for all sales and purchases of any Replimune Company securities, all exercises of stock options in which such member of the Board, Designated Corporate Person or Family Member purchases shares of Company stock and all sales of shares purchased pursuant to stock options. In particular, so-called "cashless exercises" include both exercises of options and an immediate sale of some or all of the stock acquired via the option exercise; therefore, "cashless exercises" by members of the Board, Designated Corporate Persons and Family Members also require prior clearance. In addition, all sales by members of the Board, Designated Corporate Persons and Family Members of Company stock purchased pursuant to any stock purchase plan in effect from time to time and the creation, modification or termination of a Planned Sale Program (defined below) require pre-clearance of the Permitted Designee and are subject to all the restrictions set forth in this Policy.

3. No "Short Sales"

"Short sales" of Company stock by any Company Party or Family Member are absolutely prohibited. "Short sales" include transactions in which the seller does not own Company stock at the time of the sale as well as those in which the seller owns Company stock but plans to deliver shares other than his or her own shares in connection with the sale of Company stock (a.k.a. selling short against the box). These restrictions apply to the purchase or sale of Company stock for any fiduciary account (e.g., trustee, executor, custodian) with respect to which the Company Party or Family Member makes the investment decision, regardless of whether the Company Party or Family Member has any beneficial interest in the account.

4. No Publicly Traded Options

A Company Party or Family Member should not trade in call options or put options to buy or sell Company stock. A put is an option or right to sell a specific stock at a specific price before a set date, and a call is an option or right to buy a specific stock at a specific price before a set date. Generally, call options are purchased when one believes that the price of a stock will rise, whereas put options are purchased when one believes that the price of a stock will fall. Because publicly traded options have a relatively short term, transactions in options may create the appearance that trading is based on material nonpublic information. Further, such transactions may indicate a preference for short-term performance at the expense of the Company's long-term objectives.

5. No Hedging Transactions

Company Parties are prohibited from engaging in any hedging or monetization transactions relating to any Company securities, which can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards contracts, equity swaps, collars and exchange funds. Such hedging transactions may permit Company Parties to continue to own Company securities, but without the full risks and rewards of ownership. When that occurs, the Company Parties may no longer have the same objectives as the Company's other stockholders.

6. No Margin Credit or Pledging

Company securities held in a margin account or pledged as collateral can be sold without the stock owner's consent in certain circumstances. This means that a margin sale or foreclosure sale may occur at a time when a Company Party is aware of material nonpublic information or otherwise is not permitted to trade in Company securities. Company Parties are prohibited from holding Company securities in a margin account or otherwise pledging Company securities as collateral for a loan. This prohibition does not apply to standard brokerage accounts that by their terms may provide for margin credit so long as the Company Party does not obtain margin credit with respect to any securities held in the account and the prohibition does not apply to standard brokerage accounts in which the broker may "borrow" securities provided that no purchase or sale of Company securities attributable to the Company Party occurs. Pledges of Company securities arising from certain types of hedging transactions are governed by the paragraph above captioned "No Hedging Transactions."

7. Exception for Rule 10b5-1 Planned Sale Programs

The restrictions set forth in paragraphs 1 and 2 of this Part IV do not apply to the purchase or sale of shares of Company stock pursuant to the terms of a binding contract, written instruction (including without limitation a written "limit order" delivered to a broker) or written plan (a "Planned Sale Program") for the purchase or sale of shares of Company stock that complies with the guidelines set forth in section (c) of Rule 10b5-1 (as amended and in effect from time to time, "Rule 10b5-1") promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), if and only if:

(a) the Company Party or Family Member notified the Permitted Designee of the intent to enter into, adopt, amend, modify, replace or terminate such Planned Sale Program at least five days prior to the entry into, adoption, amendment, modification, replacement or termination of the Planned Sale Program and such Planned Sale Program was reviewed and pre-approved by the Permitted Designee prior to its adoption, amendment, modification, replacement or termination;

(b) such Company Party or Family Member has entered into, adopted, amended, modified, replaced or terminated such Planned Sale Program in good faith and in accordance and full compliance with all of the provisions of Rule 10b5-1, at a time when such Company Party or Family Member was not in possession of material non-public information about the Company;

(c) such Planned Sale Program includes a representation that (i) at the time the Planned Sale Program was adopted, amended or modified, the Company Party or Family Member was not aware of any material non-public information about the Company, and (ii) the Company Party or Family Member adopted, amended or modified the Planned Sale Program in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1;

(d) such Planned Sale Program was not adopted, amended, modified, replaced, or terminated during a Blackout Period;

(e) such Planned Sale Program allows for the cancellation of a transaction and/or suspension of such Planned Sale Program upon notice and request by the Company to the individual if any proposed trade (i) fails to comply with applicable laws, or (ii) would create a material adverse consequence for the Company; and

(f) such Company Party or Family Member agrees to promptly provide to the Company upon request any information relating to the Planned Sale Program that would assist the Company in timely satisfying its disclosure obligations in connection with required Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, proxy statements, filings on Forms 3, 4 and 5 and other SEC filings.

The Permitted Designee may disapprove such Planned Sale Program if he or she in good faith believes that it is reasonably likely to result in a violation of this Policy. Once the Planned Sale Program is adopted, the Company Party or Family Member must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade.

Individuals are generally prohibited from having multiple overlapping Planned Sale Programs and, generally, an individual is limited to one Planned Sale Program designed to result in a single trade (a "single-trade plan") during any 12-month period. If you want to adopt multiple overlapping Planned Sale Programs and/or adopt a single-trade plan, you must submit a request and receive prior approval from the Permitted Designee.

Additionally, no trades pursuant to a Planned Sale Program may be made until the later of (i) 90 days after the date of the adoption, amendment, modification, or replacement of such Planned Sale Program, and (ii) two business days following the Company's disclosure of its financial results for the fiscal quarter in which the Planned Sale Program was adopted, amended, modified or replaced in an Annual Report on Form 10-K or a Quarterly Report on form 10-Q (the "Cooling-Off Period")[1]; provided, however, the Cooling-Off Period shall not exceed 120 days following the adoption, amendment, modification or replacement of the Planned Sale Program. If a Company Party or Family Member terminates a Planned Sale Program, a period of 6 months must lapse before such Company Party or Family Member may adopt a new Planned Sale Program. For the avoidance of doubt, a Planned Sale Program that expires by its terms is not subject to the foregoing restriction.

Each member of the Board and Section 16 Officer (defined below) understands that the approval or adoption of a Planned Sale Program in no way reduces or eliminates such person's obligations under Section 16 of the Exchange Act, including such person's disclosure and short-swing trading liabilities thereunder. If any questions arise, such person should consult with their own counsel in implementing a Planned Sale Program.

8. Exception for Certain Transfers

The restrictions set forth in paragraph 1 of this Part IV do not apply to bona fide gifts of Company stock by a Company Party to a trust formed for estate-planning purposes or a family limited partnership, charitable foundation or similar entity, if and only if investment and voting decisions of such organization are controlled by the transferor Company Party and the transferor Company Party has confirmed in writing that he/she will not permit the transferee to sell or otherwise transfer Company stock during a Blackout Period and has notified the Permitted Designee of the transfer by completing, executing and delivering the "Transfer Notification and Agreement" attached hereto as Exhibit A.

[1] For purposes of calculating the two business day cooling-off period, the SEC has provided guidance that the date of disclosure of the financial results is the filing date of the relevant Form 10-Q or 10-K, and the first business day for purpose of the cooling off period would be the next business day that follows the filing date Whether a form is filed before or after trading opens is irrelevant. For example, if the relevant form is filed on a Monday, trading may commence under the contract, instruction, or plan on Thursday (assuming no intervening Federal holidays).

9. Transactions Under Company Plans

This Policy does not apply in the case of the following transactions, except as specifically noted:

Stock Option Exercises. This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's employee stock option plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Restricted Stock Awards. This Policy does not apply to the vesting of any restricted stock, or the exercise of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. The Policy does apply, however, to any market sale of any restricted stock.

Employee Stock Purchase Plan. This Policy does not apply to purchases of Company securities in an employee stock purchase plan resulting from a Company Party's periodic contribution of money to the plan pursuant to an election made at the time of a Company Party's enrollment in the plan. This Policy also does not apply to purchases of Company securities resulting from lump sum contributions to such plan, provided that the Company Party elected to participate by lump sum payment at the beginning of the applicable enrollment period. This Policy does apply, however, to a Company Party's election to participate in the plan for any enrollment period, and to a Company Party's sales of Company securities purchased pursuant to the plan.

401(k) Plan. This Policy does not apply to purchases of Company securities in the Company's 401(k) plan, if permitted, resulting from a Company Party's periodic contribution of money to the plan pursuant to a payroll deduction election. This Policy does apply, however, to certain elections a Company Party may make under the 401(k) plan, including: (a) an election to increase or decrease the percentage of periodic contributions that will be allocated to a Company stock fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of a Company stock fund; (c) an election to borrow money against a Company Party's 401(k) plan account if the loan will result in a liquidation of some or all of the Company Party's Company stock fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund.

Other Similar Transactions. Any other purchase of Company securities from the Company or sales of Company securities to the Company are not subject to this Policy.

10. General Applicability

The general restrictions on trading on insider information described in Part III apply in all situations, whether or not they are within the scope of the specific restrictions set forth in this Part IV. Moreover, the fact that a securities transaction subject to this Part IV is cleared by the Permitted Designee does not excuse the person effecting the transaction from assuring that he or she complies with the legal responsibilities described in this Policy and under any applicable insider trading laws.

V. Section 16 Reporting Requirements for Directors and Officers

Members of the Board and certain Designated Corporate Persons are subject to certain reporting requirements, trading restrictions and "short swing" profit recovery provisions under Section 16 of the

Exchange Act. In particular, each member of the Board and those Designated Corporate Persons subject to Section 16 ("Section 16 Officers") must report changes of beneficial ownership in equity securities of the Company on a Form 4 electronically filed with and received by the SEC before the end of the second business day following the day on which the transaction occurs (the trade date, not the settlement date). Transactions that must be reported on Form 4 by members of the Board or Section 16 Officers pursuant to Section 16 include, without limitation, stock purchases and sales, stock option exercises, stock and option grants, restricted stock grants and most other equity compensation transactions.

In order to ensure compliance with Section 16 reporting requirements, each member of the Board or Section 16 Officer must immediately report to the Permitted Designee upon execution details of every transaction involving the Company's stock and stock options, including gifts, transfers, pledges and all transactions made pursuant to Planned Sale Programs.

VI. Confidentiality

Unauthorized disclosure of internal information about the Company, whether or not for the purpose of facilitating improper trading in Company securities, is strictly prohibited. The Company is required under Regulation FD of the federal securities laws to avoid the selective disclosure of material non-public information. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of the information immediately upon its release. Therefore, Company Parties must not discuss internal business matters or developments with anyone outside of the Company (including, without limitation, Family Members), except as required in the performance of regular corporate duties. This prohibition applies specifically, but not exclusively, to inquiries about any Replimune Company which may be made by members of the financial press, investment analysts, or others in the financial community. It is very important that all such communications on behalf of the Company be made through an appropriately designated officer under carefully controlled circumstances. If you receive any inquiries of this nature, unless you are expressly authorized to the contrary, you should decline comment and refer the inquirer to the Company's Chief Executive Officer, Chief Financial Officer or Chief Business Officer.

All Company Parties are reminded to use extreme care to ensure that confidential information is not inadvertently disclosed to others. Be particularly careful to avoid discussing any matter that might be sensitive or confidential in public places such as lobbies, airports, elevators and restaurants. Meetings in which confidential information is discussed should be conducted behind closed doors. In an effort to prevent unauthorized disclosure of the Company's information, except as part of the Company's approved ongoing marketing and other business efforts, Company Parties are prohibited from posting or responding to any posting on or in internet message boards, chat rooms, discussion groups, or other publicly accessible forums, such as social media sites, with respect to the Company and its subsidiaries. Even inadvertent "leaks" of confidential information can create problems for the Company and its officers, members of the Board and employees.

VII. Disclaimer of New Liabilities

This Policy is not intended, and shall not be deemed, to impose on the Company or its officers, members of the Board and employees any civil, criminal or other liability that would not exist in the absence of this Policy.

VIII. Policy Update

This Policy was last updated effective March 5, 2025. This Policy may be revised periodically, in which case copies will be made available to all Company Parties.

****

Please sign, date and deliver the attached acknowledgment to the Company's Chief Executive Officer or Permitted Designee after you have read this Policy.

REPLIMUNE GROUP, INC.

ACKNOWLEDGMENT

I have read, understand and agree to abide by the Replimune Group, Inc. Insider Trading Policy.

Signed:__

__

Please Print Name

Date:__

REPLIMUNE GROUP, INC.
TRANSFER NOTIFICATION AND AGREEMENT

Deliver to: Chief Executive Officer or Permitted Designee of Replimune Group, Inc.

The undersigned hereby notifies Replimune Group, Inc. (the "Company") that, on _____ [insert date – MM/DD/YY], the undersigned plans to transfer _____ shares of Company stock (the "Shares") to _____, a _____ [describe nature of entity, such as "charitable foundation" or "family trust"] controlled by the undersigned, in accordance with the subsection entitled "Exception for Certain Transfers" under Part IV of the Company's Insider Trading Policy (the "Policy").

The undersigned hereby confirms that he/she will not permit _____ to sell or otherwise transfer the Shares during a Blackout Period (as such term is defined in the Policy).

Signed:__

__

Please Print Name

Address:__

__

Date: __

EXHIBIT 21.1

Subsidiaries of Replimune Group, Inc.

Name of Subsidiary	Jurisdiction
Replimune, Inc.	Delaware
Replimune Limited	United Kingdom
Replimune Securities Corporation	Massachusetts
Replimune (Ireland) Limited	Ireland

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-265805, 333-281358 and 333-273633) and Form S-8 (Nos. 333-226323, 333-256314 and 333-272031, 333-279442, 333-282682, 333-283344, 333-283990, 333-284353, 333-284870, 333-285824, 333-286784) of Replimune Group, Inc. of our report dated May 22, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
May 22, 2025

Exhibit 31.1

CERTIFICATION 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

I, Sushil Patel, certify that:

1. I have reviewed this Annual Report on Form 10-K of Replimune Group, 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 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 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: May 22, 2025

By: /s/ SUSHIL PATEL

Sushil Patel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Emily Hill, certify that:

1. I have reviewed this Annual Report on Form 10-K of Replimune Group, 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 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 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: May 22, 2025

By: /s/ EMILY HILL

Emily Hill
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Replimune Group, Inc. (the "Company") for the fiscal year ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sushil Patel, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 22, 2025

By: /s/ SUSHIL PATEL

Sushil Patel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Replimune Group, Inc. (the "Company") for the fiscal year ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Emily Hill, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 22, 2025

By: /s/ EMILY HILL

Emily Hill
Chief Financial Officer
(Principal Financial Officer)

REPLIMUNE GROUP, INC.
CLAWBACK POLICY

Article I.
PURPOSE AND GENERAL TERMS

Section 1. Purpose.

(a) Replimune Group, Inc. (the "Company") has adopted this Compensation Recoupment Policy (this "Policy") to implement a mandatory clawback policy in the event of a Restatement in compliance with the applicable rules of the Nasdaq Stock Market ("Nasdaq"), which is set forth in Article 2 of this Policy.

(b) Any capitalized terms used but not immediately defined in this Policy have the meanings set forth in Section 7 of this Article I.

Section 2. Administration.

(a) This Policy shall be administered in the sole discretion of the Committee. The Committee shall have the discretion to interpret the Policy and make all determinations with respect to this Policy, consistent with applicable law and this Policy. Without limiting the foregoing, Article II of this Policy shall be interpreted in a manner that is consistent with the requirements of the Applicable Rules, and compliance with this Policy shall not be waived by the Committee, the Board or the Company in any respect.

(b) Any interpretations and determinations made by the Committee shall be final and binding on all affected individuals.

Section 3. Effective Date; Term. This Policy is effective as of October 2, 2023 (the "Effective Date"). Article II of this Policy applies to Incentive-Based Compensation that is Received by any Executive Officer on or after the Effective Date as described in Section 3 of Article II below.

Section 4. Amendment. The Committee may amend this Policy from time to time in its discretion, subject to any limitations under applicable law or listing standards, including, in the case of Article II, the Applicable Rules. Without limiting the forgoing, the Committee may amend this Policy as it deems necessary to reflect any amendment of the Applicable Rules or regulations or guidance issued under the Applicable Rules.

Section 5. No Substitution of Rights; Non-Exhaustive Rights.

(a) Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights that may be available to the Company pursuant to (a) the Company's equity incentive plans, including the Company's 2017 Equity Compensation Plan, the Company's 2018 Omnibus Incentive Compensation Plan and the Company's Employee Stock Purchase Plan or any successor plan thereto, or any other incentive plan of the Company or any of its subsidiaries, (b) the terms of any recoupment policy or provision in any employment agreement, compensation agreement or arrangement, or other agreement, or (c) any other legal remedies available to the Company under applicable law.

(b) In addition to recovery of compensation as provided for in this Policy, the Company may take any and all other actions as it deems necessary, appropriate and in the Company's best interest in

connection with the Committee determining that this Policy should apply, including termination of the employment of, or initiating legal action against, an Executive Officer, and nothing in this Policy limits the Company's rights to take any such appropriate actions.

Section 6. Governing Law. This Policy and all determinations made and actions taken pursuant hereto, to the extent not otherwise governed by mandatory provisions of the Applicable Rules, shall be governed by and construed in accordance with the laws of the State of Delaware without regard to choice of law principles. If any provision of this Policy shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining parts of this Policy, but this Policy shall be construed and enforced as if the illegal or invalid provision had never been included in this Policy.

Section 7. Defined Terms. The following capitalized terms used in this Policy have the following meanings:

"***Applicable Rules***" means Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder and Listing Rule 5608 of the Listing Rules of Nasdaq.

"***Board***" means the Board of Directors of the Company.

"***Committee***" means the Compensation Committee of the Board, or, in the absence of such committee, a majority of independent directors serving on the Board.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means each officer of the Company who is identified as an executive officer for the purposes of 17 CFR § 229.401(b), which is defined as the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president of the Company in charge of a principal business unit, division or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar significant policy-making functions for the Company, as determined under 17 CFR §229.401(b).

"***Financial Reporting Measures***" means (i) measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures, (ii) the Company's stock price, and (iii) total shareholder return in respect of the Company. A "Financial Reporting Measure" need not be presented within the financial statements or included in a filing with the SEC.

"***Incentive-Based Compensation***" means any compensation that is granted, earned, or vested, based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation does not include, among other forms of compensation, equity awards that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to Financial Reporting Measures, as determined to be subject to repayment pursuant to this Policy.

"***Received***" Incentive-Based Compensation is deemed "Received" for the purposes of this Policy in the Company's fiscal period during which the Financial Reporting Measure applicable to the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

"***Recovery Period***" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare a Restatement, which date is the earlier of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement, or (ii) a date that a court, regulator or other legally authorized body directs the Company to prepare a Restatement.

"***Regulators***" means, as applicable, the Securities and Exchange Commission and Nasdaq.

"***Restatement***" means that the Company is required to prepare an accounting restatement due to a material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements (i) that is material to the previously issued financial statements, or (ii) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

Article II.
DODD-FRANK RECOUPMENT POLICY FOR EXECUTIVE OFFICERS

Section 1. Recovery on a Restatement.

(a) In the event that the Company is required to prepare a Restatement, the Company shall reasonably promptly recover from an Executive Officer the amount of any erroneously awarded Incentive-Based Compensation that is Received by such Executive Officer during the Recovery Period. The amount of erroneously Received Incentive-Based Compensation will be the excess of the Incentive-Based Compensation Received by the Executive Officer (whether in cash or shares) based on the erroneous data in the original financial statements over the Incentive-Based Compensation (whether in cash or in shares) that would have been Received by the Executive Officer had such Incentive-Based Compensation been based on the restated results, without respect to any tax liabilities incurred or paid by the Executive Officer.

(b) Recovery of any erroneously awarded compensation under this Article II is not dependent on fraud or misconduct by any Executive Officer in connection with a Restatement.

(c) Without limiting the foregoing, for Incentive-Based Compensation based on the Company's stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Restatement, (i) the amount shall be based on the Company's reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received, and (ii) the Company shall maintain documentation of the determination of that reasonable estimate and provide such estimate to Nasdaq as required by the Applicable Rules.

Section 2. Covered Executive Officers and Covered Incentive-Based Compensation.

(a) This Article II covers all persons who are Executive Officers at any time during the Recovery Period for which Incentive-Based Compensation is Received or during the performance period applicable to such Incentive-Based Compensation. Incentive-Based Compensation shall not be recovered under this Article II to the extent Received by any person before the date the person served as an Executive Officer. Subsequent changes in an Executive Officer's employment status, including retirement

or termination of employment, do not affect the Company's right to recover Incentive-Based Compensation pursuant to this Article II.

(b) Article II of this Policy shall apply to Incentive-Based Compensation that is Received by any Executive Officer on or after the Effective Date and that results from attainment of a Financial Reporting Measure based on or derived from financial information for any fiscal period ending on or after the Effective Date. For the avoidance of doubt, this will include Incentive-Based Compensation that may have been approved, awarded, or granted to an Executive Officer on or before the Effective Date if such Incentive-Based Compensation is Received on or after the Effective Date.

Section 3. Methods of Recovery; Limited Exceptions.

(a) The Committee shall determine, in its sole discretion, the method of recovering any Incentive-Based Compensation Received pursuant to this Article II, consistent with applicable law, which may include, without limitation, the methods of recovery described in Article III.

(b) No recovery shall be required if any of the following conditions are met and the Committee determines that, on such basis, recovery would be impracticable:

(i) the direct expense paid to a third party to assist in enforcing this Article II would exceed the amount to be recovered; provided that prior to making a determination that it would be impracticable to recover any Incentive-Based Compensation based on the expense of enforcement, the Company shall (x) have made a reasonable attempt to recover the Incentive-Based Compensation, (y) have documented such reasonable attempts to recover, and (z) provide the documentation to Nasdaq;

(ii) recovery would violate home country law where that law was adopted prior to November 28, 2022; provided that, prior to making a determination that it would be impracticable to recover any Incentive-Based Compensation based on a violation of home country law, the Company shall (x) have obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such violation, and (y) provide a copy of such opinion to Nasdaq; or

(iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended (the "Code"), and U.S. Treasury regulations promulgated thereunder.

Section 4. Reporting; Disclosure; Monitoring. The Company shall make all required disclosures and filings with the Regulators with respect to this Policy in accordance with the requirements of the Applicable Rules, and any other requirements applicable to the Company, including the disclosures required in connection with SEC filings.

Article III.
METHODS OF RECOVERY

Section 1. Methods of Recovery. Subject to the limited exceptions set forth in Section [4] of Article II, in the event that the Committee determines that this Policy should apply, to the extent permitted by applicable law, the Company shall, as determined by the Committee in its sole discretion, take any such actions as it deems necessary or appropriate to recover Incentive-Based Compensation. The actions may include, without limitation (and as applicable):

(a) forfeit, reduce or cancel any Incentive-Based Compensation (whether vested or unvested) that has not been distributed or otherwise settled;

(b) seek recovery of any Incentive-Based Compensation that was previously paid to the Executive Officer;

(c) seek recovery of any amounts realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any Incentive-Based Compensation;

(d) recoup any amount in respect of Incentive-Based Compensation that was contributed or deferred to a plan that takes into account Incentive-Based Compensation (excluding certain tax-qualified plans, but including deferred compensation plans, and supplemental executive retirement plans, and insurance plans to the extent otherwise permitted by applicable law, including Section 409A of the Code) and any earnings accrued on such Incentive-Based Compensation;

(e) except as otherwise required by Article II, determine whether Incentive-Based Compensation should be recouped on a pre-tax or after-tax basis;

(f) offset, withhold, eliminate or cause to be forfeited any amount that could be paid or awarded to the Executive Officer after the date of determination; and

(g) take any other remedial and recovery action permitted by law, as determined by the Committee.

(h) In addition, (i) the Committee may authorize legal action for breach of fiduciary duty or other violation of law and take such other actions to enforce the obligations of the Executive Officer to the Company as the Committee deems appropriate, or (ii) in the event that an Executive Officer fails to repay or reimburse erroneously awarded compensation that is subject to recovery, the Committee may require an Executive Officer to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering erroneously awarded compensation under this Policy.

Section 2. Notice. Before the Company takes action to seek recovery of compensation pursuant to this Policy against an Executive Officer the Company shall take commercially reasonable steps to provide such individual with advance written notice of such clawback; provided that this notice requirement shall not in any way delay the reasonably prompt recovery of any erroneously awarded Incentive-Based Compensation pursuant to Article II.

Section 3. No Indemnification. The Company shall not indemnify any current or former Executive Officer against the loss of erroneously awarded compensation, and shall not pay or reimburse any such person for premiums incurred or paid for any insurance policy to fund such person's potential recovery obligations.