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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2023

OR

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

Commission File Number: 001-38906

IMMUNOVANT, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**83-2771572**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
320 West 37th Street New York, NY	**10018**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (917) 580-3099

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, $0.0001 par value per share	**IMVT**	**The Nasdaq Stock Market LLC**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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. Yes ☐ No ☒

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. Yes ☐ No ☒

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). Yes ☐ No ☒

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 registrant's common stock held by non-affiliates of the registrant, based on the closing price of the registrant's common stock on The Nasdaq Global Select Market as of September 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $238.9 million, based on the closing price of the registrant's common stock on The Nasdaq Global Select Market of $5.58 per share.

As of May 17, 2023, the Registrant had 130,408,389 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended March 31, 2023.

IMMUNOVANT, INC.
ANNUAL REPORT ON FORM 10-K

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended March 31, 2023 (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "can," "continue," "could," "design," "estimate," "expect," "forecast," "goal," "hope," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will" and "would," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the timing, progress, costs and results of our clinical trials for batoclimab, formerly referred to as IMVT-1401, and IMVT-1402;
- potential therapeutic benefits and risks in current and future indications and the ability to achieve regulatory approval in licensed jurisdictions;
- future operating or financial results and cash position;
- future acquisitions, business strategy and expected capital spending;
- the timing of meetings with and feedback from regulatory authorities as well as any submission of filings for regulatory approval of batoclimab or IMVT-1402;
- the potential advantages and differentiated profile of batoclimab and IMVT-1402 compared to existing therapies for the applicable indications;
- our ability to successfully manufacture, or have manufactured, drug product for clinical trials and commercialization;
- our ability to successfully commercialize batoclimab or IMVT-1402, if approved;
- the rate and degree of market acceptance of batoclimab or IMVT-1402, if approved;
- the effects of global factors, such as the COVID-19 pandemic, geopolitical tensions and adverse macroeconomic conditions, on our business, operations and supply chain, including the potential impact on our clinical trial plans and timelines, such as the enrollment, activation and initiation of additional clinical trial sites, and the results of our clinical trials;
- our expectations regarding the size of the patient populations for and opportunity for and clinical utility of batoclimab or IMVT-1402, if approved for commercial use;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and needs for or ability to obtain future financing to complete the clinical trials for and commercialize batoclimab or IMVT-1402;
- our dependence on and plans to leverage third parties for research and development, clinical trials, manufacturing, and other activities;
- our ability to maintain intellectual property protection for batoclimab and IMVT-1402;
- our ability to identify, acquire or in-license and develop new product candidates;
- our ability to identify, recruit and retain key personnel;

- developments and projections relating to our competitors or industry; and
- future payments of dividends and the availability of cash for payment of dividends.

You should refer to “Item 1A. Risk Factors” and elsewhere in this document for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. We qualify all of our forward-looking statements by these cautionary statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (www.immunovant.com), SEC filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our stockholders and the public about our company, our product candidates, and other matters. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website. Information 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.

Unless the context otherwise indicates, references in this report to the terms “Immunovant,” “the Company,” “we,” “our” and “us” refer to Immunovant, Inc. and its wholly owned subsidiaries.

Industry and Market Data

We obtained the industry and market data in this Annual Report on Form 10-K from our own research as well as from industry and general publications, surveys and studies conducted by third parties. Industry and general publications, studies and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. These third parties may, in the future, alter the manner in which they conduct surveys and studies regarding the markets in which we operate our business. As a result, you should carefully consider the inherent risks and uncertainties associated with the industry and market data contained in this Annual Report on Form 10-K, including those discussed in Part I, Item 1A. “Risk Factors.”

SUMMARY RISK FACTORS

You should consider carefully the risks described under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. References to "we," "us," and "our" in this section titled "Summary Risk Factors" refer to Immunovant, Inc. and its wholly owned subsidiaries. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

- Our business is currently dependent on the successful and timely development, regulatory approval and commercialization of our product candidates, batoclimab and IMVT-1402.
- Our product candidates, or anti-FcRn product candidates developed by others, may cause adverse events or undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to further suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.
- Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
- The results of our nonclinical and clinical trials may not support our proposed claims for our product candidates, or regulatory approval on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.
- Interim, "top-line" or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Roivant Sciences Ltd. owns a significant percentage of shares of our common stock and may exert significant control over matters subject to stockholder approval.
- Our business, operations, clinical development plans, timelines and supply chain could be adversely affected by the effects of health epidemics and pandemics on the manufacturing, clinical trials and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, contract research organizations, suppliers, shippers and others.
- Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which may in the future negatively impact our business and financial performance.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- Our failure to maintain or continuously improve our quality management program could have an adverse effect upon our business, subject us to regulatory actions and cause a loss of patient confidence in us or our products, among other negative consequences.
- We rely on third parties to conduct, supervise and monitor our clinical trials and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements or our quality management program fails to detect such events in a timely manner, it may harm our business.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- We plan to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.
- Our third-party manufacturers may encounter difficulties in production or our quality management program may fail to detect quality issues at our third-party manufacturers which may delay or prevent our ability to obtain marketing approval or commercialize batoclimab or IMVT-1402 if approved.

- We have a limited operating history and have never generated any product revenue.
- We will require additional capital to fund our operations. If we fail to obtain necessary financing, we may not be able to complete the development and commercialization of batoclimab or IMVT-1402.
- Raising additional funds by issuing equity securities will cause dilution to existing stockholders. Raising additional funds through debt financings may involve restrictive covenants and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.
- We rely on the license agreement with HanAll Biopharma Co., Ltd., or the HanAll Agreement, to provide us rights to the core intellectual property relating to batoclimab and IMVT-1402. Any termination or loss of significant rights under the HanAll Agreement would adversely affect our development or commercialization of batoclimab and IMVT-1402.
- The HanAll Agreement obligates us to make milestone payments, some of which may be triggered prior to our potential commercialization of batoclimab or IMVT-1402.
- We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune disease indications. Our operating results will suffer if we fail to compete effectively.
- International expansion of our business exposes us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the U.S.
- We are subject to stringent and changing privacy, data protection, and information security laws, contractual obligations, self-regulatory schemes, government regulation and standards related to data privacy and security. Further, if our security measures are compromised now or in the future, or the security, confidentiality, integrity or availability of our information technology, software, services, communications or data is compromised, limited or fails, this could result in a material adverse effect on our business.
- If securities or industry analysts do not publish research or reports about our business or publish negative reports about our business, our share price and trading volume could decline and has declined in the past upon downgrades of our common stock.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to enabling normal lives for people with autoimmune diseases. We were incorporated in Delaware in December 2018 as a blank check company under the name Health Sciences Acquisitions Corporation ("HSAC"). On December 18, 2019, Immunovant Sciences Ltd. ("ISL"), and HSAC consummated the transactions contemplated under that certain share exchange agreement dated as of September 29, 2019 by and among HSAC, ISL, the stockholders of ISL and Roivant Sciences Ltd., following the approval at the special meeting of the stockholders of HSAC held on December 16, 2019, which we refer to as the Business Combination. In connection with the closing of the Business Combination, we changed our name from HSAC to Immunovant, Inc.

Our innovative product pipeline includes batoclimab, formerly referred to as IMVT-1401, and IMVT-1402, both of which are novel, fully human monoclonal antibodies that target the neonatal fragment crystallizable receptor ("FcRn"). Batoclimab and IMVT-1402 are the result of a multi-step, multi-year research program conducted by us and HanAll Biopharma Co., Ltd. ("HanAll") to design highly potent anti-FcRn antibodies that may be optimized as a simple, subcutaneous injection with dosing that we believe can be tailored based on disease severity and stage.

Batoclimab, our first product candidate, has been dosed in small volumes (e.g., 2 mL) and with a 27-gauge needle, while still generating therapeutically relevant pharmacodynamic activity, important attributes that we believe will drive patient preference and market adoption. In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce immunoglobulin G ("IgG") antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in these disease areas.

Likewise, IMVT-1402, our second product candidate, has also been observed in nonclinical studies to reduce IgG antibody levels. Importantly, based on the anticipated human effective dose levels, the human equivalent doses of IMVT-1402 have demonstrated minimal or no impact on levels of albumin and low-density lipoprotein ("LDL") cholesterol in cynomolgus monkeys. This is a key attribute for IMVT-1402, which we believe could potentially allow its use as a treatment of chronic conditions requiring maintenance doses that achieve high degrees of IgG suppression. We are developing batoclimab and IMVT-1402 in autoimmune diseases for which there is robust evidence that pathogenic IgG antibodies drive disease manifestation and for which reduction of IgG antibodies should lead to clinical benefit.

Autoimmune diseases are conditions where an immune response is inappropriately directed against the body's own healthy cells and tissues. According to the American Autoimmune Related Diseases Association, more than 50 million people in the United States ("U.S.") suffer from one of more than 100 diagnosed autoimmune diseases. Predisposing factors may include genetic susceptibility, environmental triggers and other factors not yet known. Many of these diseases are associated with high levels of pathogenic IgG antibodies, which are the most abundant type of antibody produced by the human immune system, accounting for approximately 75% of antibodies in the plasma of healthy people. IgG antibodies are important in the defense against pathogens, such as viruses and bacteria. In IgG-mediated autoimmune diseases (an important subset of autoimmune diseases), IgG antibodies inappropriately develop against normal proteins found in the body, directing the immune system to attack specific organs or organ systems.

Unfortunately, safe and effective treatment options for patients suffering from many autoimmune diseases are lacking. Historically available treatments are generally limited to corticosteroids and immunosuppressants in early-stage disease and intravenous immunoglobulin ("IVIg") or plasma exchange in later-stage disease. These approaches often fail to address patients' needs since they are limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.

The physiologic function of FcRn is to prevent the degradation of IgG antibodies. Inhibition of FcRn, such as through the use of an anti-FcRn antibody, has been shown to reduce levels of total IgG and pathogenic IgG antibodies. We believe our completed clinical trials and other clinical trials assessing anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results, suggesting that FcRn is a therapeutically important and validated pharmacologic target to reduce levels of disease-causing IgG antibodies.

We believe that FcRn has broad therapeutic and commercial potential, with 22 indications currently being pursued by multiple companies across the anti-FcRn class. Based on third-party patient prevalence estimates, we estimate the total potential opportunity for

our FcRn franchise to be greater than two million patients in the U.S. and Europe (includes all European Union countries, Norway, Lichtenstein, Iceland, the United Kingdom, and Switzerland).

We are currently developing batoclimab for myasthenia gravis ("MG"), thyroid eye disease ("TED"), chronic inflammatory demyelinating polyneuropathy ("CIDP") and Graves' disease ("GD"). As a result of our rational design and current outlook on potential opportunities, we believe that batoclimab and IMVT-1402, if developed and approved for commercial sale, would be differentiated from currently available treatments for these and other advanced IgG-mediated autoimmune diseases.

Current Indications in Development

MG is a rare, chronic autoimmune disorder characterized by weakness and fatigue of voluntary muscles. The clinical course of MG is variable but usually progressive, and patients tend to experience fluctuating symptoms. There is an estimated prevalence of 18 cases of MG per 100,000 people in the U.S. For women, disease onset typically occurs around their 20s and 30s, whereas for men it peaks in their 50s and 60s. Overall, MG affects women more frequently than men. The disease is most often caused by autoantibodies that target the acetylcholine receptor or muscle-specific tyrosine kinase receptor at the neuromuscular junction, disrupting normal muscular function. Symptoms typically emerge in the eyes (e.g., drooping eyelids, double vision, blurred vision) and progress into the face, throat, or limbs. Some patients may experience life-threatening respiratory complications due to the weakening of muscles involved in respiration. See "*Batoclimab as a Potential Treatment for Myasthenia Gravis*" below for further discussion.

TED, also known as Graves' ophthalmopathy ("GO"), is an autoimmune disorder affecting the tissues around the eyes. It is a progressive and clinically variable disease that can become debilitating, disfiguring, or sight-threatening. The incidence of TED in the U.S. is estimated to be approximately 10 per 100,000. TED can be caused by IgG autoantibodies that form against the thyroid-stimulating hormone receptor ("TSHR"). These antibodies, which also cause Graves' disease, target the extraocular space and result in clinical manifestations of the disease. Common signs of disease include proptosis (eye bulging), tearing, periorbital edema (swelling around the eyes), redness, dry eyes, eye irritation, and pain behind the eyes; in severe cases, double vision or vision loss may occur. See "*Batoclimab as a Potential Treatment for Thyroid Eye Disease*" below for further discussion.

CIDP is an autoimmune neurological disorder characterized by damage to the myelin sheaths or the nodes on nerve fibers of the peripheral nervous system. Though the clinical course of CIDP can be variable, it is typically a chronic progressive disease if left untreated. CIDP is a rare disease that can occur in any age group, with peak onset being in the 60s and 70s. CIDP affects men twice as much as women. Its prevalence is estimated to be almost nine per 100,000 people in the U.S. CIDP appears to be mediated, at least in some patients, by IgG antibodies that are directed against targets in the myelin sheath; however, the specific target of these antibodies is not yet established. The hallmark signs of CIDP are weakness, tingling sensations, or loss of sensation in the arms and legs that is symmetrical and gradually worsens. See "*Batoclimab as a Potential Treatment for Chronic Inflammatory Demyelinating Polyneuropathy*" below for further discussion.

GD is an autoimmune disorder associated with the overproduction of thyroid hormones and is the most common cause of hyperthyroidism. Although GD can affect any age group or gender, it occurs often in women younger than 40 years of age with an estimated incidence of 35 per 100,000 people in the U.S. The disease is mediated by thyroid-stimulating IgG antibodies that cause the thyroid gland to produce an excess of thyroid hormones, resulting in systemic manifestations that affect multiple organs. Patients typically present with classic signs and symptoms of hyperthyroidism, such as heat intolerance, weight loss, anxiety, and frequent bowel movements. The disease can also manifest with ophthalmopathy (e.g., eye redness, swelling, bulging) or dermopathy. If left untreated, patients may develop arrhythmias, heart failure, or life-threatening thyroid storms. See "*Batoclimab as a Potential Treatment for Graves' Disease*" below for further discussion.

To the extent we choose to develop batoclimab and IMVT-1402 as potential treatments for certain of these and other rare diseases, we plan to seek orphan drug designation in the U.S. and Europe, where applicable. Such designations would primarily provide financial and exclusivity incentives intended to make the development of orphan drugs financially viable. In August 2022, we were granted orphan drug designation from the European Commission for batoclimab for the treatment of MG. Previously, batoclimab received orphan drug designation by the U.S. Food and Drug Administration ("FDA") for the treatment of MG. We plan to seek orphan drug designation in the U.S. and Europe for batoclimab and/or IMVT-1402 in other indications where there is a medically plausible basis for the use of batoclimab and/or IMVT-1402.

Potential New Indications

We continue to evaluate potential new indications for batoclimab and IMVT-1402 by considering a number of factors including, but not limited to, degree of unmet medical need, potential benefit offered by the treatment, target patient population size, and commercial potential.

Business Strategy

Our goal is to become a leading biopharmaceutical company in the development and commercialization of innovative therapies for autoimmune diseases with significant unmet need. To execute our strategy, we plan to:

- *Maximize the probability of success of our anti-FcRn franchise.* We plan to leverage the differentiated profiles of our FcRn inhibitors in indications where the anti-FcRn mechanism has already established clinical proof-of-concept, including MG and TED.

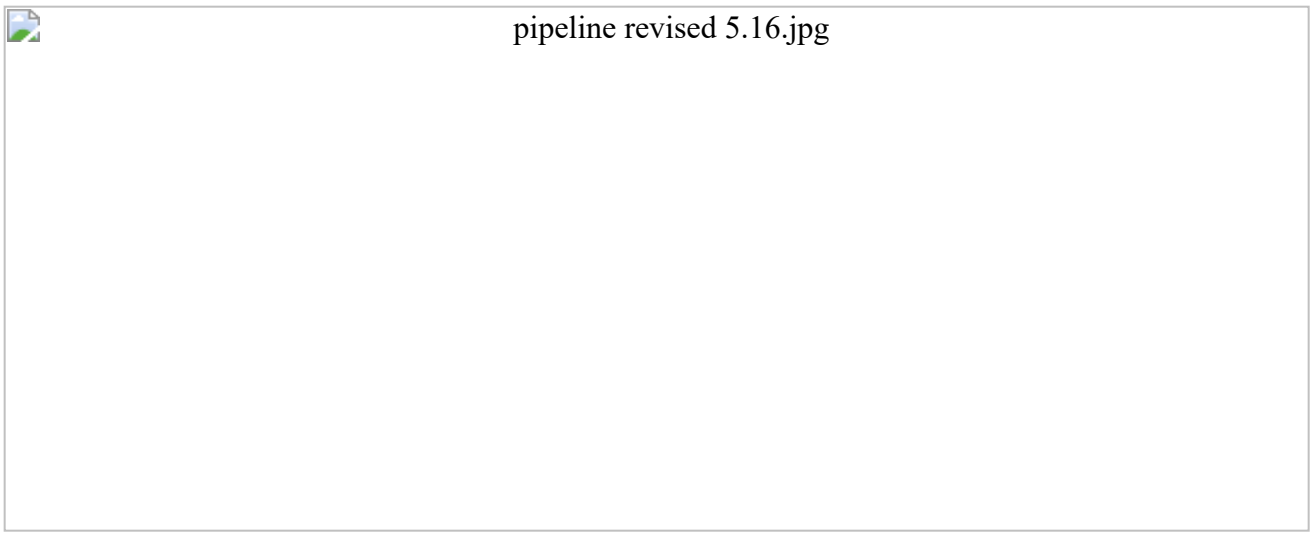
- *Maximize the breadth of indications for our anti-FcRn franchise.* In addition to pursuing indications with existing anti-FcRn proof of concept data, we are also considering first-in-class indications where the probability of technical success is good even without existing anti-FcRn clinical data based on potential to deliver clinical benefit with targeted IgG reduction.

- *Implement a rationale for the prioritization of potential indications.* We intend to prioritize potential indications (whether or not first-in-class) based on the degree of unmet medical need, the potential benefit offered by the treatment, the target patient population size, and the commercial potential.

- *Identify and acquire or in-license additional innovative therapies for autoimmune diseases.* Our controlling stockholder, Roivant Sciences Ltd. ("RSL"), and its subsidiaries, have a track record of acquiring or in-licensing products in a range of therapeutic areas. We will continue to partner and collaborate with RSL in identifying and evaluating potential acquisition and in-licensing opportunities in support of our goal to develop and commercialize innovative therapies for autoimmune diseases with significant unmet need.

Our Pipeline

The following is our current development pipeline:



Batoclimab as a Potential Treatment for Myasthenia Gravis

Myasthenia Gravis Overview

MG is an autoimmune disorder associated with muscle weakness and fatigue. MG patients develop antibodies that lead to an immunological attack on critical signaling receptor proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. This leads to muscle weakness intensified by activity, which can be localized exclusively to ocular muscles or which can be more generalized throughout the body including muscles of respiration. Patients with localized ocular disease suffer from more limited symptoms, including droopy eyelids and blurred or double vision due to compromise of eye movements. The vast majority of MG patients demonstrate elevated serum levels of acetylcholine receptor ("AChR") antibodies which disrupt signal transmission between nerve fibers and muscle fibers. These antibodies ultimately lead to fluctuating muscle weakness and fatigue.

The prevalence of MG is estimated to be 18 per 100,000 people, with up to 59,000 cases in the U.S. MG can occur at any age; however, the age of onset tends to follow a bimodal distribution. Early onset disease usually occurs in people between 10 to 30 years old and predominantly affects females. Later onset disease usually occurs in people over 50 years old and predominantly affects males. As with many autoimmune diseases, there are no known genetic alterations that specifically cause MG, and in most patients, it arises spontaneously. Approximately 3% of patients have a primary relative with MG, suggesting that there are genetic factors that may predispose development of the disease, but these genes have yet to be identified.

The symptoms of the disease can be transient and in the early stages of the disease can remit spontaneously. However, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months or remain chronic. After 15 to 20 years, some weakness often becomes fixed, with the most severely affected muscles frequently becoming atrophic. Many patients find it difficult to perform daily activities due to both insufficient improvement in symptoms even after treatment and in some the complicating long-term side effects of oral corticosteroids, a common treatment for MG. Approximately 15% to 20% of MG patients will experience at least one myasthenic crisis over their lifetimes. During myasthenic crisis, the impairment of muscles required to breathe can become life-threatening, leading to death in approximately 2% to 5% of cases. Up to 90% of patients in myasthenic crisis require intubation and mechanical ventilation leading to hospital stays lasting a median of 17 days. Over half of the patients who survive such a crisis remain functionally dependent upon discharge from the hospital.

Current Treatment Paradigm

Very early-stage MG is symptomatically treated with acetylcholinesterase inhibitors such as pyridostigmine. As the disease progresses, patients are typically treated with immunosuppressive agents such as glucocorticoids, azathioprine, mycophenolate mofetil and cyclosporine. Thymectomy may be indicated for treatment in patients with evidence of a thymoma and can be considered for treatment in some younger patients who do not have evidence of thymoma. As MG becomes more advanced, patients can be treated during exacerbations with IVIg, which provides therapeutic benefit through multiple potential mechanisms including the saturation of FcRn. Physicians direct patients with more advanced chronic disease and patients in times of crisis to therapies that reduce levels of circulating IgG antibodies via plasma exchange or a variant of this plasma exchange, immunoadsorption. The most recent agents approved for MG are eculizumab and ravulizumAb-cwvz, two complement C5 inhibitors, the use of which are limited to patients refractory to available therapy with anti-AChR-positive MG. Efgartigimod, an anti-FcRn antibody fragment, was recently approved for the treatment of MG in adult patients who are anti-AChR antibody positive. We believe there is room to improve upon this current treatment paradigm for MG, as some of these treatments can leave patients with burdensome administration requirements, significant side effects or long wait times to see treatment effect.

In 2019, we initiated a multi-center, randomized, blinded, placebo-controlled Phase 2a clinical trial of batoclimab for the treatment of MG. As evaluated in a pre-specified, pooled analysis of 15 subjects who completed Day 42 of the trial, batoclimab-treated subjects (N=10) showed a clinical improvement in both the MG-ADL scale and the MGC scale. We believe, based upon our review of data from this Phase 2a trial of batoclimab in MG, that there was sufficient proof of concept to pursue a pivotal trial to evaluate batoclimab for the treatment of MG.

Batoclimab Phase 3 Trial

In the second quarter of calendar year 2022, we initiated our Phase 3 pivotal trial of batoclimab as a treatment for MG. We expect top-line data from this trial to be available in the second half of calendar year 2024.

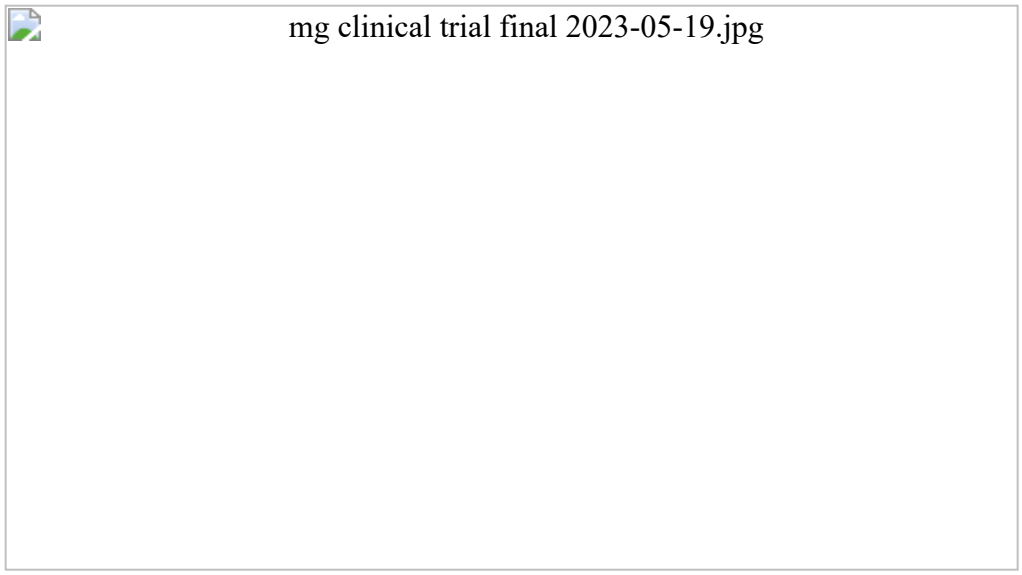
Our trial is designed to address unmet patient needs and differentiate batoclimab from other treatments for MG. Key features of the trial include:

- 12-week Induction Period: Includes doses of 680 mg subcutaneous injection weekly ("SC QW") or anchor dose of 340 mg SC QW compared to placebo. The objective is to achieve maximum efficacy at the beginning of treatment and determine the potential benefit of 680 mg SC QW (i.e., speed and depth of clinical response).

- 12-week Maintenance Period: Includes anchor doses of 340 mg SC QW and 340 mg subcutaneous injection once every two weeks compared to placebo to assess lower effective maintenance doses with potentially fewer side effects related to long term IgG suppression or serum analyte changes.

- 52-week Long-Term Extension: Includes long term safety assessment of the 2 maintenance doses; also includes tailored dosing allowing for treatment of disease exacerbations with short-term, re-induction dosing of batoclimab (680 mg SC QW x 4 weeks) followed by resumption of 340 mg SC QW.

MG Phase 3 Trial Design (N ~ 210)



QW = weekly, Q2W = once every two weeks, SC = subcutaneous injection

Batoclimab as a Potential Treatment for Thyroid Eye Disease

Thyroid Eye Disease Overview

TED, also referred to as GO, is a sight-threatening autoimmune inflammatory disorder that affects the muscles and tissues surrounding the eyes. Initial symptoms may include a dry and gritty ocular sensation, sensitivity to light, excessive tearing, double vision, and a sensation of pressure behind the eyes. At diagnosis, many patients with TED have retraction of their upper eyelids, swelling and redness surrounding the eyes, and protrusion of their eyeballs (proptosis). In some cases, swelling and stiffness of the eye muscles prevent the eyes from working together causing double vision. Approximately 3% to 5% of TED patients have a severe manifestation of the disease causing intense pain, inflammation, sight-threatening corneal ulcers, or optic neuropathy requiring surgical intervention. Decompression surgery to improve ocular function or rehabilitative surgery to improve quality of life is required in up to 20% of TED patients.

TED is most commonly caused by IgG autoantibodies that form against the TSHR. These anti-TSHR antibodies activate cells in the extraocular space that highly express TSHR, such as fibroblasts and adipocytes. Fibroblast activation causes cell proliferation and the production of hyaluronan, a substance that contributes directly to the swelling associated with TED. Hyaluronan also serves as an inflammatory signal leading to the synthesis of cytokines that cause recruitment of lymphocytes leading to extensive tissue inflammation and remodeling. Adipocyte activation leads to hyperplasia of the adipose tissue surrounding the eye causing protrusion of the eyeballs and compression of the optic nerve. Levels of anti-TSHR autoantibodies correlate positively with clinical features of TED and influence its prognosis. Exposure to other inflammatory agents, such as cigarette smoke, leads to exacerbation of the disease resulting in more severe symptoms.

In addition to anti-TSHR autoantibodies, antibodies that activate the insulin-like growth factor 1 receptor ("IGF1R") may also contribute to TED. TSHR and IGF1R have functional overlaps and stimulation of either receptor may lead to activation of similar biochemical pathways implicated in TED. Published studies investigating this pathway have led to the discovery that the IGF1R and TSHR form a receptor complex where IGF1R can augment the signaling of TSHR. The exact nature of the interaction between IGF1R and TSHR continues to be investigated; however, experimental evidence suggests that the effects of TSHR stimulating antibodies are only partially blocked by an IGF1R antagonist while they may be completely blocked with a TSHR antagonist.

TED has an estimated annual incidence of ten in 100,000 people in the U.S. The natural history of TED begins with an inflammatory phase lasting between six and 24 months that is characterized by lymphocyte infiltration, fibroblast proliferation and increases in adipose tissue. The first line of treatment for TED patients is generally immunosuppressive therapy, including high doses of corticosteroids. Treatment of patients with immunosuppressive therapies during this active inflammatory phase can lead to reduction in symptoms and can alter the course of the disease. However, once the initial inflammatory phase is over, immunosuppressive therapies are ineffective and levels of fibrosis that have developed as the result of acute inflammation are only reversible by surgery. We estimate that 15,000 to 20,000 patients in the U.S. have active TED each year and are eligible for treatment with therapy directed at the causative anti-TSHR antibodies.

Current Treatment Paradigm

As a first option, patients with active TED are treated with immunosuppressive therapy such as high doses of corticosteroids, typically administered intravenously or orally. Corticosteroids are not effective in all patients, and approximately one-third of patients will relapse. This therapy is associated with an increased risk of acute and severe organ damage, bone thinning, weight gain, diabetes, hypertension, osteoporosis and depression. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED.

Orbital radiation therapy is used as a means of reducing the infiltration of lymphocytes and can be used in conjunction with corticosteroids or immunosuppressive therapy. Similar to these anti-inflammatory and immunosuppressive drugs, radiation therapy is most effective in the active stage of TED.

Patients with moderate-to-severe active TED not responding to corticosteroids can be treated with cyclosporine or mycophenolate mofetil, two broad immunosuppressive drugs. These drugs are associated with numerous side effects related both to their general immunosuppressive effects as well as to inherent toxicities, such as hypertension, kidney disease and gastrointestinal toxicity.

Small case studies have identified rituximab as an alternate way of inducing immunosuppression in patients with TED. Rituximab (Roche) is a monoclonal antibody that binds to an antigen specific to B cells, leading to their destruction. However, rituximab is associated with the potential for serious side effects, such as infusion-related reactions. Rare cases of progressive multifocal encephalopathy and other viral infections have also been reported.

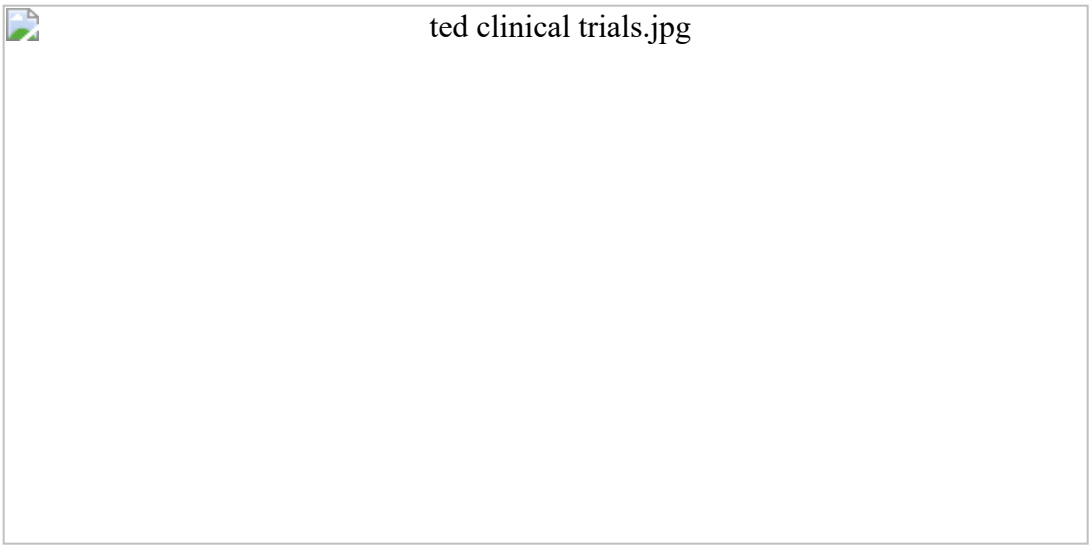
Surgery is considered to be a treatment option in patients with a highly active disease who have been treated with corticosteroids or immunosuppressive therapy but continue to have progressive disease. The goal of surgery is to reduce the pressure causing proptosis, reduced eye movement and loss of visual acuity. Because of its invasive nature, surgery is typically reserved for inactive disease.

In 2019, we initiated an open-label, single-arm Phase 2a clinical trial of batoclimab for the treatment of TED. In 2019, we also initiated a randomized, masked, placebo-controlled Phase 2b clinical trial of batoclimab for the treatment of TED. Our voluntary pause in dosing in February 2021 resulted in unblinding the Phase 2b trial and the primary endpoint was not significant. However, our analysis of exploratory endpoints from the Phase 2b trial, in addition to the findings from the Phase 2a trial, increased our confidence in the anti-FcRn mechanism of action for patients with TED, and they provide part of the basis for our interest in moving forward with further development of TED.

Batoclimab Phase 3 Clinical Program

In the fourth quarter of calendar year 2022, we initiated our Phase 3 clinical program to evaluate batoclimab as a treatment for TED. For each of two Phase 3 trials of batoclimab in TED, we expect that approximately 100 subjects will enter the trial and be randomized to either a treatment arm or placebo arm. Subjects randomized to the treatment arm will be dosed with 680 mg of batoclimab QW for 12 weeks followed by 340 mg of batoclimab QW for 12 weeks. This batoclimab-treated group of subjects will be compared to subjects that are dosed with placebo QW for 24 weeks. This treatment period will last for 24 weeks and the primary efficacy endpoint will be measured as proptosis responders at Week 24 vs placebo where responders are defined as ≥ 2 mm reduction from baseline in proptosis in the study eye without deterioration of ≥ 2 mm increase in the fellow eye. We expect top-line results from this program to be available in the first half of calendar year 2025.

TED Phase 3 Trial Design



Batoclimab as a Potential Treatment for Chronic Inflammatory Demyelinating Polyneuropathy

Chronic Inflammatory Demyelinating Polyneuropathy Overview

CIDP is believed to be an immune mediated neuropathy characterized by demyelination of peripheral nerves and nerve roots that is driven by pathologic, autoreactive immunoglobulin G (IgG) antibodies. Worldwide, the reported prevalence of CIDP ranges from 0.8 to 8.9 per 100,000 persons. The average age of onset is about 50 years, with relapsing disease course associated with younger age of patients, and men are predominantly affected in an approximately 2:1 ratio relative to women.

CIDP typically presents with progressive or relapsing, symmetric involvement of both proximal and distal extremity muscle weakness over the course of several weeks. The pathophysiology of CIDP is not completely understood. However, it is thought that an inciting process such as molecular mimicry causes activation of autoreactive T cells. Activated T cells cross the blood-nerve barrier (“BNB”) via adhesion molecules and diapedesis, where they secrete metalloproteinases and pro-inflammatory cytokines that increase the permeability of the BNB and stimulate autoantibody production by plasma cells. The damaged BNB permits passage of soluble factors such as autoantibodies and activated macrophages, which also release pro-inflammatory cytokines and reactive oxygen species thus propagating the inflammatory cycle. Upon accessing the nerve, autoantibodies can bind to neuronal proteins including myelin glycoproteins resulting in axonal degeneration and demyelination. Autoantibody induced degeneration and demyelination causes characteristic electrophysiologic alterations of the peripheral nerves and is clinically manifested by the sensorimotor deficits of CIDP.

Current Treatment Paradigm

With respect to clinical management, IVIg, corticosteroids, and plasma exchange ("PLEX") are considered as first-line therapy in the treatment of CIDP. The treatment paradigm involves initiation of therapy with one of these three agents. For patients who fail to achieve objective improvement (i.e., of impairment and disability) after 3 months of treatment, a second or third first line agent may be tried. Alternative options include rituximab, cyclophosphamide, or cyclosporine, although there is limited evidence supporting their use as treatments for CIDP. Once objective improvement is achieved, the patient may be switched to maintenance treatment, the goal of which is to reduce the dose or frequency of treatment to the minimum effective level. For maintenance therapy, patients may be switched from IVIg to subcutaneous immunoglobulin ("SCIg"); and immunomodulatory agents such as azathioprine, cyclosporine, or mycophenolate may be used for IVIg dose-reducing, corticosteroid-sparing or PLEX frequency-reducing effect. Increasing the dose or frequency of treatment or combining treatments is a consideration for patients who continue to experience active disease. For long term management of clinically stable patients, therapy should be periodically reduced or stopped to assess if treatment is still required.

Despite the availability of the therapies described above, there remains significant unmet medical need for patients with CIDP. For example, although immunoglobulin therapy (IVIg, SCIg) is effective, it may be associated with significant side effects and complications such as severe headache, thromboembolism, and hemolysis. Additionally, IVIg therapy imposes a burden on patients' time and requires in-person attendance visits at infusion center access to home health agency support for at-home administration remains limited. The availability of IVIg has also been constrained at times due to supply conditions. Currently available SCIg therapy often requires frequent administration across multiple infusion sites using an external pump to deliver the requisite volume of therapy, which presents attendant challenges to patients requiring therapy on a continuous basis. Corticosteroid therapy, though effective, has been linked with a number of well-known serious adverse events (e.g., weight gain, hypertension, diabetes, and osteoporosis), especially with chronic use. PLEX is a specialized procedure requiring central venous access and is not universally available. The immunomodulatory therapies that may be used in CIDP are all associated with significant potential risks, including the possibility of malignancy and/or infection. For example, these include azathioprine – cytopenia; cyclosporine – hypertension, nephrotoxicity; mycophenolate – blood dyscrasias including neutropenia and red blood cell ("RBC") aplasia; rituximab – renal toxicity; and cyclophosphamide – cardiac, pulmonary, and renal toxicity as well as bone marrow suppression and infertility. To summarize, the currently available treatments are associated with significant potential risk of adverse events, generally impose a high burden on patient's time and effort and may be subject to restricted availability.

Batoclimab Phase 2b Trial

In the fourth quarter of calendar year 2022, we initiated a pivotal Phase 2b trial of batoclimab as a treatment for CIDP. We expect initial data from the open-label period of this trial (where one of two blinded doses of batoclimab are delivered) to be available in the first half of calendar year 2024.

Our trial is intended to develop a potentially best-in-class chronic anti-FcRn therapy in CIDP. Key features of the trial include:

- Three cohorts consisting of adult participants diagnosed with CIDP per European Academy of Neurology/Peripheral Nerve Society CIDP guidelines, 2021 revision. Randomized cohorts are defined by CIDP treatment at screening (i.e., Ig or PLEX, corticosteroid or no treatment).

- Washout period of ≤ 12 weeks: Participants who fail to worsen by the end of the washout period will be withdrawn from the study.

- Period 1 - Randomized Treatment (12 weeks): Two dose regimens include doses of 680 mg subcutaneous injection weekly ("QW SC") or 340 mg QW SC. Non-responders who complete Period 1 will be withdrawn from the study after completing Week 12 and the subsequent 4-week follow-up visit.

- Period 2 - Randomized Withdrawal (≤ 24 weeks): Includes doses of 340 mg QW SC or placebo.

- Primary endpoint: Proportion of relapse events in Period 2 for patients receiving Ig or PLEX at time of screening (Cohort A).

- Long Term Extension: Participants that relapse in Period 2 or complete Period 2 without relapse will be eligible for participation in the Long-term Extension Study. Participants without relapse will receive doses of 340 mg QW while those that relapse in Period 2 will receive an initial dose of 680 mg QW for 4 weeks followed by the 340 mg QW dose.

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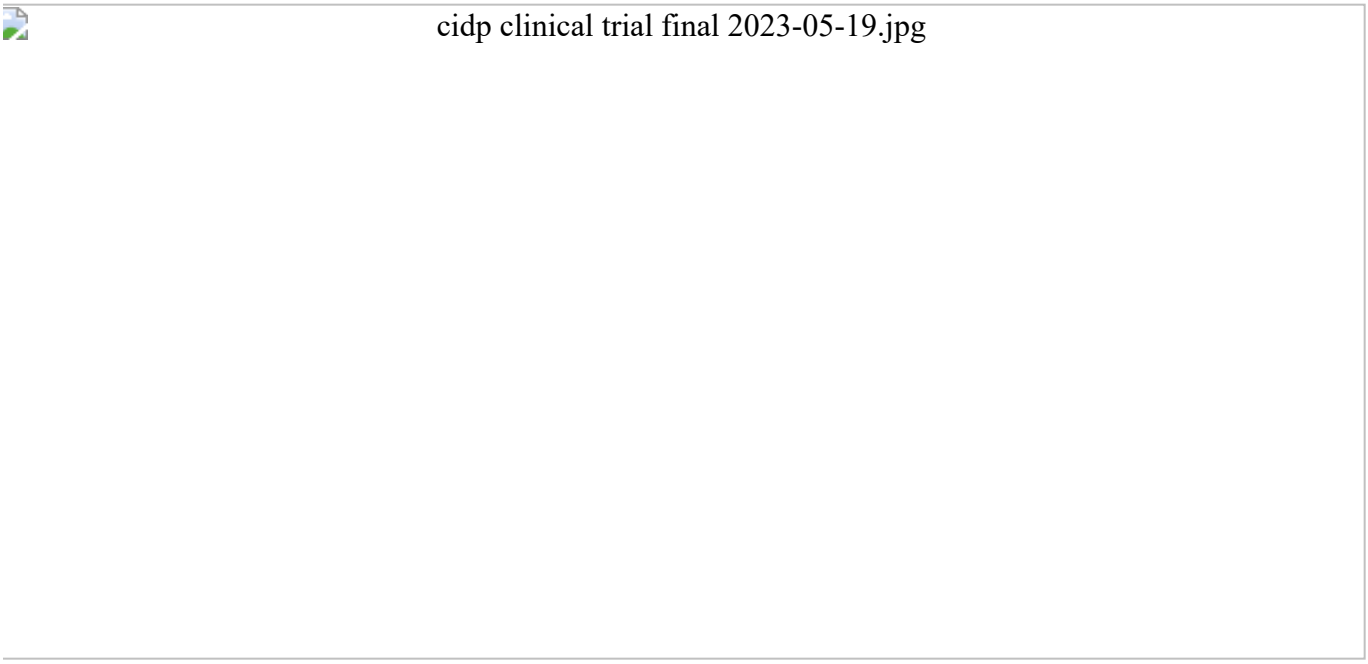
CIDP Phase 2b Trial Design



Batoclimab as a Potential Treatment for Graves' Disease

Graves' Disease Overview

GD is an autoimmune disease that affects the thyroid gland. Patients with GD develop autoantibodies to the thyroid-stimulating hormone receptor ("TSHR-Ab") present on the thyroid gland, which induces increased and uncontrolled secretion of thyroid hormones (hyperthyroidism). Because thyroid hormones play an important role in controlling functions of many organs such as heart, central and peripheral nervous system, muscle, bone, and skin, the presence of excessive thyroid hormones is associated with a variety of signs and symptoms including enlarged thyroid gland (goiter), palpitations, arrythmia, anxiety, weight loss, insomnia, osteoporosis, and pretibial myxedema. These manifestations can be mild to severe depending on the degree of thyroid hormone elevation and age. While neurogenic symptoms like anxiety and tremor are more common among younger patients, older patients tend to present with cardiovascular complications such as rapid and/or irregular heartbeat or even heart failure. The presence of TSHR-Ab is also involved in the pathogenesis of GO, also known as TED, which is more likely to occur in patients with GD who have a more severe degree of hyperthyroidism, larger goiter, history of smoking, and have been treated with radioiodine ("RAI").

The reported incidence and prevalence of GD varies according to the methodology applied, but it is estimated that it affects approximately 2% of women and 0.2% of men globally, with an incidence of approximately 20–40 cases per 100,000 population per year. GD is the most common cause of hyperthyroidism and occurs at all ages but especially in adults aged between 20 and 50 years and women of reproductive age.

Current Treatment Paradigm

The main treatment goal of GD is to reduce thyroid hormone levels. There are 3 options available: surgery, RAI, and oral antithyroid drugs ("ATDs"). Surgery, which involves removal of the entire thyroid gland (thyroidectomy) is an option, especially for patients with large goiters, women planning pregnancy, and, in some cases, patients who have failed to respond to ATDs. Although any such surgical procedure may lead to an immediate resolution of the hyperthyroidism, it is associated with a number of complications, including parathyroid gland injury, which may lead to transient or persistent hypocalcemia, and damage of the laryngeal nerve. In addition, to reduce the risk of acute complications during the procedure, patients often require pre-operative treatments to ensure cardiovascular and thyroid hormone stability.

Treatment with RAI destroys the thyroid because ionizing radiation causes deoxyribonucleic acid damage. It is considered treatment of choice in several countries, especially if ATDs are contraindicated or among patients who do not respond to this drug class. Since RAI can worsen TED, it is not recommended in patients with TED or in smokers who are at higher risk of developing TED, and in woman who are pregnant or lactating. Finally, recent data suggest an association between RAI radioiodine and several types of cancer. In the U.S., RAI has been the preferred therapy, but a trend in recent years is to increase the use of ATD and reduce the use of RAI. In addition to the potentially increased risk of cancer after RAI, an association with sustained increases in TSHR-Ab titers and risk for de novo Graves' GO and worsening of pre-existing ophthalmopathy have all been drivers of this shift in care away from RAI.

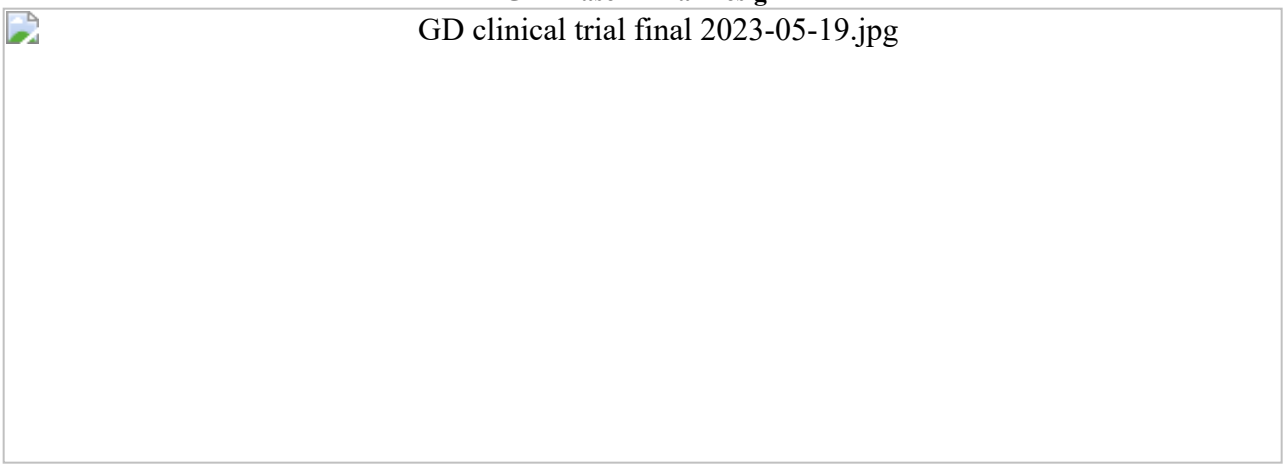
Since surgery is anatomically invasive and RAI is accompanied by exposure to radiation, both are considered more aggressive treatments than ATD. Furthermore, in addition to their invasiveness, the requirement for lifelong thyroid hormone replacement therapy after RAI and surgery leads to a preference for ATD as a primary therapy in Asia, Latin America, and Europe.

The most commonly used ATDs in the U.S. are the thionamides, methimazole and propylthiouracil. While these drugs are considered generally safe, their chronic use can be associated with hepatotoxicity, pancreatitis and bone marrow toxicity. For this reason, patients need laboratory monitoring, and complete blood count and liver function tests are needed before treatment initiation. Treatment with ATD is usually administered for 12 to 18 months according to the American and European guidelines with remission rates of 50% to 55% achieved within this period. However, many patients experience a relapse after discontinuation of ATD. Younger age (<40 years), TED, smoking, large thyroid volume, TSHR-Ab, and biochemically more severe disease with high hormone levels free thyroxine and total triiodothyronine significantly increase the risk of relapse of GD. A recent study showed that GD patients with persistent stimulating TSHR-Ab levels had a 6 fold increased risk for relapse after ATD withdrawal, indicating that stimulating TSHR-Ab levels are better predictors of GD relapse after ATD withdrawal than general TSHR-Abs. Collectively, these data suggest that a treatment for GD targeting the reduction or elimination of circulating stimulating TSHR-Ab would address the underlying autoimmune pathogenesis of the disease and would restore normal thyroid function.

Batoclimab Phase 2 Trial

In the second quarter of calendar year 2023, we initiated a proof-of-concept Phase 2 clinical trial in GD in Germany. We expect initial results from this trial to be available in the fourth quarter of calendar year 2023.

GD Phase 2 Trial Design



A: Additional inclusion and exclusion criteria not listed

IMVT-1402

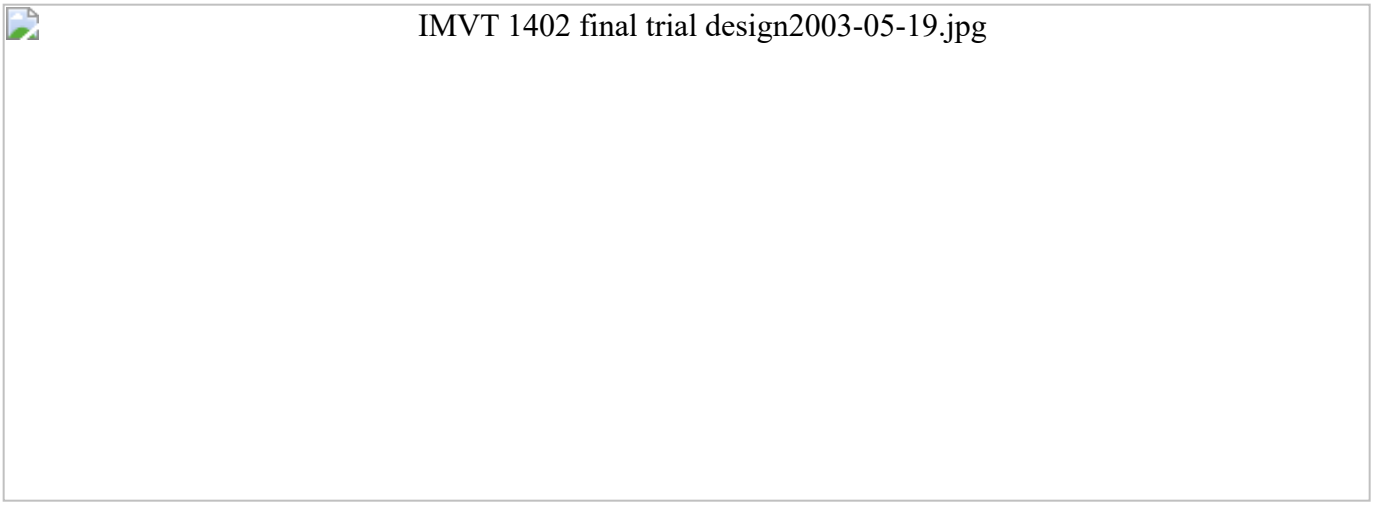
Overview

IMVT-1402 is a fully human monoclonal antibody that inhibits FcRn and was part of a group of antibodies licensed from HanAll under the HanAll Agreement (as defined below). IMVT-1402 has three key product attributes that potentially differentiate it from other FcRn inhibitors. First, in nonclinical studies, we observed that IMVT-1402 had a similarly deep IgG reduction to what we observed with batoclimab in nonclinical studies. Second, we have completed CMC and formulation work for IMVT-1402 to enable the same convenient route of administration and simple subcutaneous delivery as batoclimab. Finally, in a head-to-head nonclinical study comparing IMVT-1402 with batoclimab at doses above the expected human effective dose, IMVT-1402 showed minimal or no impact on albumin and LDL cholesterol.

Phase 1 Clinical Trial of IMVT-1402 in Healthy Volunteers

In the second quarter of calendar year 2023, the FDA cleared our Investigational New Drug ("IND") application for IMVT-1402 and we initiated a Phase 1 clinical trial of IMVT-1402 in healthy volunteers in New Zealand after approval of the Clinical Trial Application ("CTA") by the regulatory authority, MEDSAFE. The clinical trial will evaluate the safety, tolerability and pharmacodynamic profiles of IMVT-1402, a subcutaneously administered, FcRn inhibitor. We expect initial data from single-ascending dose cohorts to be available in August or September 2023 and from multiple-ascending dose cohorts in October or November 2023. The Phase 1 trial design is presented below:

IMVT-1402 Phase 1 Clinical Trial Design



IMVT-1402 is delivered as a 2 mL simple subcutaneous injection with a 27-guage needle at a concentration of 150 mg/mL in the Subcutaneous Dose cohorts. Additional or optional cohorts may include 1,200 mg IV single-ascending dose, 150 mg SC multiple-ascending dose and 450 mg SC multiple-ascending dose. The first multiple-ascending dose cohort will be initiated after review of pharmacokinetic ("PK") and safety data from single-ascending dose cohorts at the same or higher dose levels, with the final dose selection for the first multiple-ascending dose cohort dependent on this PK review. Single and multiple ascending dose cohorts will be initiated following review of safety data and PK data from all previously dosed cohorts.

Nonclinical Studies of IMVT-1402

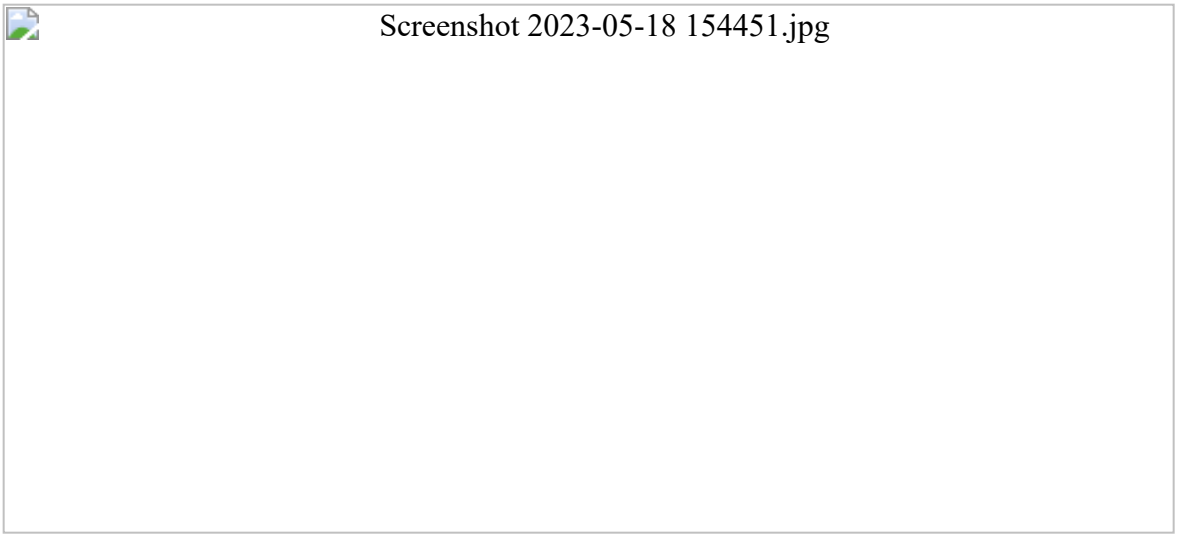
Based on monkey and human data from molecules in the anti-FcRn class, dose-dependent IgG suppressions can be achieved with an anti-FcRn treatment up to approximately 80% of baseline values in human studies; and the PK and pharmacodynamics ("PD") of FcRn blockade are highly translatable from cynomolgus monkeys to humans. IMVT-1402, our second anti-FcRn product candidate, has also been observed in nonclinical studies in cynomolgus monkeys to reduce IgG levels to a degree similar to batoclimab. Importantly, based on the anticipated human effective dose levels, the human equivalent doses of IMVT-1402 have demonstrated minimal or no impact on levels of albumin and low-density lipoprotein ("LDL") cholesterol in cynomolgus monkeys. This is a key attribute for IMVT-1402, which we believe could potentially allow its use as a treatment of chronic conditions requiring maintenance doses that achieve high degrees of IgG suppression. We are developing batoclimab and IMVT-1402 in autoimmune diseases for which there is robust evidence

that pathogenic IgG antibodies drive disease manifestation and for which reduction of IgG antibodies would be expected to lead to clinical benefit.

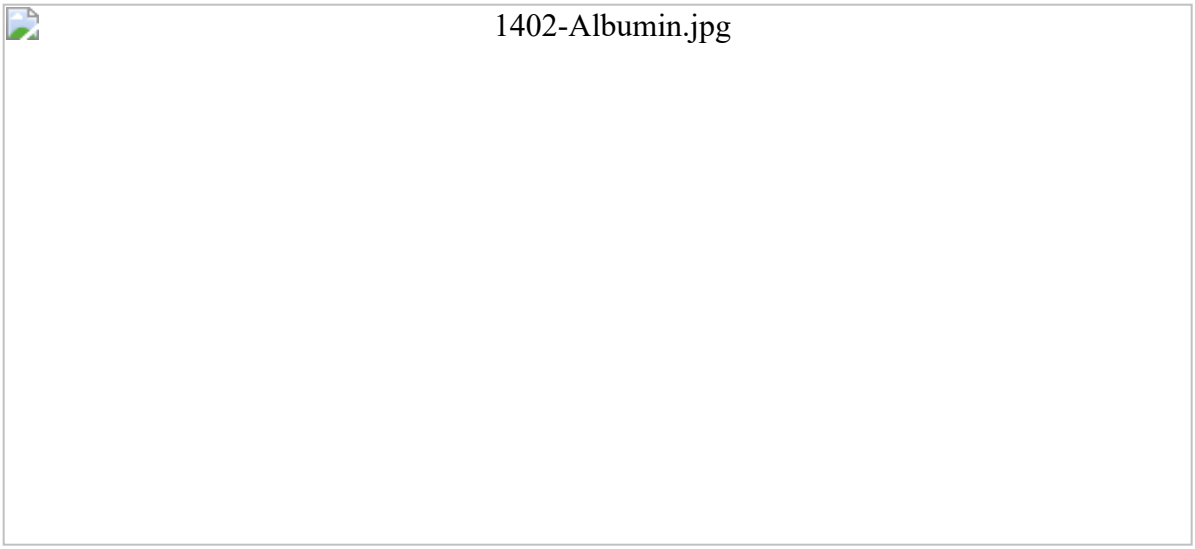
Pharmacodynamic Data

In a head-to-head, placebo-controlled nonclinical study, IMVT-1402 has been observed to achieve similarly deep IgG reduction as batoclimab and have minimal or no impact on levels of albumin and low-density lipoprotein cholesterol at doses well above the anticipated human effective dose. We believe this profile could be best in class.

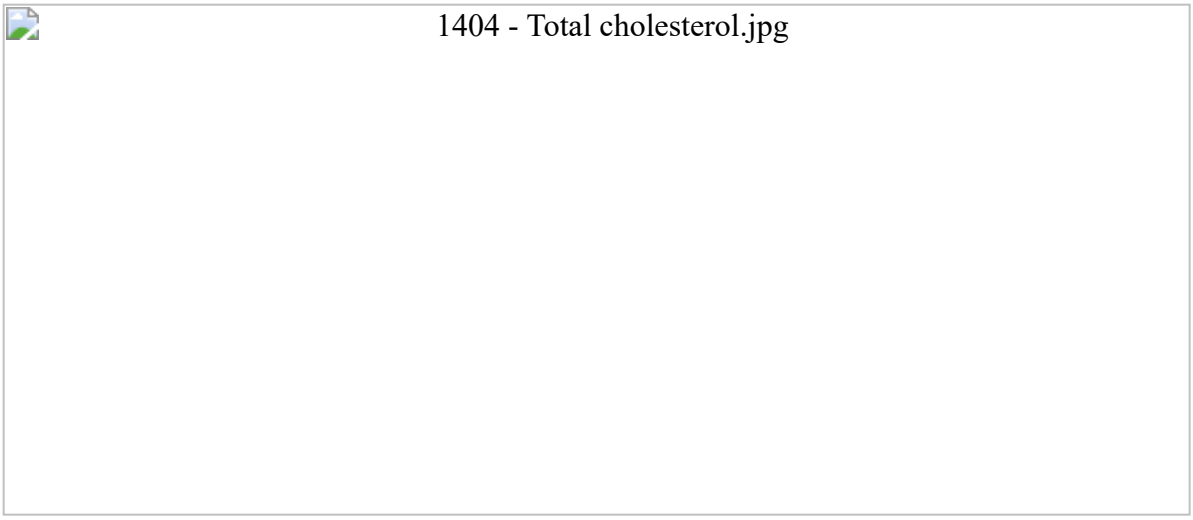
Mean Reduction of Total IgG Levels in Head-to-Head Study of IMVT-1402 and Batoclimab in Cynomolgus Monkey



Mean Change in Albumin in Head-to-Head Study of IMVT-1402 and Batoclimab in Cynomolgus Monkey



Mean Change in Total Cholesterol in Head-to-Head Study of IMVT-1402 and Batoclimab in Cynomolgus Monkey

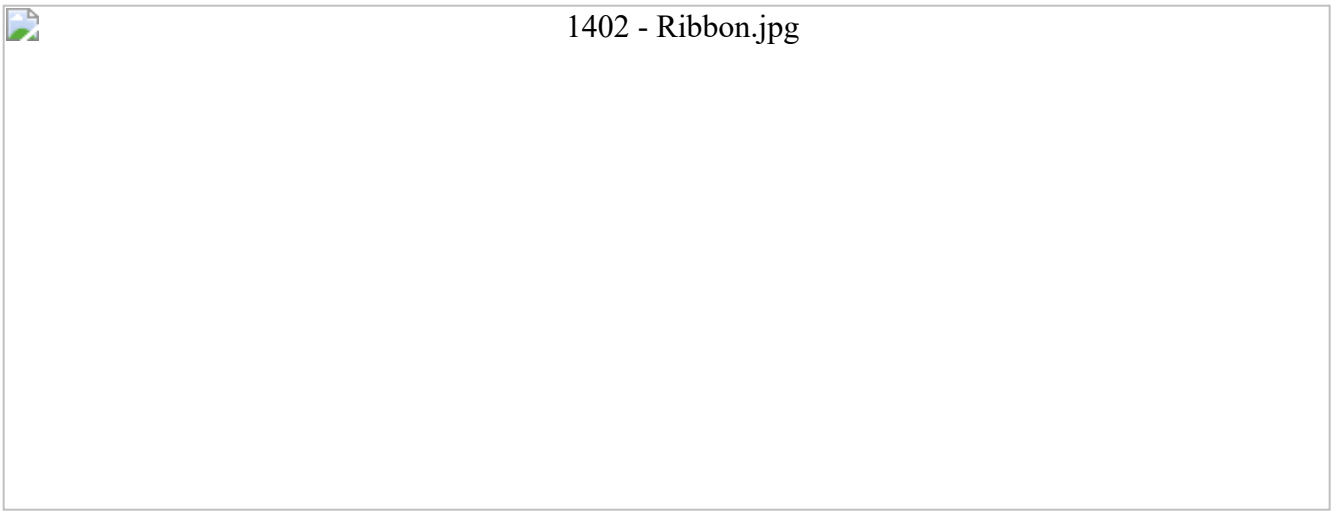


Mean Change in LDL Cholesterol in Head-to-Head Study of IMVT-1402 and Batoclimab in Cynomolgus Monkey

X-Ray Crystallography Structure Analysis

The lack of observed albumin impact by IMVT-1402 is corroborated by x-ray crystallographic structures of FcRn complexes with IMVT-1402 and batoclimab. It is apparent that IMVT-1402 orients differently from batoclimab when bound to FcRn.

Ribbon Representations of X-Ray Crystallographic Structures of IMVT-1402- and Batoclimab-FcRn Complexes



Key Agreements

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, Roivant Sciences GmbH ("RSG"), a wholly owned subsidiary of RSL, entered into a license agreement with HanAll (the "HanAll Agreement"). Under the HanAll Agreement, RSG received (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to (a) develop, import and use (i) the antibody referred to as batoclimab, (ii) certain back-up and next-generation antibodies (including IMVT-1402), and (iii) products containing such antibodies, and (b) to commercialize such products, in the U.S., Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America, or the Licensed Territory, for all human and animal uses, during the term of the agreement. With respect to these licenses, RSG also received the right to grant a sublicense, with prior written notice to HanAll of such sublicense, to: (1) a third party in any country in the Licensed Territory outside of the U.S. and E.U.; (2) an affiliate of RSG in any country in the Licensed Territory; and (3) a third party in the U.S. and E.U. only after submission of a biologics license application ("BLA") in the U.S. or a Marketing Authorization Application in the E.U. Pursuant to the HanAll Agreement, RSG granted to HanAll an exclusive, royalty-free license under certain RSG patents, know-how and other intellectual property controlled by RSG relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the Licensed Territory. HanAll also reserves the right to conduct discovery or research activities with the batoclimab antibody, and certain back-up and next-generation antibodies (including IMVT-1402), with or through a contract research organization or service provider in the Licensed Territory.

In December 2018, we obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to batoclimab and IMVT-1402 in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and our wholly owned subsidiary, Immunovant Sciences GmbH, or ISG, for an aggregate purchase price of $37.8 million.

Under the HanAll Agreement, the parties may choose to collaborate on a research program directed to the research and development of next generation FcRn inhibitors in accordance with an agreed plan and budget. We are obligated to reimburse HanAll for half of such research and development expenses incurred by HanAll, up to an aggregate reimbursement amount of $20.0 million. Intellectual property created by HanAll pursuant to this research program will be included in our license; intellectual property created by us pursuant to this research program will be included in HanAll's license. As of March 31, 2023, we do not have any additional amounts payable to HanAll for research and development costs incurred and reported to us pursuant to the HanAll Agreement. As of March 31, 2022, $0.4 million was payable to HanAll for research and development costs incurred and reported to us pursuant to the HanAll Agreement.

In the fourth quarter of calendar year 2022, we achieved our second development and regulatory milestone under the HanAll Agreement of $10.0 million, which was paid in the first quarter of calendar year 2023 and recorded as acquired in-process research and development expenses in the accompanying consolidated statement of operations for the year ended March 31, 2023. We will be responsible for future contingent payments and royalties, including up to an aggregate of $432.5 million (after an aggregate amount of $20.0 million of milestone achievements as of March 31, 2023) upon the achievement of certain development, regulatory and sales milestone events. We are also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens percentage of net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of: (A) the date on which the last valid claim of the licensed patents expire, (B) the date on which the data or market exclusivity expires or (C) 11 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country.

Except for cost-sharing in connection with the research program, we are solely responsible, at our expense, for all other activities related to the research, development and commercialization of licensed products for the Licensed Territory. We may use a third party for manufacturing activities necessary for the research, development and commercialization of licensed products for the Licensed Territory. In addition, under the HanAll Agreement, we have agreed to use commercially reasonable efforts to develop and commercialize licensed products in the Licensed Territory. Each party has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory.

Under the HanAll Agreement, we have the sole right, but not the obligation, to control the prosecution, defense and enforcement of the licensed patents in the Licensed Territory, and HanAll has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which we elect not to exercise such rights.

The HanAll Agreement will expire on a product-by-product basis on the expiration of the last royalty term with respect to a given licensed product, unless earlier terminated. We may terminate the HanAll Agreement in its entirety without cause upon 180 days' written notice following 30 days of discussion. Either party may terminate the HanAll Agreement upon 60 days' written notice for uncured material breach (or 30 days in the case of non-payment), or immediately upon written notice if the other party files a voluntary petition, is subject to a substantiated involuntary petition or for certain other solvency events. HanAll may terminate the HanAll Agreement if we or our affiliates challenge the validity or enforceability of any of the licensed patents.

Product Service Agreement and Master Services Agreement

On November 17, 2021, Immunovant, Inc.'s wholly owned subsidiary, Immunovant Sciences GmbH ("ISG"), a limited liability company formed under the laws of Switzerland, entered into a Product Service Agreement, ("PSA"), with Samsung Biologics Co., Ltd., ("Samsung"), pursuant to which Samsung will manufacture and supply us with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. We previously entered in a Master Services Agreement, ("MSA"), with Samsung, dated April 30, 2021, which governs certain terms of our relationship with Samsung. Upon execution of the PSA, we committed to purchase process performance qualification batches of batoclimab and pre-approval inspection batches of batoclimab which may be used for regulatory submissions and, pending regulatory approval, commercial sale. In addition to these, we are obligated to purchase additional batches of batoclimab in the four-year period of 2026 through 2029.

The PSA will continue until the later of December 31, 2029 or the completion of the services thereunder, unless the PSA is terminated earlier. If we make a final decision to stop all development of batoclimab and all attempts to obtain regulatory approval for batoclimab, then we will have the right to terminate the PSA with 30 days' written notice to Samsung as long as such notice is provided no later than January 2024. Upon such termination of the PSA, we will pay Samsung for non-cancellable service fees and costs that Samsung incurs and for all batches of batoclimab scheduled to be manufactured during the two-year period following such termination. In addition, either party may terminate the PSA on account of (i) the other party's material breach of the PSA that is not cured within a specified period after the termination notice, (ii) the other party's insolvency or bankruptcy, or (iii) certain force majeure events.

As of March 31, 2023, the minimum purchase commitment related to this agreement was estimated to be approximately $33.3 million.

We are a Member of the Roivant Family of Companies

We are a majority-owned subsidiary of RSL and have benefited from our ability to leverage the Roivant model and the greater Roivant platform. The period of time between our formation and operational maturation was shortened based on the support from centralized Roivant functions available since creation. This includes operational functions as well as access to Roivant's proprietary technology and digital innovation platforms. Consistent with its model, Roivant has also provided us with access to an embedded team of scientific experts, physicians and technologists to help optimize clinical development and commercial strategies. In the future, we may have the ability to benefit from Roivant's economies of scale and scope, including but not limited to the opportunity to:

- leverage Roivant's business development engine and vast network of industry relationships for the identification of, and access to, new assets and synergistic partnerships;
- enter channel partnerships with other members of the Roivant family of companies (including but not limited to technology-focused companies built by Roivant), with the goal of delivering efficiencies in the development and commercialization process;
- access Roivant's human capital engine to recruit new employees from within and beyond the biopharmaceutical industry;
- enable its employees to participate in Roivant's career development program which facilitates employee mobility across members of the Roivant family of companies;
- benefit from shared learnings, best practices, and external industry relationships across the Roivant family of companies; and
- derive certain benefits of scale upon becoming a commercial-stage company.

For a description of our transactions under agreements with related parties, refer to Part II, Item 8. Financial Statements and Supplementary Data, Note 5 – Related Party Transactions.

For a discussion on RSL's significant ownership of our shares of common stock and related possible risks, please refer to Item 1A. Risk Factors, *"RSL owns a significant percentage of shares of our common stock and may exert significant control over matters subject to stockholder approval."*

Sales and Marketing

We do not currently have our own marketing, sales or distribution capabilities. In order to commercialize batoclimab, IMVT-1402 or any future product candidate, if approved for commercial sale, we would have to develop a sales and marketing infrastructure. We intend to build a small, targeted sales organization in the U.S., targeting specialist physicians that treat high numbers of patients with autoimmune conditions. We believe these physicians treat a majority of patients with the autoimmune indications that we intend to target and most often serve as the diagnosing and treating physicians for such indications. We may opportunistically seek strategic collaborations to maximize the commercial opportunities for batoclimab, IMVT-1402 or any future product candidates inside and outside the U.S.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of batoclimab and IMVT-1402, and there are a limited number of manufacturers that operate under the FDA's current Good Manufacturing Practice ("cGMP") requirements (particularly for the development of antibodies) that might be capable of manufacturing for us. We currently rely and intend to continue to rely on contract manufacturing organizations ("CMOs"), for both drug substance and drug product. See *Product Service Agreement and Master Services Agreement* above for a description of the agreements pursuant to which Samsung will manufacture and supply us with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. Currently, we contract with well-established third-party manufacturers for the manufacture of our drug substance and our drug product. We expect to engage additional third-party manufacturers to support any pivotal clinical trials for our product candidates as well as commercialization of our product candidates, if approved, in the U.S. or other jurisdictions. In addition, we continue to augment the organization by recruiting personnel with experience to manage the CMOs producing our product candidates and other product candidates or products that we may develop in the future.

Our outsourced approach to manufacturing relies on CMOs to first develop cell lines and manufacturing processes that are compliant with cGMP then produce material for nonclinical studies and clinical trials. Our agreements with CMOs may obligate them to develop a production cell line, establish master and working cell banks, develop and qualify upstream and downstream processes, develop drug product process, validate (and in some cases develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for nonclinical testing, produce cGMP-compliant drug substance, or produce cGMP-compliant drug product. We conduct audits of CMOs prior to initiation of activities under these agreements and monitor operations to ensure compliance with the mutually agreed process descriptions and cGMP regulations.

Competition

We expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases, including multiple agents which are in the same class as batoclimab and IMVT-1402. We are aware of several FcRn inhibitors that are in clinical development. These include efgartigimod (argenx SE), nipocalimab (Johnson & Johnson) and rozanolixizumab (UCB). Each of efgartigimod, nipocalimab, and rozanolixizumab is currently under development for the treatment of MG.

In a Phase 3 trial evaluating subcutaneous efgartigimod for generalized myasthenia gravis ("gMG"), argenx reported noninferiority between subcutaneous efgartigimod and VYVGART™ (efgartigimod alfa-fcab) IV based on total IgG reduction at day 29, in addition to a higher incidence of injection-site reactions compared to the IV formulation and six patients that showed worsening of their MG symptoms over the course of the study. Subcutaneous efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. ENHANZE® facilitates subcutaneous injection delivery of higher-volume biologics that are typically administered via infusion. In a Phase 2 trial conducted in MG, UCB's rozanolixizumab was infused subcutaneously, over 30 minutes, and was observed to reduce mean IgG levels by approximately 56% and approximately 68% after three and six weekly 7 mg/kg infusions, respectively. In December 2021, UCB announced positive topline results from the Phase 3 MycarinG study evaluating rozanolixizumab in adults with gMG. Johnson & Johnson's nipocalimab is in clinical development with a subcutaneous formulation.

In January 2023, the FDA accepted for filing and granted Priority Review UCB's Biologic License Application ("BLA") for rozanolixizumab for the treatment of gMG. In December 2021, the FDA approved VYVGART™ (efgartigimod alfa-fcab) for the treatment of gMG in adult patients who are anti-acetylcholine receptor ("AChR") antibody positive. VYVGART™ is administered intravenously and represents the first-and-only FDA-approved FcRn blocker; and the first approved therapy designed to reduce pathogenic IgGs, an underlying driver of gMG.

Batoclimab and IMVT-1402, if approved, may also face competition from agents with different mechanisms of action. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED. The most commonly prescribed first-line agents for the treatment of MG are acetylcholinesterase inhibitors, such as pyridostigmine, which are marketed by several manufacturers of generic medicines. IVIg is also routinely used for patients with MG. Eculizumab (marketed by AstraZeneca), an antibody inhibitor of the C5 protein, was approved in 2017 for the treatment of generalized MG in patients who are positive for anti-AChR antibodies. Another C5 complement inhibitor, Ultomiris (ravulizumab-cwvz), was approved in April 2022 in the U.S. for the treatment of adult patients with gMG who are anti-AChR antibody-positive. The first line of treatment for TED patients is generally immunosuppressive therapy, including high doses of corticosteroids. Other broad immunosuppressive drugs, such as cyclosporine, cyclophosphamide, mycophenolate mofetil and azathioprine, are used when patients do not respond adequately to corticosteroids. Rituximab (Roche), a monoclonal antibody that binds to an antigen specific to antibody-producing B cells, may also be used as a treatment for TED and other IgG-mediated autoimmune diseases. Johnson & Johnson is developing its hypersialylated IVIg, M254, in a variety of autoimmune indications. Other product candidates in development for the treatment of MG include: zilucoplan (UCB), a peptide inhibitor of C5, and inebilizumab (Horizon Therapeutics), a CD19-targeted humanized monoclonal antibody, both of which are currently in Phase 3 development. In November 2022, UCB announced that its new drug application for zilucoplan for the treatment of gMG in adult patients has been accepted by the FDA.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries could result in even more resources being concentrated among a small number of our competitors.

Accordingly, competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for any of our targeted indications by a competitor could render our product candidates non-competitive or obsolete, or reduce the demand for its product candidate before it can recover its development and commercialization expenses.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for batoclimab, IMVT-1402 and any of our future product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to any products we develop or processes we use may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates.

Following our assumption of all rights, title, interest and obligations under the HanAll Agreement from RSG in December 2018, by virtue of the license of patent rights under the HanAll Agreement, ISG is the exclusive licensee of certain patents, patent applications and know-how directed to batoclimab, IMVT-1402, and certain back-up and next-generation antibodies, and products containing such antibodies, in the licensed territory. As of May 17, 2023, the in-licensed patent portfolio includes a patent family covering batoclimab with pending patent applications and/or issued patent(s) in the U.S., Argentina, Brazil, Canada, Colombia, European Patent Office, Egypt, Israel, Mexico and Saudi Arabia. This in-licensed patent family was filed in 2015 and discloses anti-FcRn antibodies, including batoclimab, pharmaceutical compositions thereof, methods of treating autoimmune disease using the same, polynucleotides encoding such antibodies, expression vectors including such polynucleotides, host cells transfected with such recombinant expression vectors, methods of manufacturing such antibodies and methods of detecting FcRn in vivo or in vitro using such antibodies. Notably, in this in-licensed patent family, a U.S. patent was issued on July 2, 2019, with claims directed to batoclimab as defined by its CDRs and epitope or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof. Furthermore, another U.S. patent was issued in this in-licensed patent family on January 28, 2020, with claims directed to batoclimab as defined by its CDRs or antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of producing such antibody or antigen-binding fragment. A further patent was issued in the U.S. on March 28, 2023 with claims to an isolated anti-FcRn antibody other than batoclimab or an antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of preparing such antibody or antigen-binding fragment. A European patent in this family was issued on May 10, 2023 with claims directed to batoclimab as defined by its heavy and light chain variable sequences. There are also issued patents in this family in Canada, Israel, Mexico, and Saudi Arabia. In this family, applications are pending in Brazil, Argentina, the U.S. and in Europe. The patents of this patent family may expire in 2035, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity, or other governmental fees.

In addition, the in-licensed patent portfolio includes another patent family that discloses a pharmaceutical formulation for an anti-FcRn antibody. This patent family includes pending applications in the U.S., and in Europe, Israel, Canada, Brazil, Mexico and Argentina, and any patent issued in this patent family may expire in 2041, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity, or other governmental fees.

Additionally, as of May 17, 2023, independent of the licensed patent portfolio, ISG owns patent families directed to methods of treating thyroid eye disease (Graves' ophthalmopathy) and methods of treating warm autoimmune hemolytic anemia using anti-FcRn antibodies that include patent applications in the U.S. as well as foreign counterparts in certain jurisdictions. Any patent issued from these patent families may expire in 2039 and 2040, respectively, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity, or other governmental fees.

ISG also has rights to an in-licensed patent family covering IMVT-1402 and its uses to treat autoimmune disease. Three U.S. provisional applications and one Korean application are pending in this family. Any patent issued from this patent family may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity, or other governmental fees.

ISG also owns U.S. provisional patent applications directed to methods of treating Graves' Disease and methods of treating Chronic Inflammatory Demyelinating Polyneuropathy using anti-FcRn antibodies including batoclimab and IMVT-1402. Any patent issued from these patent families may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity, or other governmental fees.

ISG also owns a U.S. provisional application directed to high concentration protein formulations with polysorbate excipients and methods of making the same. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity, or other governmental fees.

In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date, as the term of a patent granted on a utility patent application filed after June 8, 1995 expires 20 years after the non-provisional U.S. filing date (or any earlier filing date relied upon under 35 U.S.C. 120, 121, or 365(c)), with the timely payment of maintenance fees. In certain instances, the patent term may be adjusted to add additional days to compensate for certain delays incurred by the U.S. Patent and Trademark Office ("USPTO") in the examination process, issuing the patent and/or the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the patent extension granted for FDA regulatory review is only applied to a single patent that covers either the product candidate or a method of using or manufacturing the same which has not expired at the time of FDA approval. Additionally, the period of time the patent is extended may not exceed five years, and the total patent term, including the period of time the patent is extended, must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. The protection afforded by a patent with respect to a particular product varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, its coverage, the availability of regulatory-related extensions, the availability of legal remedies in the particular country and the validity and enforceability of the patent under the local laws. ISG owns a trademark for IMMUNOVANT, the corporate logo, and a composite trademark for its corporate logo with the IMMUNOVANT mark. As of May 17, 2023, this trademark portfolio includes pending trademark applications and/or registered trademarks in the U.S. and/or foreign jurisdictions. Under the HanAll Agreement, we have the right to market batoclimab in the Licensed Territory under the trademark(s) of our choice, subject to regulatory approval. However, upon termination of the HanAll Agreement, we must assign to HanAll all rights, title and interest in and to any and all trademarks we use in the development, manufacture or commercialization of the licensed products.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our product candidates or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

Government Regulation

The FDA and other regulatory authorities at federal, state, supranational, national and local levels, including in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we wish to conduct studies or seek approval or licensure of batoclimab, IMVT-1402 or any future product candidate.

FDA Drug Approval Process

In the U.S., the FDA regulates biologics under both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act and their implementing regulations. The process required by the FDA before biologic product candidates may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with applicable regulations and guidance, including the FDA's current Good Laboratory Practices ("GLP") regulations, International Council for Harmonisation ("ICH") guidance, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated at least annually or when significant changes are made;

- approval by an institutional review board ("IRB") or ethics committee for each clinical site before the trial is commenced;

- conduct of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice ("GCP"), and other clinical-trial related regulations and guidance to evaluate the safety, purity and potency of the proposed biologic product candidate for each proposed indication;

- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials that includes manufacturing information and substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;

- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;

- potential FDA audit of selected clinical investigation sites, preclinical studies, and/or Immunovant as clinical trial sponsor to assess compliance with FDA's GCP standards;

- payment of user fees for FDA review of the BLA (unless a fee waiver applies);

- agreement with FDA on the final labeling for the product and the design and implementation of any required Risk Evaluation and Mitigation Strategy ("REMS"); and

- FDA review and approval, or licensure, of the BLA, including satisfactory completion of an FDA Advisory Committee review, if applicable, to permit commercial marketing or sale of the product for particular indications for use in the U.S.

Our product candidates are being developed to be registered as pre-filled syringes and autoinjectors, which means that they are subject to regulation as combination products because they are composed of both a biologic product and device product. If approved and marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, the primary mode of action is attributable to the biologic component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, our product candidates are subject to the IND framework for premarket development and approval through the BLA pathway. Based on our understanding of FDA's combination device expectations, we do not anticipate that the FDA will require a separate medical device authorization for the syringe or autoinjector, but this could change during the course of its review of any marketing application that we may submit.

European Union Drug Approval Process

In the European Union ("E.U."), medicinal products can only be commercialized after a related marketing authorization ("MA"), has been granted. A company may submit a marketing authorization application ("MAA") either on the basis of the centralized, or decentralized procedure or mutual recognition procedure.

To obtain an MA for a product in the E.U., an applicant must submit an MAA either under a centralized procedure administered by the EMA or one of the procedures administered by the competent authorities of E.U. Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the European Economic Area ("EEA") (which is comprised of the 27 Member States of the E.U. plus Norway, Iceland and Liechtenstein). We have focused on the centralized procedure as we expect it to be the relevant procedure for our product candidates.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs"), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

An MA granted through the centralized procedure has, in principle, an initial validity of five years. An MA granted through the centralized procedure may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA. To support the application, the MA holder must provide the EMA with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the E.U. market for a centralized MA within three years after authorization ceases to be valid (the so-called sunset clause).

The E.U. also provides opportunities for market exclusivity. Upon receiving an MA in the E.U., innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization during a period of eight years from the date on which the reference product was first authorized in the E.U. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies.

Our product candidates designed to be delivered to patients by dedicated medical devices, may be subject to E.U. requirements applicable to combination products. In the E.U., products that are a combination of a medicinal product and a medical device are regulated as either a medicinal product or a medical device, depending on which component has the primary mode of action.

Medical devices that incorporate a medicinal product as an integral part that has an action ancillary to the action of the medical device are regulated as medical devices in accordance with Regulation (E.U.) 2017/745 on Medical Devices ("MDR"). However, the quality, safety and usefulness of the medicinal product must also be verified as part of the device and a scientific opinion from a national competent authority of an E.U. Member State or from the EMA, depending on its nature and therapeutic intention, must be sought regarding the quality and safety of the medicinal product, including the benefit or risk of its incorporation into the medical device. Where a medical device incorporates a medicinal product as an integral part as a single use drug delivery system, it is regulated as a medicinal product. In this case, the relevant General Safety and Performance Requirements ("GSPRs") of the MDR will apply to the safety and performance of the device element.

Brexit and the Regulatory Framework in the United Kingdom

Following the result of a referendum in 2016, the United Kingdom ("U.K.") left the E.U. on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the E.U., the U.K. was subject to a transition period until December 31, 2020 (the Transition Period) during which E.U. rules continued to apply. The U.K. and the E.U. have signed a E.U.-U.K. Trade and Cooperation Agreement ("TCA"), which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the U.K. and E.U.'s relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the E.U. and the U.K. in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice ("GMP"), inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extend to procedures such as batch release certification.

Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a "third country," a country that is not a member of the E.U. and whose citizens do not enjoy the E.U. right to free movement. Northern Ireland will continue to follow many aspects of the E.U. regulatory rules, particularly in relation to trade in goods. As part of the TCA, the E.U. and the U.K. will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The U.K. has unilaterally agreed to accept E.U. batch testing and batch release However, the E.U. continues to apply E.U. laws that require batch testing and batch release to take place in the E.U. territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the E.U. market for commercial use.

As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the U.K. Since this date, companies established in the U.K. cannot use the centralized procedure and instead must follow one of the U.K. national authorization procedures to obtain an MA to market products in the U.K.

The U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") offers new assessment procedures for marketing authorization applications for medicinal products. The procedures may lead to a marketing authorization in Great Britain (England, Scotland, and Wales), the United Kingdom, or Northern Ireland, depending on the procedure which is undertaken. The new marketing authorization application assessment procedures include:

- The European Commission Decision Reliance Procedure. Until 31 December 2023, the MHRA may rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in E.U. Member States through decentralized and mutual recognition procedures to be granted in the U.K. or Great Britain. MHRA aims to review such applications, including the entire dossier as reviewed by the CHMP, within 67 days. Should that review be successful, it will lead to the grant of a marketing authorization in Great Britain;

- National marketing authorization applications. The MHRA offers a timeline of no more than 150 days (excluding clock-stop periods where further information is requested) for the assessment of national applications for the marketing authorization of a medicinal product in the U.K., Great Britain or Northern Ireland;

- The Unfettered Access Procedure, which permits holders of a valid marketing authorization in Northern Ireland, obtained via the E.U. marketing authorization procedures or via the Northern Ireland national route, to submit an application to seek recognition of such existing marketing authorization in Great Britain; and

- The 'rolling review' route, which allows companies to make an application in stages, throughout the product's development, rather than as a consolidated full dossier submission. This route is available for new active substances in the U.K., Great Britain or Northern Ireland or for similar biological medicinal products in Great Britain.

Nonclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the U.S., we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The IND includes the clinical protocols and general development plan, as well as results of animal and in vitro studies assessing the toxicology, PK, pharmacology and PD characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions. In such a case, the IND may be placed on clinical hold until the IND sponsor and the FDA resolve the outstanding concerns or questions. The FDA also may impose clinical holds at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Submission of an IND therefore does not guarantee that FDA authorization to begin a clinical trial will be granted or that, once begun, issues will not arise that adversely impact, suspend or terminate such studies.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments and additional information such as toxicology or Chemistry, Manufacturing and Controls ("CMC") data in support of the investigational product(s). For new indications, a separate new IND is usually required. Outside of the U.S., clinical trial applications are generally required to conduct clinical studies in each country. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or independent data monitoring committee, which provides direction for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an

unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Information about most clinical trials must be submitted within specific timeframes for publication on the *www.clinicaltrials.gov* website. For purposes of BLA/MAA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, tolerability, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on pharmacodynamics and effectiveness.
- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple global clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to support chronic use of a product during marketing.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA or, in certain circumstances, mandated after approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting or in some cases to support full approval for products that are approved via an accelerated pathway as described below. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA, and IND safety reports must be submitted to the FDA, other regulators, and investigators within a regulated timeframe for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure or adverse events reported by anti-FcRn product candidates developed by others.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. The FDA may require such testing to occur on a lot-by-lot basis in order to release product for clinical use. 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.

BLA Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other information. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies. There can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Once a BLA has been submitted, the FDA reviews the BLA within 60 days to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the FDA does not always meet PDUFA goal dates, and the review process can be significantly extended by FDA requests for additional information or clarification or Company submissions of substantial data during the review. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions with emphasis on risk and benefit of the molecule and proposed indications, and provide 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. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites, preclinical studies, and/or the sponsor to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, and where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter prior to inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, completion of other significant and time-consuming requirements related to clinical trials, and/or conduct of additional preclinical studies or manufacturing activities. Even if such data and information are submitted, the FDA may determine that the BLA does not satisfy the criteria for approval. FDA approval of a BLA must be obtained before a biologic may be marketed in the U.S. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied and may require additional clinical testing or safety information.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed, which could limit the commercial value of the product. For example, the FDA may approve the BLA with a REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product, and could include medication guides, healthcare professional and/or patient communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA will evaluate if any labeling or risk management plans are necessary to ensure safe use of the product in the targeted patient population and indication. Once approved, the FDA has the authority to withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may impose post-marketing requirements and commitments such as additional manufacturing data or testing; additional preclinical data or evaluation; additional clinical data from Phase 3 studies (e.g. long-term extension data); and may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs and other Marketing Authorization Procedures

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy and accelerated approval.

A product is eligible for priority review if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Priority review designation means the FDA's goal under PDUFA is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review). To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation is intended to facilitate development and expedite review of a product, and also provides opportunities for frequent interactions with the FDA review team. The FDA may also review complete sections of the BLA for a fast track product on a rolling basis before the entire application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA. The review clock generally does not begin until the final section of the BLA is submitted.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA will take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a validated surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than survival or irreversible morbidity and is reasonably likely to predict an effect on survival, irreversible morbidity or another clinical benefit. As a condition of accelerated approval, the FDA requires the sponsor to perform adequate and well-controlled post-marketing confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Approval may be withdrawn if the confirmatory study does not verify the anticipated clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which the sponsor must plan to provide all commercial materials and seek approval prior to the launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review and approval will not be shortened. Furthermore, priority review, fast track designation, breakthrough therapy designation, and accelerated approval do not change the standards for approval and may not ultimately expedite the development or approval process.

In the E.U., innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME"), scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the E.U. or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the E.U., a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or automatically shorten the duration of, the regulatory review or approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Orphan exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee. A designated orphan product may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

In the E.U., Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the E.U. when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the E.U. to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the E.U., or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Following the U.K.'s departure from the E.U. there is no pre-marketing authorization orphan designation in Great Britain. Instead, orphan designation is applied for at the same time as applying for a marketing authorization. While the criteria to be granted an orphan medicinal product designation remain effectively the same in Great Britain as in the European Union, the designation will be based on the prevalence of the relevant condition in Great Britain. It is therefore possible that conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not or would not have been designated as orphan conditions in the E.U. will be designated as such in Great Britain. The U.K. legislation offers similar market exclusivity conditions for medicinal products with an orphan designation. However, U.K.-wide marketing authorization applications including orphan designation can only be submitted if there is no active orphan designation granted in the E.U.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FDASIA amended the FDCA to require that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs.

Under the Best Pharmaceuticals for Children Act ("BPCA"), a drug or biologic product can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study or studies in accordance with an FDA-issued "Written Request" for such a study or studies within a defined timeframe.

In the E.U., Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all E.U. Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC"), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity. For other countries outside of the E.U., such as certain countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market or product recalls;

- fines, warnings or untitled letters or holds on post-approval clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the FDA to permit the import or export of products; or

- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and misbranding. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including monetary penalties. Physicians may prescribe, in their independent medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication (or thirty days in advance of their first use if approved via the accelerated approval pathway). Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

Where an MA is granted in relation to a medicinal product in the E.U., the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the U.S., both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual E.U. Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the E.U., the advertising and promotion of medicinal products are subject to both E.U. and E.U. Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under E.U. legislation, the details are governed by regulations in individual E.U. Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the E.U. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the E.U.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act ("Affordable Care Act") signed into law in 2010 includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe, but no interchangeable biologic has been approved in the U.S. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

In the E.U., there is a special regime for biosimilars, or biological medicinal products that are similar to an approved reference medicinal product but that do not meet the definition of a generic medicinal product owing to in particular differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal. Biosimilars are approved in accordance with the same quality, safety and efficacy standards which apply to biological medicinal products. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization, including comparative clinical and non-clinical studies with the reference biological medicinal product to demonstrate that the biosimilar is both highly similar to the reference product (notwithstanding natural variability inherent to all biological medicines) and that there are no clinically meaningful differences between the biosimilar and the reference medicine in terms of safety, quality, and efficacy. However, the biosimilar manufacturer is not required to replicate the testing results or trial data contained in the dossier of the reference biological medicinal product. Guidelines from the EMA detail the type of quantity of supplementary data that must be provided to support authorization of different types of biological product.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., our current and future operations are subject to regulation and oversight by various federal, state and local authorities in addition to the FDA, including but not limited to, Centers for Medicare & Medicaid Services ("CMS") or other divisions of the U.S. Department of Health and Human Services ("HHS") (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments and regulatory authorities. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar state laws, each as amended, as applicable. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may be subject to healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and transparency, and physician sunshine laws. Some of our pre-commercial activities are subject to certain of these laws.

The federal Anti-Kickback Statute 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 the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and, for example, prescribers, purchasers, third party payors, pharmacies, and pharmacy benefit managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from the reach of the Anti-Kickback Statute. The exceptions and safe harbors are interpreted narrowly by enforcement authorities, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending any product payable by the federal health care programs 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 statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, where an arrangement does not clearly meet the terms of an applicable exception or safe harbor, the legality of the arrangement will be evaluated on a case-by-case basis based on prudential factors that authorities, including the HHS of Inspector General, utilize to determine whether a particular arrangement poses a risk of fraud and abuse to the federal health care programs (e.g., increasing costs to government payors). Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor, and we cannot rule out the possibility that enforcement authorities, including the Office of Inspector General, could scrutinize our practices in the future.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act 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. Violations of the Anti-Kickback Statute can result in significant civil and criminal fines and penalties, imprisonment, and exclusion from federal healthcare programs. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act ("FCA") (discussed below).

The federal false claims laws, including the FCA, which can be enforced by private citizens through civil whistleblower or "qui tam" actions, and the Civil Monetary Penalties Law, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, 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 knowingly making a false statement to improperly avoid, decrease or conceal 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. Pharmaceutical and other healthcare companies have been, and continue to be, prosecuted under these laws, among other things, for various conduct. For example, enforcement has pursued manufacturers allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product, and also for causing false claims to be submitted because of the marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, 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 money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes that were added by HIPAA 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.

If we were to enter into a "business associate" relationship with a "covered entity" ("covered entities" being group health plans, certain healthcare providers, and "healthcare s") or other "business associates", we would be subject to the HHS regulations related to data privacy, security and security breach notification under the Administrative Simplification provisions of HIPAA (Title II, Subtitle F of HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Those regulations authorize the imposition of civil and criminal penalties, damages, injunctions, attorneys' fees and costs. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act") within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor (i.e., are not exclusive to government payors). We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts.

We are subject to the Federal Drug Supply Chain Security Act ("DSCSA") enacted by the U.S. government, which requires development of an electronic pedigree to track and trace each prescription biologic at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period from its enactment on November 27, 2013. In addition, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution. Compliance with DSCSA and current and future U.S. federal or state electronic pedigree requirements could require significant capital expenditures, increase our operating costs and impose significant administrative burdens. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Additionally, to the extent that we have business operations in foreign countries, sell any of our products in foreign countries and jurisdictions, or engage with physicians from other countries, including Canada or the E.U., we may be subject to additional, comparable, regulation.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and results of operations.

Privacy, Data Protection and Information Security

Because our business involves the collection, use, storage, and transmission of personal information, we are subject to numerous federal, state, local and foreign laws, regulations, and other obligations relating to privacy, data protection, and information security. Such laws may include Section 5(a) of the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, the California Privacy Rights Act of 2020, the California Online Privacy Protection Act, the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the E.U. GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), and the European Union's ePrivacy Directive. Countries around the world have adopted or are proposing similar laws and regulations relating to privacy, data protection, and information security, and we may become subject to them as we expand our operations into new geographic markets.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which Immunovant may obtain regulatory approval. In the U.S. and in foreign markets, sales of any products for which Immunovant receives regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, which decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

We may develop products that, once approved, may be administered by a physician, and these products also may have difficulty obtaining coverage and adequate reimbursement levels based on payor cost sensitivities and the potential application of formulary management controls (e.g., step edits through alternative therapies). Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to closely evaluating their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult given the potential cost sensitivities often associated with branded drugs and drugs administered under the supervision of a physician. It is not clear that third party payors will accept the pharmacoeconomic benefits of products that we commercialize, and we also may need to undertake detailed studies of any therapies that we commercialize in order to demonstrate their pharmacoeconomic benefits, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective for certain patients, including depending on the nature of the FDA approvals that we may receive. There is no assurance of coverage or adequate reimbursement for our products under either government programs or from commercial payors. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. 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 product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the E.U., pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Other countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, some E.U. Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other E.U. Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many E.U. Member States have increased the amount of discounts that pharmaceutical companies are required to offer. These efforts could continue as countries attempt to manage healthcare expenditures. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products onto national markets. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E.U. Member States, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices.

In addition, some EEA countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual E.U. Member States. In December 2021, the E.U. HTA Regulation was adopted. The purpose of the Regulation is to introduce joint clinical assessments at E.U. level. When it enters into application in 2025 the Regulation will be intended to harmonize the clinical benefit assessment of HTA across the European Union.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the U.S. has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become a close focus of government and state regulators. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement rates are attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future, which could have a downward pressure on our commercialization efforts.

Healthcare Reform

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23% and 13% of the Average Manufacturer Price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- requirements to report certain financial arrangements with certain healthcare providers and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow on biologic products.

Since its enactment, there have been legal and political challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Cuts and Jobs Act of 2017 ("TCJA") included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. It is unclear how any future challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is also unclear.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2032 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, presidential executive orders and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare and other government 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 being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

The Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("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 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. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us 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.

Additional Regulation

In addition to the foregoing, state and federal laws regarding safe working conditions, environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Human Capital

Our Vision and Culture

We are driven by our vision of enabling normal lives for patients with autoimmune diseases. We champion an environment where all feel a sense of belonging by promoting a creative and collaborative workplace that leads to genuine connection and innovation. As a diverse workforce, we are committed to inclusion and equity across race, gender, age, religion, physical ability, identity, sexual orientation, and experience. Together, our vision and strength as a team are driven by our values focused on accountability to patients, constantly adapting to drive toward our vision and inviting all voices to bring powerful ideas to life. We believe if our employees are well aligned with our values and culture, they will be highly engaged, which will support their performance and impact on the organization.

Employees

As of March 31, 2023, we had 164 full-time permanent employees, primarily in the U.S. Of these employees, approximately 70% have advanced degrees including but not limited to Ph.D., M.D., and M.B.A., and approximately 82% were engaged in research and development activities. More than half of our workforce, as well as our senior management team, is comprised of women. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we have not had any work stoppages. We believe our relationship with our employees is good.

As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing, reimbursement and distribution. In addition, we also expect to hire additional personnel in order to sustain operations as a public company.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our equity incentive plan is to attract, retain, and motivate our employees, non-employee directors, and consultants through the granting of stock-based compensation and performance cash awards. Our cash bonus awards are based on Company and departmental progress toward key annual goals and employee performance.

Available Information

Our website is www.immunovant.com. We are subject to the informational requirements of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and file or furnish reports, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act, proxy statements and other information with the U.S. Securities and Exchange Commission (the "SEC"). We make copies of these reports and other information available free of charge through our website as soon as reasonably practicable after we file or furnish them with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information contained on the websites referenced in this Annual Report is not incorporated by reference into this filing, and the website addresses are provided only as inactive textual references.

Item 1A. Risk Factors

Our business involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report, including our consolidated financial statements and the related notes appearing elsewhere in this Annual Report. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows and, if so, our future prospects would likely be materially and adversely affected. If any of such events were to happen, the trading price of shares of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Development, Regulatory Approval and Commercialization

Our business is currently dependent on the successful and timely development, regulatory approval and commercialization of our product candidates, batoclimab and IMVT-1402.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that our primary efforts and expenditures over the next few years will be devoted to the advancement of batoclimab and IMVT-1402. Accordingly, our business currently depends on the successful completion of our clinical trials for batoclimab and IMVT-1402 and subsequent regulatory approval and commercialization of these product candidates, which is uncertain. Delays or failures in the clinical trials for batoclimab or IMVT-1402, for example due to the voluntary pause of our batoclimab clinical trials announced in February 2021 and resulting inconclusive study results, have and could in the future significantly impact and harm our business. See "*Risks Related to Development, Regulatory Approval and Commercialization – Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes*."

We cannot be certain that batoclimab or IMVT-1402 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, packaging, approval, sale, marketing, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping of pharmaceutical products, including antibody-based products, are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries which may vary from one country to another. We are not permitted to market our product candidates in the U.S. until we receive approval of a BLA or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries for marketing authorization. In addition, we have not yet demonstrated our ability to complete later-stage or pivotal clinical trials for our product candidates. We have not submitted a BLA for batoclimab or IMVT-1402 to the FDA or any comparable application to any other foreign regulatory authority. Obtaining approval of a BLA or similar foreign regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of batoclimab or IMVT-1402 for many reasons, including:

- we may not be able to demonstrate that our product candidates are safe and effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant foreign regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant foreign regulatory authorities for marketing approval;
- the FDA or other relevant foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our clinical trials of batoclimab for the treatment of MG, TED, CIDP and GD and IMVT-1402;
- the CROs that we retain to conduct clinical trials may take actions outside of our control or otherwise commit errors or breaches of protocols that materially adversely impact our clinical trials and ability to obtain market approvals;
- the FDA or other relevant foreign regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of our product candidates outweigh its safety risks;
- the FDA or other relevant foreign regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of our product candidates or may require additional studies;
- the FDA or other relevant foreign regulatory authorities may not accept data generated from our clinical trial sites;
- if our BLA or other foreign application is reviewed by an advisory committee, the FDA or other relevant foreign regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA or other relevant foreign regulatory authorities may require development of a REMS or similar strategy imposed by foreign regulatory authorities, as a condition of approval;
- the FDA or other relevant foreign regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant foreign regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidate;
- the FDA or other relevant foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant foreign regulatory authorities may change their approval policies or adopt new regulations.

Even if we do receive regulatory approval to market batoclimab or IMVT-1402, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market batoclimab or IMVT-1402. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized.

In addition, if our product candidates encounter safety or efficacy problems, such as the observed lipid findings from our clinical trials of batoclimab, developmental delays, regulatory issues, supply issues, or other problems in one of our target indications, our development plans for our product candidates could be significantly harmed in other indications, which would have a material adverse effect on our business. Further, competitors who are developing product candidates in the autoimmune disease field, including IgG-mediated autoimmune indications, or that target the same indications or use the same mechanism of action as us may experience problems with their product candidates that could suggest problems with our product candidates that would potentially harm our business.

Our product candidates, or anti-FcRn product candidates developed by others, may cause adverse events or undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to further suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

Adverse events ("AEs") or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, European Commission, or other competent regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics. In addition, AEs or undesirable side effects caused by related product candidates or anti-FcRn product candidates developed by others could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, European Commission, or other competent regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics.

If unacceptable AEs or side effects arise in the development of our or others' anti-FcRn product candidates, we, other reviewing entities, clinical trial sites or regulatory authorities could suspend, vary or terminate our clinical trials or the regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. If an unacceptable frequency or severity of AEs or new safety signals are reported in our or others' anti-FcRn clinical trials, our ability to obtain regulatory approval may be negatively impacted. Treatment-related side effects arising from, or those potentially arising from, our product candidates or those from other companies targeting similar autoimmune indications or using the same mechanism of action could affect the design of clinical studies, target patient population, enrollment and conduct of the studies, patient recruitment or the ability of enrolled patients to complete our clinical trials, eventual labeling and risk management, or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

For example, AEs associated with batoclimab in our clinical trials previously caused us to pause dosing in our clinical trials of batoclimab. The most commonly reported AE in our Phase 1 clinical trial was mild erythema and swelling at the injection site, which typically resolved within hours. We voluntarily paused dosing in our early phase clinical studies of batoclimab to evaluate treatment-induced elevations in total cholesterol and LDL levels observed in some trial subjects. After evaluation of the available safety data and following discussions with multiple regulatory authorities, we are continuing our clinical development of batoclimab. While we do not expect that increases in LDL over a short-term treatment duration would pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab at higher doses will need to incorporate any potential unfavorable effects on lipid profiles. In addition, protocols that contain long-term treatment extensions will likely include protocol-directed guidelines for the management of any observed lipid abnormalities. These occurrences have harmed, and any reoccurrences may continue to harm, our business, financial condition and prospects.

Furthermore, it is possible we will not be able to agree upon sufficient risk mitigation with all regulatory authorities and that our development of our product candidates will not continue in certain countries or for certain indications. Even if we are able to continue clinical development of our product candidates with such risk mitigations, any future approval and marketing would suffer from the risks of potential AEs or side effects and potential impact of mitigating measures, including, among others, limited indication, monitoring, a Risk Evaluation and Mitigation Strategy ("REMS") or similar strategy imposed by foreign regulatory authorities, potential additional safety studies and other adverse labeling.

If any of our product candidates is approved and then causes serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, vary or limit their approval of the product or require a REMS (or similar strategy imposed by foreign regulatory authorities) to impose restrictions on the product's distribution or require other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the distribution or marketing of the particular product or the manufacturing processes for the product or any component thereof, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, require other labeling changes or require field alerts or other communications to physicians, pharmacies or the public;
- we may be required to change the way the product is administered or distributed, conduct additional clinical trials, change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we may be required to repeat a nonclinical study or clinical trial or terminate a program, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we may be sued and held liable for harm caused to patients, or may be subject to fines, restitution or disgorgement of profits or revenues;
- physicians may stop prescribing the product;
- reimbursement may not be available for the product;
- we may elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing such product candidate, if approved.

Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.

Batoclimab and IMVT-1402 are still in clinical development and will require extensive clinical testing before we are prepared to submit a biologics license application ("BLA") or other similar application for regulatory approval. We cannot provide you any assurance that we will submit a BLA for regulatory approval for our product candidates within our projected timeframes or whether any such application will be approved by the relevant regulatory authorities. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other foreign regulatory authorities may not agree with our proposed analysis plans or trial design for any clinical trials for our product candidates; during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of a BLA or similar foreign regulatory application. The FDA or a foreign regulatory authority may also find that the benefits of our product candidates in any of our target indications do not outweigh its risks, including the risks associated with elevated lipid levels and lower albumin levels, in a manner sufficient to grant regulatory approval. The clinical trial process is also time-consuming and costly and relies on the collaboration with many contract research organizations ("CROs") and clinical trial sites.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation delaying the next stage of clinical development or submission of a BLA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit negative safety signals in later stage clinical trials that they did not exhibit in nonclinical or earlier-stage clinical trials. A number of companies in the pharmaceutical industry, including biotechnology and biopharmaceutical companies, have suffered significant setbacks in or the discontinuation of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Likewise, the results of early nonclinical studies and clinical trials of our product candidates, some of which were not conducted by us, may not be predictive of the results of our planned development programs and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

If we fail to successfully complete our clinical trials of our product candidates and demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates our business, financial condition and prospects would be harmed. The commencement and completion of clinical trials may be delayed by several factors, including:

- failure to obtain regulatory authorization to commence a clinical trial or reach a consensus with regulatory authorities regarding the design or implementation of our studies;
- unforeseen safety issues or subjects experiencing severe or unexpected AEs;
- continuation of previously identified safety issues, despite our program-wide safety strategy to characterize the safety profile of batoclimab in response to the previously reported change in albumin and lipids;
- occurrence of AEs in trials of the same class of agents conducted by other sponsors or AEs reported by anti-FcRn product candidates developed by others;
- lack of effectiveness during clinical trials;
- resolving any dosing issues or limitations, including those raised by the FDA or other foreign regulatory authorities;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to add a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other foreign regulatory authorities;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;
- an institutional review board (“IRB”), refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- ethics committees issuing negative opinions regarding a clinical trial or requiring substantial modifications of a proposed clinical trial;
- premature discontinuation of study participants from clinical trials or missing data at a level that impacts study integrity;
- failure to manufacture or release sufficient quantities of our product candidates or placebo or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our and global quality standards for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

In addition, we, the FDA or another foreign regulatory authority may suspend our clinical trials in an entire country at any time, or an IRB may suspend its clinical trial sites within any country, if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including good clinical practice ("GCP"), or that we are exposing participants to unacceptable health risks, or if the FDA or other foreign regulatory authority, as the case may be, finds deficiencies in our investigational new drug application ("IND") or equivalent applications for other countries or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from our product candidates, if approved, may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional nonclinical or clinical studies to bridge our modified product candidate to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, which could impact the commercial viability of our product candidates.

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

In addition, the FDA's, the competent authorities of the E.U. Member States', the EMA's, the European Commission's and other comparable regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the E.U. recently evolved. The E.U. Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the E.U. Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each E.U. Member State, leading to a single decision for each E.U. Member State. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all E.U. Member States concerned, and a separate assessment by each E.U. Member State with respect to specific requirements related to its own territory, including ethics rules. Each E.U. Member State's decision is communicated to the sponsor via the centralized E.U. portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose clinical trial application was made on the basis of the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In light of the entry into application of the CTR on 31 January 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR will be required for clinical trials which will have at least one site active in the E.U. on 30 January 2025. A transitioning application would need to be submitted to the competent authorities of E.U. Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past 30 January 2025. This would require financial, technical and human resources. If we are unable to transition our clinical trials in time, the conduct of those clinical trials may be negatively impacted.

It is currently unclear to what extent the U.K. will seek to align its regulations with the E.U. The U.K. regulatory framework in relation to clinical trials is derived from existing E.U. legislation (as implemented into U.K. law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove most E.U.-derived legislation from the U.K. statute book by the end of 2023, may result in a divergence of approach between the E.U. and the U.K.

On January 17, 2022, the U.K. Medicines and Healthcare products Regulatory Agency launched an eight-week consultation on reframing the U.K. legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the U.K. chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the U.K. not to closely align its regulations with the new approach that will be adopted in the E.U. may have an effect on the cost of conducting clinical trials in the U.K. as opposed to other countries and/or make it harder to seek a marketing authorization in the E.U. for our product candidates on the basis of clinical trials conducted in the U.K.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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

We may encounter delays or difficulties in enrolling or be unable to enroll a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate or be stopped, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials for MG, TED, CIDP and GD due to existing alternative treatments available, including teprotumumab for the treatment of TED, IVIg, plasma exchange and steroids for CIDP and anti-thyroid drugs for GD, as patients may decline to enroll or decide to withdraw from our clinical trials due to the risk of receiving placebo.

Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents and our ability to successfully complete prerequisite studies before enrolling certain patient populations. Our product candidates are focused in part on addressing rare autoimmune indications, and we have focused our initial development efforts on the treatment of MG, TED, CIDP and GD with limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner, and could be faced with limited patient pools as we pursue other indications.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients once a paused clinical trial has been resumed. For example, in February 2021, we reported that we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some patients treated with batoclimab. These results may make it more difficult to recruit and retain patients for clinical trials in the future, including our ongoing and planned trials of batoclimab in MG, TED, CIDP and GD and IMVT-1402. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

The results of our nonclinical and clinical trials may not support our proposed claims for our product candidates, or regulatory approval on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior nonclinical testing and clinical trials. In addition, preclinical testing may not adequately uncover drug side effects. In particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our Phase 1 and Phase 2 clinical trials of batoclimab will be observed in any future clinical trials. Likewise, positive results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and lack statistical significance, which further limits the reliability of such data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after positive results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings observed while clinical trials were underway and safety or efficacy observations in clinical trials.

As previously disclosed, we voluntarily paused dosing in our early phase clinical studies of batoclimab to evaluate treatment-induced elevations in total cholesterol and LDL levels observed in some trial subjects. Our failure to successfully complete our clinical trials of batoclimab and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market batoclimab would significantly harm our business.

Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon the indication. Any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our expectations for differentiation or the effectiveness or safety of our product candidates. The FDA has substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we propose. In addition, only a small percentage of biologics under development result in the submission of a BLA to the FDA, or other similar applications with other relevant foreign regulatory authorities, and even fewer are approved for commercialization.

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

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular 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 top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line 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, top-line data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of shares of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize batoclimab, IMVT-1402 or any future product candidate, our business, operating results, prospects or financial condition may be harmed.

We may not be able to successfully develop and commercialize our product candidates on a timely basis or at all.

Our product candidates, batoclimab and IMVT-1402, are novel therapeutic antibodies and their potential therapeutic benefits are unproven. While results from animal studies of IMVT-1402 show potentially clinically meaningful reductions in IgG with minimal or no impact on levels of albumin and LDL and early clinical trials of batoclimab have shown meaningful reductions in IgG antibody levels in healthy volunteers and patients, batoclimab and/or IMVT-1402 may not demonstrate in patients any or all of the pharmacologic or clinical benefits we believe they may possess. IMVT-1402 has shown positive data in an exploratory study in cynomolgus monkeys, but these results may not translate to people. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for our product candidates in large-scale, pivotal clinical trials or in obtaining marketing approval thereafter for any indication. Results from our early-stage clinical trials are not necessarily predictive of the results of our planned clinical trials. If results from our Phase 1 and Phase 2 clinical trials cannot be replicated, or if the increase in total cholesterol and LDL levels or total albumin reductions observed in our Phase 2 clinical trial of batoclimab cannot be mitigated, we may be unable to successfully develop, obtain regulatory approval for and commercialize batoclimab for the treatment of MG, TED, CIDP and GD or any other autoimmune indication. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize our product candidates, raise capital, expand our business or continue our operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize batoclimab, IMVT-1402 or any future product candidate, and our ability to generate product revenue will be impaired.

Batoclimab, IMVT-1402 and any future product candidate that we may develop, as well as the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by similar regulatory authorities outside the U.S. Failure to obtain marketing approval for, and thus commercialize any product candidate, could negatively impact our ability to generate any revenue from product sales.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that our product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor any collaborator is permitted to market our product candidates in the U.S. or any other jurisdiction until we receive regulatory approval of a BLA from the FDA or similar approval from comparable regulatory authorities outside of the U.S.

The time required to obtain approval of a BLA by the FDA or similar approval from comparable regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authority. Prior to submitting a BLA to the FDA or any comparable application to any other foreign regulatory authorities for approval of any product candidate, we will need to complete pivotal Phase 3 clinical trials to demonstrate favorable results with respect to safety, tolerability and efficacy. In addition, approval policies, regulations, or the type and amount of clinical data necessary to obtain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Securing marketing approvals requires the submission of extensive manufacturing, nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of our product candidates for the specified indications. We expect to rely on third-party CROs, consultants and our collaborators to assist us in filing and supporting the applications necessary to obtain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approval, commercialize our product candidates and generate product revenue.

Batoclimab and IMVT-1402 are antibody proteins that could cause an immune response in patients, resulting in the creation of harmful or neutralizing antibodies against these therapeutic proteins, preventing or limiting regulatory approval or our ability to commercialize our product candidates.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of proteins such as monoclonal antibodies, even those that are fully human in nature, including our product candidate, can cause an immune response, resulting in the creation of antibodies directed against the therapeutic protein. These anti-drug antibodies can have no effect or can neutralize the effectiveness of the protein or require that higher doses be used to obtain a therapeutic effect. Whether anti-drug antibodies will be created and how they react can often not be predicted from nonclinical studies or clinical trials and their detection or appearance is often delayed. As a result, neutralizing antibodies may be detected at a later date or upon longer exposure periods, such as following more chronic administration in longer lasting clinical trials. In some cases, detection of neutralizing antibodies can even occur after pivotal clinical trials have been completed. Therefore, there can be no assurance that neutralizing antibodies will not be detected in future clinical trials or at a later date upon longer exposure (including after commercialization). If anti-drug antibodies reduce or neutralize the effectiveness of any of our product candidates, the continued clinical development or receipt of marketing approval for such product candidate could be delayed or prevented and, even if such product candidate is approved, its commercial success could be limited, any of which would impair our ability to generate revenue and continue operations.

We have in-licensed the rights to batoclimab and IMVT-1402 in limited territories. Any adverse developments that occur during any clinical trials or manufacturing conducted by third parties, including HanAll, in other jurisdictions may affect our ability to obtain regulatory approval or commercialize our product candidates.

We have in-licensed the right to develop, manufacture and commercialize batoclimab and certain back-up and next-generation antibodies (including IMVT-1402) in the Licensed Territory. HanAll or any of its sublicensees or collaborators, over which we have no control, has the right to develop, manufacture and commercialize these product candidates in geographies outside of our Licensed Territory. If an impact to the characterization of the safety profile occurs in studies conducted by HanAll or third parties in other jurisdictions outside of our Licensed Territory, the FDA or other foreign regulatory authorities may delay, limit or deny approval of these product candidates or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs and time to market. If we receive FDA or foreign regulatory authority approval for batoclimab or IMVT-1402 and a new or serious safety issue is identified in connection with clinical trials conducted by third parties in other jurisdictions outside of our Licensed Territory, the FDA or foreign regulatory authority may withdraw or vary their approval or restrict our ability to market and sell our products or may require additional testing or evaluation. In addition, treating physicians may be less willing to administer our product candidates due to concerns over such AEs, which would limit our ability to successfully commercialize these product candidates. In addition, issues may arise in connection with the manufacturing process for batoclimab or IMVT-1402 utilized by HanAll or any of its sublicensees or collaborators, which could affect our ability to obtain regulatory approval for or commercialize these product candidates.

We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune disease indications. Our operating results will suffer if we fail to compete effectively.

The markets for autoimmune disease therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for our targeted autoimmune disease indications, including MG, TED, CIDP and GD. We anticipate that, if we obtain regulatory approval of any of our product candidates, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target indications. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Even if a biosimilar product is less effective than our product candidates, a less effective biosimilar may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience. Our product candidates, if approved, are expected to present a novel therapeutic approach for MG, TED, CIDP and GD and other targeted indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our product candidates, if approved, provide an attractive alternative to existing and other new therapies to gain a share of some patients' discretionary budgets and to gain physicians' attention within their clinical practices. Some of the companies that may offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

We expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases, including multiple agents which are in the same class as batoclimab or IMVT-1402. We are aware of several FcRn inhibitors that are in clinical development. These include, efgartigimod (argenx SE), nipocalimab (Johnson & Johnson) and rozanolixizumab (UCB). In January 2023, the FDA accepted for filing and granted Priority Review UCB's Biologic License Application ("BLA") for rozanolixizumab for the treatment of gMG. In December 2021, the FDA approved VYVGART™ (efgartigimod alfa-fcab) for the treatment of gMG in adults who test positive for the anti-acetylcholine receptor ("AChR") antibody. VYVGART™ represents the first-and-only FDA-approved FcRn blocker, and the first approved therapy designed to reduce pathogenic IgGs, an underlying driver of gMG.

We also expect to face competition from agents with different mechanisms of action. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED. The most commonly prescribed first-line agents for the treatment of MG are acetylcholinesterase inhibitors, such as pyridostigmine, which are marketed by several manufacturers of generic medicines. IVIg is also routinely used for patients with MG. Eculizumab (marketed by AstraZeneca), an antibody inhibitor of the C5 protein, was approved in 2017 for the treatment of gMG in patients who are positive for anti-AChR antibodies. Another C5 complement inhibitor,
Ultomiris (ravulizumab-cwvz), was approved in April 2022 in the U.S. for the treatment of adult patients with gMG who are anti-AChR antibody-positive. The first line of treatment for patients with TED is generally immunosuppressive therapy, including high doses of corticosteroids. Other broad immunosuppressive drugs, such as cyclosporine, cyclophosphamide, mycophenolate mofetil and azathioprine, are used when patients do not respond adequately to corticosteroids. Rituximab (Roche), a monoclonal antibody that binds to an antigen specific to antibody-producing B cells, may also be used as a treatment for TED and other IgG-mediated autoimmune diseases. Johnson & Johnson is developing its hypersialylated IVIg, M254, in a variety of autoimmune indications. Other product candidates in development for the treatment of MG include zilucoplan (UCB), a peptide inhibitor of C5, and inebilizumab (Horizon Therapeutics), a CD19-targeted humanized monoclonal antibody, both of which are currently in Phase 3 development. In November 2022, UCB announced that its new drug application for zilucoplan for the treatment of gMG in adult patients has been accepted by the FDA.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. In December 2022, Amgen agreed to acquire Horizon Therapeutics for approximately $27.8 billion, expanding its rare disease pipeline. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Due to varying regulatory requirements in certain foreign countries, there are many more products and procedures available for use to treat autoimmune diseases in some international markets than are approved for use in the U.S. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market their products. As a result, we expect to face more competition in these markets than in the U.S.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies in our target indications that are superior to other products in the market;
- demonstrate through our clinical trials that batoclimab, IMVT-1402 or any future product candidate is differentiated from existing and future therapies;
- attract qualified scientific, product development, manufacturing and commercial personnel;
- obtain patent or other proprietary protection for batoclimab, IMVT-1402 and any future product candidates;
- obtain required regulatory approvals, including approvals to market batoclimab, IMVT-1402 or any future product candidate we develop, in ways that are differentiated from existing and future products and treatments;
- have commercial quantities of any approved product manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- successfully commercialize batoclimab, IMVT-1402 or any future product candidate, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors;

- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies; and
- avoid regulatory exclusivities or patents held by competitors that may inhibit our products' entry to the market.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced treatments would have an adverse impact on our business, financial condition and prospects.

Additional time may be required to obtain marketing authorizations for pre-filled syringe presentations of batoclimab or IMVT-1402 because it would be subject to regulation as a combination product.

Combination products are therapeutic and diagnostic products that combine drugs, devices and/or biological products. A pre-filled syringe or autoinjector presentation of our product candidates would be considered a combination product that requires coordination within the FDA and in similar foreign regulatory authorities for review of its device and biologic components. Although the FDA and similar foreign regulatory authorities have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of these product candidates due to uncertainties in the product development and approval process.

In the E.U., combination products are not subject to a single regulatory pathway. Products combining a medical device and a medicinal product are either regulated as a medicinal product or a medical device depending on which product has the primary mode of action. Alternatively, they can be regulated by two separate procedures, with elements regulated as a medicinal product and elements as a medical device. Authorities involved in the regulatory assessment of combination products may include the EMA, national competent authorities of E.U. Member States and Notified Bodies.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended use. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are positive, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the U.S. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. We do not have any product candidates approved for sale in any jurisdiction, including in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Our failure to maintain or continuously improve our quality management program could have an adverse effect upon our business, subject us to regulatory actions and cause a loss of patient confidence in us or our products, among other negative consequences.

Quality management plays an essential role in contract manufacturing of drugs or drug products, conducting clinical trials, preventing defects, improving our product candidates and services and assuring the safety and efficacy of our product candidates. Our goal is to maintain a robust quality management program, which includes the following broad pillars of quality:

- monitoring and assuring regulatory compliance for clinical trials, manufacturing and testing of good practice ("GxP") products;
- monitoring and providing oversight of all GxP suppliers (e.g., contract development manufacturing organizations and CROs);

- establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain and distribution operations; and
- cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality.

Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, monetary sanctions, injunction to halt manufacture and distribution of drugs or drug products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity or a loss of patient confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of potential future sales, which could have an adverse effect on our business, financial condition and results of operations.

A portion of our manufacturing, laboratory research, and clinical trial activities takes place in Asia. A significant disruption in that region, such as a trade war or political unrest, could materially adversely affect our business, financial condition, and results of operations.

We currently and expect to continue to engage in contract manufacturing, conduct clinical trials, and perform laboratory research activities outside the U.S., including in Asia. Any disruption in production or inability of our manufacturers in Asia to produce adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. We also conduct certain laboratory research, and expect to have clinical trial sites, in Asia. We are, thus, exposed to the possibility of product supply disruption, clinical trial delays, and increased costs in the event of changes in governmental policies, political unrest or unstable economic conditions in Asia. Any disruption of these activities could materially and adversely affect our business and results of operations.

Even if we obtain regulatory approval for a product candidate, we will still face extensive ongoing quality and regulatory compliance requirements and our product may face future development and quality or regulatory compliance difficulties.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, AE reporting, storage, recordkeeping, conduct of potential post-market studies and post-market commitment and requirements, export, import and advertising and promotional activities for such product, among other things, by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with current good manufacturing practice ("cGMP") requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval. In addition, the FDA or other foreign regulatory authorities may require that contraindications, warnings or precautions, including in some cases, a boxed warning be included in the product labeling, which could limit sales of the product. Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although the FDA and other foreign regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the U.S. and other comparable regulations in foreign jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, U.S. Department of Justice, State Attorneys General and other foreign regulatory authorities alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, later discovery of previously unknown AEs caused by our product candidates or reported by anti-FcRn product candidates developed by others, or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements may yield various results, including:

- restrictions on the manufacture of such product;
- restrictions on the labeling or marketing of such product, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;

- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;

- requirement of a REMS or additional risk management plans (or similar strategy imposed by foreign regulatory authorities.);
- Warning or Untitled Letters;
- withdrawal of the product from the market;
- recall of a product;
- fines, restitution or disgorgement of profits or revenues;
- suspension, variation or withdrawal of marketing approvals;
- refusal to permit the import or export of such product;
- product seizure; or
- lawsuits, injunctions or the imposition of civil or criminal penalties.

The FDA and other foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of batoclimab, IMVT-1402 or any future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or to 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.

For example, certain policies of the current U.S. administration may impact our business and industry. It is difficult to predict how these policies will be implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these policies impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Even if we receive marketing approval for batoclimab, IMVT-1402 or any future product candidate, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if we receive marketing approval for a product candidate, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue or become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the safety, efficacy, risk-benefit profile and potential advantages, including in the case of batoclimab subcutaneous delivery method, compared to alternative, competing or existing treatments, which physicians may perceive to be adequately effective for some or all patients;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable foreign regulatory authorities;
- any restrictions on the use of the product candidate and the prevalence and severity of any side effects;
- the content of the approved product label;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any biosimilar treatments;
- our ability to offer our products for sale at competitive prices;
- the cost, convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing or competing therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement at any given price level of our product candidates;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of our product candidate, if approved, together with other medications.

Market acceptance of new products for the treatment of MG, TED, CIDP and GD may also be affected by the perception that existing available treatments, such as pyridostigmine, corticosteroids and immunosuppressants, are sufficient to treat the majority of these patients. The perception that existing available treatments are sufficient to treat the majority of patients with a specific disease is a risk also applicable to the market acceptance of IMVT-1402. In addition, our product candidates, if approved, may compete with other approved FcRn inhibitors or other FcRn inhibitors under development that have demonstrated similar levels of IgG reductions in completed clinical trials to date. In addition, the potential patient population for our initial indication and other autoimmune indications that we may target are relatively small. This could affect the rate of adoption and as a result, market acceptance of our product candidates, if approved, could be much slower than anticipated.

We cannot assure you that batoclimab, IMVT-1402 or any future product candidate, if approved, will achieve broad market acceptance among physicians, patients and third-party payors. The failure of any such product candidate that receives regulatory approval or clearance to achieve market acceptance or commercial success would adversely affect our business and results of operations.

We may expend our limited resources to pursue one or more particular indications and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and management resources. As a result, we may forego or delay pursuit of opportunities with other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs for specific indications may not yield any commercially viable products. Any such failures would adversely affect our business and results of operations.

If we are unable to establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, if approved.

We do not currently have any infrastructure for the sales, marketing or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, compliance, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization.

We expect to build a focused sales, distribution and marketing infrastructure to market our product candidates in the U.S., if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, develop an appropriate compliance function, provide adequate training to sales and marketing personnel and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact its commercialization. If the commercial launch of our product candidate, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs;
- the inability to obtain sufficient access and reimbursement for our product candidate, if approved; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of any product candidate, we may be forced to delay potential commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring any product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to any of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may not become profitable. We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We have been granted orphan drug designation for batoclimab for the treatment of MG, and may seek orphan drug designation for batoclimab for other indications, IMVT-1402 or other product candidates we develop, but we may be unable to obtain such further designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted.

As part of our business strategy, we have in the past and may in the future seek orphan drug designation for any product candidates we develop, and we may be unsuccessful. In July 2021, we were granted orphan drug designation in the U.S. by the FDA for batoclimab for the treatment of MG and, in August 2022, we received orphan drug designation from the European Commission for batoclimab for the treatment of MG. We plan to seek orphan drug designation from the FDA for batoclimab and/or IMVT-1402 where there is a medically plausible basis for batoclimab and/or IMVT-1402's use, as well as with respect to other product candidates we may develop. We may also seek orphan drug designation for batoclimab and/or IMVT-1402 for the treatment of other indications in the E.U. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S.

Although we intend to seek additional orphan drug designation for batoclimab from the FDA and the European Commission, we may never receive such further designation. Moreover, obtaining orphan drug designation for batoclimab for the treatment of MG does not mean we will be able to obtain such designation for any other indications. Even if we were to obtain additional orphan drug designation for batoclimab from the FDA or the European Commission, we may not be the first to obtain marketing approval for the same drug for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of batoclimab could be blocked for years if another company obtains approval and orphan drug exclusivity for the same drug and same condition before us. If we do obtain market exclusivity in the U.S. or in the E.U., it may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA or the European Commission later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication and different drugs for the same condition may already be approved and commercially available. Orphan drug designation does not convey any automatic advantage in, or shorten the duration of, the development or FDA or other foreign regulatory authority review and approval process.

If we obtain approval to commercialize our product or any future product candidate outside of the U.S., a variety of risks associated with international operations could adversely affect our business.

If our product candidates or any future product candidate is approved for commercialization outside of the U.S., we expect that we will be subject to additional risks related to entering into international business relationships, including:

- different post-approval regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection of intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- workforce uncertainty, economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign tax, reimbursement, pricing and insurance regimes;
- any foreign partners or collaborators not fulfilling their respective regulatory reporting requirements and any foreign regulatory authorities taking actions with respect to such failures, which would be reportable to the FDA;
- any foreign partners or collaborators not informing us of any new post-marketing safety signals in a timely manner;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

- potential noncompliance with the Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), the United Kingdom Bribery Act 2010 (the “U.K. Bribery Act”) or similar antibribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in commercializing any product, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers are subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support efforts, charitable organizations and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we obtain marketing approval. Such laws include, among others:

- the federal Anti-Kickback Statute, which broadly prohibits the exchange of any “remuneration” related to items or services for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. Violations of the federal Anti-Kickback Statute also may constitute a false or fraudulent claim for purposes of the False Claims Act (“FCA”);
- the federal criminal and civil false claims laws, including the FCA, through civil whistleblower or “qui tam” actions, and the Civil Monetary Penalties Law, which impose criminal and civil penalties against individuals or entities for, among other things, causing false or fraudulent claims to be presented for payment to the federal government;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually the ownership and investment interests held by such physicians and their immediate family members;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing and state and local laws that require the registration of pharmaceutical sales representatives;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices; and
- federal, state and foreign laws governing the privacy and security of personal information, including health information, such as HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their implementing regulations, which may require us to, among other data protection measures, provide notices, obtain individual consents to use and disclose information, give individuals rights with respect to their information and keep the information secure. Enforcement of such laws could result in civil and criminal penalties as well as, in some circumstances, damages and related costs in defending private actions, including class actions.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, authority guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. The issuance of a subpoena or an investigation, regardless of the merits, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may have a significant adverse effect on our business and results of operations.

There have been, and continue to be, numerous executive, legislative and regulatory changes and proposed changes regarding the U.S. healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the U.S. there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, boosting pricing transparency, improving quality and/or expanding patient access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 and related legislation (collectively, the "Affordable Care Act"), substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced an "average manufacturer price" calculation for drugs and biologics that are inhaled, infused, instilled, implanted or injected and that are not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) established a Medicare Part D coverage gap discount program, in which manufacturers currently must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (6) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (7) created a licensure framework for follow-on biologic products; and (8) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017 ("TCJA") was enacted, which included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2032 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

At the state level, individual states in the U.S. are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded 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 being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell it profitably, if approved.

Market acceptance and sales of any approved product that we develop will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. There is no assurance that our product candidates, if approved, would achieve adequate coverage and reimbursement levels.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidate that we develop through approval will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidate that we develop. Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the U.S. and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. There can be no assurance that our product candidates, if approved, will be considered medically reasonable and necessary or cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the U.S. and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if approved for sale.

Many E.U. Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the E.U. Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some E.U. Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. Member States, including those representing the larger markets. The HTA process, which is currently governed by national laws in each E.U. Member State, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual E.U. Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between E.U. Member States.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/E.U. was adopted in the E.U. This Regulation which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among E.U. Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at E.U. level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit E.U. Member States to use common HTA tools, methodologies, and procedures across the E.U., working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual E.U. Member States will continue to be responsible for assessing non- clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in E.U. Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the E.U. could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the E.U. may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the E.U. Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of E.U. and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Risks Related to Our Business, Financial Position and Capital Requirements

Our business, operations, clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics and pandemics on the manufacturing, clinical trials and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, suppliers, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Many geographic regions imposed, or in the future may impose or re-impose, “shelter-in-place” orders, quarantines or similar orders or restrictions to control the spread of COVID-19 and its variants. Our headquarters is located in New York City, we have business operations in North Carolina and our contract manufacturers are located in the U.S. and in South Korea. At present, we have implemented work-from-home policies for all employees. The effects of our work-from-home policy, including any plans to return to the office, may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur or re-occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the U.S. and other countries or the availability or cost of materials, which could disrupt our supply chain. For example, any manufacturing supply interruption of batoclimab, which is currently manufactured at facilities in the U.S. and in South Korea, or IMVT-1402 or any future product candidates, could adversely affect our ability to conduct clinical trials of batoclimab, IMVT-1402 and any future product candidates. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we strive to carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. See "*Risks Related to Our Dependence on Third Parties*."

The COVID-19 pandemic impacted clinical site enrollment and some participants' ability to follow office visit schedules and protocols. Given the uncertain course of the COVID-19 pandemic, it is impossible to predict with certainty any future impact it, or any future health epidemics or pandemics, may have on our operations or our ongoing and planned clinical trials of IMVT-1402 or batoclimab in MG, TED, CIDP and GD. For example, clinical trial sites have experienced limited capacity and staffing shortages in a post-COVID 19 environment, partially due to personnel having been reassigned during the pandemic, resulting in a backlog of patient enrollment and delayed site initiations across the industry. Our inability to successfully recruit and retain patients and principal investigators and site staff could adversely impact our clinical trial operations.

The spread and duration of COVID-19 and its variants has also led to disruption and volatility in the global capital markets, which increases the cost of and adversely impacts access to capital and increases economic uncertainty. The trading prices for our common stock and other biopharmaceutical companies have, at times, been highly volatile as a result of the COVID-19 pandemic. To the extent the COVID-19 pandemic or a similar health epidemic or pandemic adversely affects our business, financial results and value of our common stock, it may also affect our ability to access capital, which could in the future negatively affect our liquidity.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to obtain regulatory approval or fail to become commercially viable. We have never generated any product revenue and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was $211.0 million and $156.7 million for the fiscal years ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $566.3 million.

We expect to continue to incur substantial and increasing losses through the commercialization of batoclimab, IMVT-1402 or any future product candidate, if approved, and we currently have no products that are approved for commercial sale. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of batoclimab, IMVT-1402 or any future product candidate, obtain necessary regulatory approvals for such product candidate and manufacture and successfully commercialize such product candidate alone or in collaboration with others. We cannot assure you that we will be able to achieve or maintain profitability even if we successfully commercialize batoclimab, IMVT-1402 or any future product candidate. If we do successfully obtain regulatory approval to market a product candidate, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we obtain regulatory approval, the number of competitors in such markets, the accepted price for our product candidates, the reimbursement environment for our product candidates and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities for batoclimab, IMVT-1402 or any future product candidate is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such product candidate, even if approved. Failure to become and remain profitable may adversely affect the market price of shares of our common stock and our ability to raise capital and continue operations.

We expect our research and development expenses in connection with our development program for batoclimab and IMVT-1402 to continue to be significant. In addition, if we obtain regulatory approval for batoclimab or IMVT-1402, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses had and will continue to have an adverse effect on our results of operations, financial position and working capital.

We have a limited operating history and have never generated any product revenue.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, manufacturing and commercializing pharmaceutical products, including antibody-based products.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of and obtain the necessary regulatory approvals for batoclimab, IMVT-1402 and any future product candidates we develop. We have never been profitable, have no products approved for commercial sale and have not generated any product revenue.

Even if we receive regulatory approval for batoclimab, IMVT-1402 or any future product candidate, we do not know when or if we will generate product revenue.

Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of batoclimab, IMVT-1402 or any future product candidate in the U.S. and in other jurisdictions;
- add operational, financial and management information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of batoclimab, IMVT-1402 or any future product candidate manufactured at acceptable cost and quality levels and in compliance with FDA and other foreign regulatory requirements;
- attract and retain experienced management and advisory teams;
- raise additional funds when needed and on terms acceptable to us;
- commercially launch batoclimab, IMVT-1402 or any future product candidate, if approved, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- set an acceptable price for any approved product and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of any approved product in the medical community and with third-party payors and consumers;
- compete effectively with other biotechnology and pharmaceutical companies targeting autoimmune disease indications; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, including delays in subject enrollment or interruptions in clinical trial supplies or investigational product, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if batoclimab, IMVT-1402 or any future product candidate is approved for commercial sale, we anticipate incurring significant costs associated with its commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed and you may lose some or all of your investment.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates or technologies or to enter into collaborations or strategic alliances for the development and commercialization of any such future product candidates.

We may seek to identify and acquire or in-license novel product candidates or technologies in the autoimmune disease field. The process by which we identify product candidates and technologies may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- the process by which we identify and decide to acquire product candidates or technologies, including through the business development support we receive from RSL and its subsidiaries pursuant to the Services Agreements, may not be successful;
- potential product candidates may, upon further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases; or
- the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs or higher than expected acquisition or integration costs.

We may choose to focus our efforts and resources on a potential product candidate or technology that ultimately proves to be unsuccessful. We also cannot be certain that, following an acquisition or in-licensing transaction, we will achieve the revenue or specific net income that justifies such transaction. Further, time and resources spent identifying, acquiring and developing potential product candidates or technologies may distract management's attention from our primary business or other development programs. If we are unable to identify and acquire suitable product candidates for clinical development, this could adversely impact our business strategy, our financial position and share price.

In the future, we may also decide to collaborate with other pharmaceutical companies for the development and potential commercialization of our product candidates in the U.S. or other countries or territories. We will likely face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a 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.

We will require additional capital to fund our operations. If we fail to obtain necessary financing, we may not be able to complete the development and commercialization of batoclimab and IMVT-1402.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize batoclimab and IMVT-1402. These expenditures will include costs associated with the HanAll Agreement, pursuant to which we are required to reimburse HanAll for half of budgeted research and development costs incurred by them with respect to batoclimab (up to an aggregate reimbursement amount of $20.0 million), make payments in connection with the achievement of certain development and regulatory milestones prior to generating any product sales (including the initiation of certain clinical trials for batoclimab or IMVT-1402), make significant further payments upon the achievement of certain sales milestones and make tiered royalty payments in connection with the commercial sale of batoclimab or IMVT-1402, if approved.

We will require additional capital to complete the development and potential commercialization of batoclimab and IMVT-1402. Because the length of time and activities associated with successful development of our product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all, and our ability to raise additional capital may be adversely impacted by global economic conditions, including the continuing disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, decades-high inflation, rising interest rates, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and other factors. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the timing, progress, costs and results of our clinical trials for batoclimab and IMVT-1402;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;
- the cost of future product candidates or technologies that we may acquire or in-license;
- the effect of competing market developments;
- the cost and timing of completion of commercial-scale and other manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for batoclimab, IMVT-1402 or any future product candidate in regions where we choose to commercialize such product candidate, if approved, on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

We do not have any committed external source of funds. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of batoclimab, IMVT-1402 and any future product candidates or potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of batoclimab or IMVT-1402, we are unable to estimate the associated amounts of increased capital outlays, operating expenditures and capital requirements.

Raising additional funds by issuing equity securities will cause dilution to existing stockholders. Raising additional funds through debt financings may involve restrictive covenants and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common stockholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or batoclimab, IMVT-1402 or any future product candidate or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We rely on the HanAll Agreement to provide us rights to the core intellectual property relating to batoclimab and IMVT-1402. Any termination or loss of significant rights under the HanAll Agreement would adversely affect our development and commercialization of batoclimab and IMVT-1402.

We have licensed our core intellectual property relating to batoclimab and IMVT-1402 from HanAll under the HanAll Agreement. If, for any reason, the HanAll Agreement is terminated or we otherwise lose those rights, it would adversely affect our business. The HanAll Agreement imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. We are also required to reimburse HanAll for half of budgeted research and development costs incurred by them with respect to batoclimab and IMVT-1402, up to an aggregate reimbursement amount of $20.0 million. If we breach any material obligations or use the intellectual property licensed to us in an unauthorized manner, under the HanAll Agreement, we may be required to pay damages to our collaborators and they may have the right to terminate the applicable licenses, which would result in us being unable to develop, manufacture and sell batoclimab, if approved.

The HanAll Agreement obligates us to make milestone payments, some of which may be triggered prior to our potential commercialization of batoclimab and IMVT-1402.

We will be responsible for future contingent payments and royalties under the HanAll Agreement, including up to an aggregate of $432.5 million (after an aggregate amount of $20.0 million of milestone achievements as of March 31, 2023) upon the achievement of certain development and regulatory milestone events (including the initiation of certain clinical trials for batoclimab or IMVT-1402), which events will occur prior to our planned commercialization of batoclimab or IMVT-1402. Accordingly, we will be required to make such payments prior to the time at which we are able to generate any revenue, if any, from commercial sales of batoclimab or IMVT-1402. Following commercialization, we may be required to make significant further payments upon the achievement of sales milestones and make tiered royalty payments in connection with the commercial sale of batoclimab and/or IMVT-1402, if approved. There can be no assurance that we will have the funds necessary to make such payments or be able to raise such funds when needed on terms acceptable to us or at all. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategies.

We are highly dependent on the skills and leadership of our senior management team and key employees. Our senior management and key employees have previously and may terminate their positions with us at any time. If we lose members of our senior management team or key employees, our ability to successfully implement our business strategies could be adversely affected. Replacing these individuals may be difficult, cause disruption to our business and may take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to develop, manufacture, obtain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense and we may be unable to hire, train, retain or motivate additional key personnel. We do not maintain “key person” insurance for any members of our senior management team or other employees.

We plan to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to hire, either directly, or through any current or future subsidiaries of ours, additional employees for our managerial, finance and accounting, legal, clinical, scientific and engineering, regulatory, operational, manufacturing, medical affairs, business development and sales and marketing teams.

We may have difficulties identifying, hiring, integrating and retaining new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors, including training additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of batoclimab, IMVT-1402 and any future product candidate. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize batoclimab, IMVT-1402 or any future product candidate and compete effectively will partly depend on our ability to effectively manage any future growth.

Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and our business will be harmed.

Our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors or potential collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our or our affiliates' employees and contractors, including principal investigators, CROs, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such regulatory authorities, manufacturing and the GCP or cGMP standards, federal, state and foreign healthcare fraud and abuse laws and data privacy or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations.

Additionally, we are subject to the risk that a person, including any person who may have engaged in any fraud or misconduct, or government agency could allege such fraud or other misconduct, even if none occurred. Furthermore, we rely on our CROs and clinical trial sites to adequately report data from our clinical trials. For example, any failure by such parties to adequately report safety signals to us in a timely manner from any such trials may also affect the approvability of our product candidates or cause delays and disruptions for the approval of our product candidate, if at all. If our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors are alleged or found to be in violation of any such regulatory standards or requirements or become subject to a corporate integrity agreement or similar agreement and curtailment of our operations, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs or comparable foreign programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings and additional reporting requirements and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the U.S.

Part of our business strategy involves potentially expanding internationally with third-party collaborators to seek regulatory approval for batoclimab, IMVT-1402 and any future product candidates outside the U.S. Doing business internationally involves a number of risks, including but not limited to:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidate, if approved, in various countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those resulting from the COVID-19 pandemic;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including pandemics and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, the U.K. Bribery Act and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and consequently, negatively impact our financial condition and results of operations.

We are subject to stringent and changing privacy, data protection, and information security laws, contractual obligations, self-regulatory schemes, government regulation and standards related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with such obligations could harm our reputation, subject us to significant fines and liability, disrupt our clinical trials or otherwise adversely affect our business.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect about patients and healthcare providers in connection with clinical trials in the U.S. and abroad ("Process" or "Processing") necessary to operate our business for legal, marketing and other business-related purposes.

There are numerous federal, state, local and foreign laws, regulations and guidance regarding privacy, data protection, information security and Processing ("Data Protection Laws"), the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or Data Protection Obligations (as defined below).

For example, U.S. states have increasingly begun to introduce comprehensive privacy legislation. The California Consumer Privacy Act of 2018 ("CCPA"), which went into effect on January 1, 2020, affords consumers expanded privacy protections. Aspects of the CCPA and its interpretation and enforcement remain uncertain. The potential effects of the CCPA are far-reaching and may require us to modify our Processing practices and policies and to incur substantial costs and expenses in an effort to comply. For example, the CCPA gives California residents expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches and statutory damages ranging from $100 to $750 per violation, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements. The CCPA will be expanded substantially on January 1, 2023 when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16 and establish a new California Privacy Protection Agency to implement and enforce the new law. While certain clinical trial activities are exempt from the CCPA's requirements, other personal information that we handle may be subject to the CCPA, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities. Virginia has similarly enacted a comprehensive privacy law, the Consumer Data Protection Act, Colorado recently enacted the Colorado Privacy Act, and Utah recently passed the Utah Consumer Privacy Act, all laws of which emulate the CCPA and CPRA in many respects. Further, proposals for comprehensive privacy, data protection, and information security legislation are advancing in several other states. A patchwork of differing laws would increase the cost and complexity of operating our business and increase our exposure to liability.

We also expect that there will continue to be new or amended laws, regulations, and industry standards concerning privacy, data protection, and information security proposed and enacted in various foreign jurisdictions. For example, in May 2018, the General Data Protection Regulation ("GDPR") went into effect in the EEA. The GDPR imposes more stringent data protection requirements and requires us to give more detailed disclosures about how we collect, use and share personal information, contractually commit to data protection measures in our contracts with clients, maintain adequate data security measures, notify regulators and affected individuals of certain data breaches, meet extensive privacy governance and documentation requirements and honor individuals' data protection rights, including their rights to access, correct and delete their personal information. The GDPR provides greater penalties for noncompliance than previous data protection laws. Companies that violate the GDPR can face private litigation, restrictions on data processing and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. Our or our customers', partners', or vendors' failure to comply with the GDPR could lead to significant fines imposed by regulators or restrictions on our ability to process personal information as needed to provide our product and services or conduct clinical trials in the EEA. We may also be obligated to assist our customers, partners, and vendors with their own compliance obligations under the GDPR, which could require expenditure of significant resources. Assisting our customers, partners, and vendors in complying with the GDPR or complying with the GDPR ourselves may cause us to incur substantial operational costs or require us to change our business practices.

In addition, the regulation of data transfers between the EEA and U.K. remains subject to post-Brexit uncertainty. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers of personal information from the EEA to the U.K. to continue without restriction for a period of four years ending June 27, 2025. During these four years, the European Commission will continue to monitor the legal situation in the U.K. and can intervene if the U.K. deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal information from the EEA to the U.K. will require a valid transfer mechanism and companies making such transfers may be required to implement new processes and put new agreements in place to continue making such transfers. Additionally, although U.K. privacy, data protection and information security law is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

In addition, the GDPR includes restrictions on cross-border data transfers. A decision by the Court of Justice of the European Union (CJEU) (the Schrems II ruling) has invalidated the E.U.-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe. Similarly, the Swiss Federal Data Protection and Information Commissioner opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. On June 4, 2021, the European Commission adopted new Standard Contractual Clauses ("SCCs") that are designed to be a mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, the SCCs are a valid mechanism to transfer personal information outside of the EEA. The SCCs, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the transferred personal information. Moreover, due to potential legal challenges, uncertainty exists regarding whether the SCCs will remain a valid mechanism. The new SCCs may increase the legal risks and liabilities under European privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs, any transfers by us or our vendors of personal information from Europe may not comply with European data protection laws, which may increase our exposure to European data protection laws' heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of European personal information outside of Europe (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products. The U.K. is not subject to the European Commission's revised SCCs but has published its own transfer mechanism, the International Data Transfer Agreement ("IDTA"), which enables transfers from the U.K. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and the U.K. GDPR and doing so will require significant effort and cost. In addition, additional measures may be required even when relying on SCCs or the IDTA, where the laws of the importer's country do not offer an adequate level of protection, such as the U.S. Use of SCCs and IDTA must consequently be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals.

On March 25, 2022, the European Commission and the U.S. announced that they had agreed, in principle, on a successor of the previously invalidated Privacy Shield Framework, the Trans-Atlantic Data Privacy Framework. On October 7, 2022, President Biden signed an Executive Order on "Enhancing Safeguards for U.S. Signals Intelligence Activities". The European Commission is now preparing a draft adequacy decision for adoption that takes into account the Executive Order. However, a related adoption is not expected before spring 2023 and it is remained to be seen whether the new adequacy decision would withstand scrutiny by the CJEU if the adequacy decision's validity was to be challenged.

Further, the risk of GDPR litigation may increase because of a recent decision of the CJEU. The CJEU ruled that a consumer protection association may bring representative actions alleging breaches of the GDPR even when the consumer protection association does not have a mandate to take action from any specific individuals and a specific breach of any individual's data protection rights was not demonstrated.

We are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications and frameworks ("Privacy Policies"), and contractual obligations to third parties related to privacy, data protection, information security and Processing ("Data Protection Obligations"), including without limitation, operating rules and standards imposed by industry organizations.

Data Protection Laws and data protection worldwide is, and is likely to remain, uncertain for the foreseeable future. We strive to comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations, but we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel, partners or vendors do not comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations.

If we, our vendors or business partners fail, or are perceived to have failed, to address or comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations, or if our Privacy Policies are, in whole or part, found to be inaccurate, incomplete, deceptive, unfair or misrepresentative of our actual practices, it could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, reduce the use of our products, interrupt or stop clinical trials, result in litigation and liability, result in an inability to process personal information or to operate in certain jurisdictions, cause a material adverse effect on our business operations or financial results or otherwise result in a material adverse effect on our business.

With applicable Data Protection Laws, Privacy Policies and Data Protection Obligations imposing complex and burdensome obligations, and with substantial uncertainty over the interpretation and application of these requirements, we have faced and may face additional challenges in addressing and complying with these obligations and making necessary changes to our Privacy Policies and practices, and may incur material costs and expenses in an effort to do so, any of which could materially adversely affect our business operations and financial results, and may limit the adoption and use of, and reduce the overall demand for, our products, which could have an adverse impact on our business.

We may in the future receive inquiries or be subject to investigations, proceedings or actions by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect on our business, including without limitation, interruptions of or require changes to our business practices, the diversion of resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary Processing, or other remedies that adversely affect our business. See Part II, Item 1, Legal Proceedings for additional information. We may in the future face litigation regarding our privacy and information security practices and Processing, including without limitation, class action litigation, which could result in a material adverse effect on our business.

If our security measures are compromised now or in the future, or the security, confidentiality, integrity or availability of our information technology, software, services, communications or data is compromised, limited or fails, this could result in a material adverse effect on our business, including without limitation, a material interruption to our operations, harm to our reputation, significant fines, penalties and liability, breach or triggering of Data Protection Laws, Privacy Policies and Data Protection Obligations or material disruption of our clinical trials or other business activity.

In the ordinary course of our business, we collect, Process and store proprietary, confidential and sensitive information, including personal information (including health information), intellectual property, trade secrets and proprietary business information owned or controlled by ourselves or other parties ("Sensitive Information").

We may use third-party service providers and subprocessors to help us operate our business and engage in Processing on our behalf, such as RSL and its affiliates, our CROs and other contractors. We may also share Sensitive Information with our partners or other third parties in conjunction with our business. If we, our service providers, partners or other relevant third parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of or inadvertent exposure or disclosure of Sensitive Information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data (collectively a "Security Breach"), it may result in a material adverse effect on our business, including without limitation, disruptions of our drug development programs, delays in our regulatory approval efforts, regulatory investigations or enforcement actions, litigation, indemnity obligations, negative publicity and financial loss.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-state and nation-state-supported actors now engage and are expected to continue to engage in attacks, including without limitation, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We may also be the subject of software bugs, malicious code (such as viruses and worms), employee theft or misuse, supply chain attacks, denial-of-service attacks (such as credential stuffing) and ransomware attacks, phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data or other computer assets, adware or other similar issues. Additionally, the COVID-19 pandemic, our remote workforce and the potential increase in cyberattacks following the onset of hostilities by Russia towards Ukraine pose increased risks to our information technology assets and data. Moreover, security incidents can result in the diversion of funds and interruptions, delays or outages in our operations and services, including due to ransomware attacks, which have increased in frequency and severity.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations (including our clinical trial activities) or information technology in an effort to protect against Security Breaches and to mitigate, detect and remediate actual and potential vulnerabilities. Applicable Data Protection Laws, Privacy Policies and Data Protection Obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect against Security Breaches. While we have implemented security measures designed to protect against Security Breaches, there can be no assurance that our security measures or those of our service providers, partners and other third parties will be effective in protecting against all Security Breaches and adverse effects on our business that may arise from such breaches. The recovery systems, security protocols, network protection mechanisms and other security measures that we (and our third parties) have integrated into our platform, systems, networks and physical facilities, which are designed to protect against, detect and minimize Security Breaches, may not be adequate to prevent or detect service interruption, system failure or data loss.

We have not always been able in the past and may be unable in the future to detect, anticipate, measure or prevent Security Breaches or threats or techniques used to detect or exploit vulnerabilities in our (or our service providers, partners or other relevant third parties') information technology, services, communications or software because such threats and techniques change frequently, are often sophisticated in nature and may not be detected until after an incident has occurred. In addition, security researchers and other individuals have and will continue to actively search for and exploit actual and potential vulnerabilities in our (or our third parties') information technology and communications. We cannot be certain that we will be able to address any such vulnerabilities, in whole or part, and there may be delays in developing and deploying patches and other remedial measures to adequately address vulnerabilities.

Applicable Data Protection Laws, Privacy Policies and Data Protection Obligations may require us to notify relevant stakeholders of Security Breaches, including affected individuals, customers, regulators and credit reporting agencies. Such disclosures are costly and the disclosures or the failure to comply with such requirements could lead to adverse effects on our business including, without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable Data Protection Laws, Privacy Policies or Data Protection Obligations related to information security or Security Breaches.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive or confidential information, including preventing us from conducting clinical trials, tests or research and development activities and preventing us from managing the administrative aspects of our business.

While we maintain general liability insurance coverage and coverage for errors or omissions, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or adverse effects on our business arising out of our privacy and security practices, Processing or Security Breaches or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of batoclimab, IMVT-1402 and any future product candidate in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, other pharmaceutical companies, government authorities or others taking or otherwise coming into contact with any approved products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- impairment of our business reputation and significant negative media attention;
- delay or termination of clinical trials, or withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;
- distraction of management's attention from our primary business;

- substantial monetary awards to patients or other claimants;
- inability to commercialize any product candidate, if approved;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for any product candidate, if approved; and
- loss of revenue.

The product liability insurance we currently carry and any additional product liability insurance coverage we acquire in the future 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. If we obtain marketing approval for batoclimab, IMVT-1402 or any future product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization any approved product.

Disruptions at the FDA and other government authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's or comparable foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions, as applicable. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other foreign regulatory authorities may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government authorities, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA adopted a risk-based approach to the inspection of foreign and domestic manufacturing facilities and similar restrictions. The use of alternative regulatory tools may delay FDA or foreign regulatory authority actions. If a prolonged government shutdown occurs or if global health concerns prevent the FDA or other foreign regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have an adverse effect on our business.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and uncertainty about economic stability. For example, the Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and rely on third parties to produce clinical supplies and commercial supplies of batoclimab and IMVT-1402. The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production or our quality management program may fail to detect quality issues at our third-party manufacturers which may delay or prevent our ability to obtain marketing approval or commercialize batoclimab or IMVT-1402 if approved.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. We rely on third parties to produce clinical supplies and commercial supplies of batoclimab and IMVT-1402. For example, in November 2021, we entered into an agreement with Samsung Biologics Co., Ltd. to manufacture and supply us with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. Additional third-party vendors may be difficult to identify for our product candidate process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. Any significant delay in the supply of batoclimab, IMVT-1402 or the raw material components thereof, or in placebo controls for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of batoclimab, IMVT-1402 or any future product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for batoclimab, IMVT-1402 or any future product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of such product candidate. In addition, batoclimab and IMVT-1402 are biologics and require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Our future success depends on our ability to maintain and continuously improve our quality management program to monitor the manufacturing processes used by third-party manufacturers and our reliance on third-party manufacturers does not relieve us of our regulatory responsibilities. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims and insufficient inventory. A quality or safety issue emanating from manufacturing failures may result in adverse inspection reports, warning letters, monetary sanctions, injunction to halt manufacture and distribution of drugs or drug products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses.

The facilities used by our contract manufacturers to manufacture batoclimab, IMVT-1402 or any future product candidate must be approved by the FDA and comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit our BLA to the FDA or comparable applications to foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidate. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market batoclimab, IMVT-1402 or any future product candidate, if approved. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products. Further, our reliance on third-party manufacturers entails risks, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing, which can be difficult for a biologic product;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

- potential disputes with third parties that might delay work under third-party contracts;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell any product candidate, if approved, in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacture of another company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical trial delays, cost overruns, delay or failure to obtain regulatory approval or impact our ability to successfully commercialize our products, as well as product recalls or product withdrawals. Some of these events could be the basis for FDA or other foreign regulatory authority action, including injunction, recall, seizure or total or partial suspension of production.

We rely on third parties to conduct, supervise and monitor our clinical trials and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements or our quality management program fails to detect such events in a timely manner, it may harm our business.

We currently do not have the ability to independently conduct nonclinical studies that comply with good laboratory practice ("GLP") requirements. We also do not currently have the ability to independently conduct any clinical trials. We rely exclusively on CROs and clinical trial sites, which need to comply with GCP, to ensure the proper and timely conduct of our clinical trials and we have limited influence over their actual performance.

We rely upon CROs to monitor and manage data for our clinical programs, as well as for the execution of nonclinical studies. We control only certain aspects of our CROs' 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 the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GLP and GCP regulations and guidelines enforced by the FDA and equivalent foreign regulations and guidelines, including the International Council for Harmonization guidelines, enforced by foreign regulatory authorities for batoclimab or any of our future product candidates that are in nonclinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations and our reliance on the CROs does not relieve us of our regulatory responsibilities. Therefore, the success of our clinical trials depends on our ability to maintain and continuously improve our quality management program to monitor our CROs' compliance with applicable regulations. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical trials before approving our marketing applications. Accordingly, if we or our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the relevant regulatory approval process. Failure by our CROs to properly execute study protocols in accordance with applicable law could also create product liability and regulatory risks for us as sponsors of those studies. Further, our or our CROs' inability to address a quality or safety issue may result in, among others, adverse inspection reports, warning letters, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses.

While we will have agreements governing their activities, our CROs are not our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our (or their own) clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop could be harmed, our costs could increase and our ability to generate revenue could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could adversely impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

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

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause batoclimab or any future product candidate 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, FDA notification or FDA approval or similar. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of batoclimab, IMVT-1402 or any future product candidate or jeopardize our ability to commence sales and generate revenue.

Risks Related to Our Intellectual Property

Our product candidates for which we intend to seek approval as a biological product may face competition sooner than anticipated.

In the U.S., the Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. New biologics, such as batoclimab or IMVT-1402, may be entitled to regulatory exclusivity under the BPCIA. The BPCIA grants new biologics 12 years of FDA-granted exclusivity. Further, under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. During the period of exclusivity, however, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own clinical data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. After the expiration of the exclusivity period, the FDA can approve a biosimilar product through an abbreviated approval process. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that our product candidates, batoclimab and IMVT-1402, as biological products, should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we are unable to obtain and maintain patent protection for batoclimab, IMVT-1402 or any future product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our brand, current and future drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to batoclimab, IMVT-1402 and any future product candidates and their uses. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad in the Licensed Territory related to our current and future drug development programs and product candidates, successfully defending our intellectual property rights against third-party challenges and successfully enforcing our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. We generally apply for patents in those countries in the Licensed Territory where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. We may also make statements to regulatory authorities during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable.

The patent applications that we in-license in the U.S. or in other foreign countries may fail to result in issued patents with claims that protect our product candidates or result in patents that are narrowed, invalidated or held unenforceable following challenge in certain jurisdictions. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of any patent protection we obtain. Even if patents do successfully issue based on our patent applications and even if such patents cover our product candidates, uses of our product candidates or other aspects related to our product candidates, third parties may challenge their validity, ownership, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our product candidates, if approved, and technologies. Other companies may also design around our patents. Third parties may have blocking patents that could prevent us from marketing our product candidates, if approved, or practicing our own patented technology. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate while under patent protection could be reduced. If any of our patents expire or are challenged, invalidated, circumvented or otherwise limited by third parties prior to the commercialization of our product candidates and if we do not own or have exclusive rights to other enforceable patents protecting our product candidates, competitors and other third parties could market products that are substantially similar to ours and our business would suffer.

If the patent applications we hold or have in-licensed with respect to our development programs and our product candidates fail to issue, if their breadth or strength of protection is threatened or if they fail to provide meaningful exclusivity for our product candidates, batoclimab and IMVT-1402, it could dissuade companies from collaborating with us to develop our product candidates and threaten our ability to commercialize future drugs. Any such outcome could have an adverse effect on our business. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such application.

The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal, scientific and factual questions, and has in recent years been the subject of much litigation. The standards that the U.S. Patent and Trademark Office (“USPTO”) and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Patent reform legislation in the U.S. could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the Leahy Smith America Invents Act (the "Leahy-Smith Act") was signed into law in 2011 and includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter party review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

Publications of discoveries in scientific literature often lag behind the actual discoveries and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not until a patent issues. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect batoclimab, IMVT-1402 or any future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our patent rights, allow third parties to commercialize batoclimab, IMVT-1402 or any future product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize batoclimab, IMVT-1402 or any future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices, both in the U.S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Moreover, patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Without patent protection for batoclimab, IMVT-1402 or any future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The validity, scope and enforceability of any patents that cover a biologic subject to approval by the FDA via a BLA, such as batoclimab, can be challenged by third parties.

For biologics subject to approval by the FDA via a BLA, such as batoclimab or IMVT-1402, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological products. Due to the large size and complexity of biological products as compared to small molecules, a biosimilar must be "highly similar" to the reference product with "no clinically meaningful differences between the two." The BPCIA, requires a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties' basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims it could result in the invalidation of or render unenforceable some or all of the relevant patent claims or result in a finding of non-infringement. Such litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business and may result in unfavorable results that could limit our ability to prevent third parties from competing with batoclimab, IMVT-1402 or any future product candidates.

We may not be able to protect or enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on batoclimab, IMVT-1402 or any future product candidates in all countries throughout the world would be prohibitively expensive and even in countries where we have sought protection for our intellectual property, such protection may be less extensive than that provided in the U.S. The requirements for patentability may differ in certain countries, particularly developing countries and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect patent rights to the same extent as federal laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in certain jurisdictions. Competitors may exploit our inventions in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we may obtain patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services and our competitive position in the international market would be harmed.

Many countries, including E.U. countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent and the protection it affords is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. The patent family directed to the composition of matter of batoclimab has a natural projected expiration date in 2035 in the U.S. and in foreign jurisdictions. The patent family directed to the composition of matter of IMVT-1402 and its use in treating autoimmune diseases has a natural projected expiration date in 2043 in the U.S. and in foreign jurisdictions. The patent family directed to the formulation of batoclimab has a natural projected expiration date in 2041 in the U.S. and in foreign jurisdictions. The patent family directed to the use of batoclimab for treating TED has a natural projected expiration date in 2039 in the U.S. and in foreign jurisdictions. The patent families directed to the use of batoclimab and IMVT-1402 for treating GD and the use of batoclimab and IMVT-1402 for treating CIDP each have a natural projected expiration date in 2043 in the U.S. and in foreign jurisdictions. The patent family directed to the method of manufacturing of, and formulations produced by such method, covering manufacturing and formulations of batoclimab, has a natural projected expiration date in 2044 in the U.S. and in foreign jurisdictions. Given the amount of time required for the development, testing and regulatory review of any new product candidate, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for batoclimab, IMVT-1402 or other product candidates that we may identify, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property rights in the U.S. and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. Depending upon the timing, duration and specifics of FDA marketing approval of batoclimab or other product candidates that we may identify, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA premarket regulatory review process. A 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 claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries, including the E.U., upon regulatory approval of our product candidates, based on similar legislation. Nevertheless, we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval to market competing products sooner and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering batoclimab, IMVT-1402 or other product candidates that we may identify even where that patent is eligible for patent term extension or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for patents we may later in-license or jointly own, we may not have the right to control patent prosecution, including filing with the USPTO a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of these patents was eligible for patent term extension under the Hatch-Waxman Act, we might not be able to control whether a petition to obtain a patent term extension would be filed or obtained from the USPTO.

We do not have rights to protect intellectual property in certain territories and may be unable to adequately protect our rights.

We do not have rights to develop, manufacture, use or commercialize batoclimab, IMVT-1402 or other assets licensed from HanAll in jurisdictions outside the Licensed Territory. One or more third parties may challenge patents corresponding to the patent portfolio licensed to us from HanAll in jurisdictions outside the Licensed Territory and HanAll may not reasonably cooperate in the defense and enforcement of such patents with us, which could impair our ability to defend or enforce our rights to corresponding patents in jurisdictions within the Licensed Territory.

If we fail to comply with our obligations under any license, collaboration or other agreements, including the HanAll Agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We have licensed certain intellectual property rights, including certain intellectual property rights covering our product candidates, batoclimab and IMVT-1402, from HanAll. We are heavily dependent on the HanAll Agreement for the development, manufacture and commercialization of our product candidates, batoclimab and IMVT-1402. If, for any reason, our licenses under the HanAll Agreement are terminated or we otherwise lose those rights, it could adversely affect our business. The HanAll Agreement imposes and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and HanAll, as the licensor, may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or having to negotiate new or reinstated licenses on less favorable terms or enable a competitor to gain access to the licensed technology.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our third-party relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us as well as our partners; and
- the priority of invention of patented technology.

In addition, the agreement under which we currently license intellectual property or technology from HanAll is complex, and certain provisions in the agreement may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have an adverse effect on our business, financial condition, results of operations and business prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize such affected product candidates, which could have an adverse effect on our business, financial conditions, results of operations and business prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and fee payment during the life of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering batoclimab, IMVT-1402 or any of our future product candidates, our competitors might be able to enter the market earlier than anticipated, which would have an adverse effect on our business.

We may need to license intellectual property from third parties and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of any of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize batoclimab, IMVT-1402 or any future product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights may delay or prevent the development and commercialization of our product candidates.

Our commercial success depends in part on our ability to operate while avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, *inter partes* review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidate. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defending these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, importing, marketing or otherwise commercializing our product candidates or any future product candidates. Any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise have an adverse effect on our business, results of operation, financial condition or cash flows.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our 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, which could have an adverse effect on the price of shares of our common stock. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock. The occurrence of any of these events may have an adverse effect on our business, results of operation, financial condition or cash flows.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates or any future product candidates, resulting in either an injunction prohibiting our sales or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates or any future product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S. and abroad that is or may be relevant to or necessary for the commercialization of our product candidates or any future product candidates in any jurisdiction. Patent applications in the U.S. and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Therefore, patent applications covering our product candidates or any future product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or any future product candidates, including the use thereof, provided such pending patent applications result in issued patents, our ability to develop and market our product candidates or any future product candidates can be adversely affected in jurisdictions where such patents issue.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidate, if approved. We may incorrectly determine that our applicable product candidate is not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates or any future product candidates, if approved.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents.

An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives or could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution.

Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. For patents and patent applications that we may in-license, we may have a limited right or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on batoclimab, IMVT-1402 or any future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our 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. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect batoclimab, IMVT-1402 or any of our future product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our product candidates, batoclimab and IMVT-1402, and any future product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. or USPTO rules and regulations could increase the uncertainties and costs.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"). Under the Bayh-Dole Act, the federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, including as a result of our reliance on third parties, our business and competitive position could be harmed.

In addition to seeking patents for our product candidate, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. Despite these efforts and the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information due to our reliance on third parties, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Monitoring unauthorized uses and disclosures of our intellectual property is difficult and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. Further, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them or those to whom they communicate it from using that technology or information to compete with us. If any of our trade secrets or other proprietary information were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

We may be subject to claims that our licensors, employees, consultants, independent contractors or we have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, independent contractors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the know-how or confidential information of their former employer or other third parties, we may be subject to claims that we or our employees, consultants, collaborators or independent contractors have inadvertently or otherwise used or disclosed know-how or confidential information of their former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could result in customers seeking other sources for the technology, or in ceasing from doing business with us. 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 our product candidate. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patents, trade secrets or other intellectual property.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached and we may be forced to bring claims against third parties or defend claims they may bring against us to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidate. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have an adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities and have an adverse effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs or in-license needed technology or any future product candidates. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our product candidates or any future product candidates, if approved.

Any trademarks and trade names we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks and trade names as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties may have used trademarks similar and identical to our trademarks in certain jurisdictions and may have filed or may in the future file for registration of such trademarks. Third parties may oppose or attempt to cancel our trademark applications or trademarks or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we may not be able to use these trademarks to market our products in those countries and could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or affect financial or other obligations under the relevant agreement, any of which could have an adverse effect on our business, financial condition, results of operations and business prospects.

We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.

We may seek to acquire or in-license additional product candidates or technologies to grow our product offerings and intellectual property portfolio. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidates from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such product candidates or technology. We may also be unable to identify product candidates or technology that we believe are an appropriate strategic fit for our company and protect intellectual property relating to, or necessary for, such product candidates and technology.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates or technology on terms that would allow us to make an appropriate return on our investment.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such granted patent. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus challenged or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights afford only limited protection, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to batoclimab, IMVT-1402 or future product candidates but that are not covered by the claims of the patents that we own or have licensed;
- others may be able to make a product that is similar to our product candidates and not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we, our licensor or any collaborators might not have been the first to file patent applications covering certain of our or our licensor's inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- patents that we own or have exclusively licensed may not provide us with any competitive advantage or may be held invalid or unenforceable as a result of legal challenges;

- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, our business, financial condition, results of operations and business prospects could be adversely affected.

General Risks Related to an Investment in Our Securities

RSL owns a significant percentage of shares of our common stock and may exert significant control over matters subject to stockholder approval.

As of May 17, 2023, RSL beneficially owned approximately 56.6% of the voting power of our outstanding shares of common stock. Therefore, we are controlled by RSL and RSL has the ability to substantially influence us and exert significant control through this ownership position. It is possible RSL may be able to control elections of directors, the issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL is publicly traded and its interests may not always coincide with our corporate interests or the interests of other stockholders and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. There may be changes to the management or ownership of RSL, or to RSL's business model, that could impact RSL's interests in a way that may not coincide with our corporate interests or the interests of other stockholders. Any such changes may diminish or eliminate entirely any benefits we expect to derive from our membership in the Roivant family of companies. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

RSL has the right to elect a certain number of directors to our board of directors.

RSL has the right to elect a certain number of Series A preferred stock directors ("Series A Preferred Directors") to our board of directors in accordance with our amended and restated certificate of incorporation (our "Certificate of Incorporation"). While the directors appointed by RSL are obligated to act in accordance with their applicable fiduciary duties, they may have equity or other interests in RSL and accordingly their interests may be aligned with RSL's interests, which may not always coincide with our corporate interests or the interests of our other stockholders. Until such time as Roivant holds less than 50% of the voting power of our outstanding shares of capital stock entitled to vote generally at an election of directors, the directors appointed by Roivant will be able to determine the outcome of all matters presented to the board of directors.

Our organizational and ownership structure may create significant conflicts of interests.

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of shares of our common stock, on the one hand, and RSL, on the other hand. Certain of our directors and employees have equity interests in RSL and accordingly, their interests may be aligned with RSL's interests, which may not always coincide with our corporate interests or the interests of our other stockholders. Further, our other stockholders may not have visibility into the RSL ownership of any of our directors or officers, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors' or officers' RSL ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with RSL, RSI and RSG. These entities and their stockholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of shares of our common stock. Any material transaction between us and RSL, RSI, RSG or any other affiliate of RSL is subject to our related party transaction policy, which requires prior approval of such transaction by our audit committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

The market price of shares of our common stock has been and is likely to be highly volatile, and you may lose some or all of your investment.

The market price of shares of our common stock has been and is likely to continue to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- results of clinical trials for batoclimab, IMVT-1402 or any future product candidate or those of our competitors;
- sales of shares of our common stock by us or sales or purchases of our common stock by our stockholders in the future, including RSL;
- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- any delay in filing a BLA or similar application for batoclimab, IMVT-1402 or any future product candidate and any adverse development or perceived adverse development with respect to the FDA or other foreign regulatory authority's review of that BLA or similar application, as the case may be;
- failure to successfully develop and commercialize batoclimab, IMVT-1402 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to batoclimab or any future product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for batoclimab, IMVT-1402 or any future product candidate or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;
- significant lawsuits, including patent or stockholder litigation and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of shares of our common stock;
- sales of a substantial number of shares of shares of our common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell shares;
- sales or purchases of shares of our common stock by our directors or officers subject to Section 16 of the Exchange Act;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands or the public fact of an investigation by a government agency, whether meritorious or not;
- the size of our public float;
- trading liquidity of shares of our common stock;
- investors' general perception of our company and our business;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. For example, we currently have one such putative class-action complaint brought against us. We could incur substantial costs defending this or similar lawsuits, as well as diversion of the time and attention of our management, any or all of which could seriously harm our business. Furthermore, the stock markets have recently experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including potentially worsening economic conditions, increased inflation and other adverse effects or developments, including political, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance. The market price of shares of our common stock may decline, and you may lose some or all of your investment.

We are subject to securities litigation, which is expensive and could divert management attention and adversely impact our business.

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, in February 2021, a securities class action complaint was filed against us, certain of our officers and a board member of HSAC. The case is still pending. This or any future securities litigation could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities. See Part II, Item 1. Legal Proceedings for more information.

We are a "controlled company" within the meaning of the applicable Nasdaq Global Select Market ("Nasdaq") listing rules and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.

RSL controls a majority of the voting power of our outstanding shares of common stock. As a result, we are a "controlled company" within the meaning of applicable Nasdaq listing rules. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company." In addition, for so long as the RSL designated directors control all matters presented to our board of directors for a vote, we will be a "controlled company." For so long as we remain a "controlled company," we may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We intend to use all or some of these exemptions. As a result, you may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements.

If securities or industry analysts do not publish research or reports about our business or publish negative reports about our business, our share price and trading volume could decline and has declined in the past upon downgrades of our common stock.

The trading market for shares of our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade shares of our common stock or change their opinion of shares of our common stock, our share price would likely decline, as happened in August 2021. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Because we do not anticipate paying any cash dividends on shares of our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on shares of our common 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. As a result, capital appreciation, if any, of shares of our common stock would be your sole source of gain on an investment in shares of our common stock for the foreseeable future.

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002 (the "Sarbanes Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to continue to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We qualify as a "smaller reporting company" within the meaning of the Exchange Act and are taking advantage of certain exemptions from disclosure requirements available to smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We qualify as a "smaller reporting company" as defined in the Exchange Act. We are taking advantage of certain of the scaled disclosures available to smaller reporting companies including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("Section 404"), presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and plan to present reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

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

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. To maintain compliance with Section 404, we engage 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 dedicate internal resources, engage outside consultants and refine and revise a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm, if an auditor attestation regarding our internal controls over financial reporting is applicable, will be able to conclude that our internal control over financial reporting is effective as required by Section 404.

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

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of shares of our common stock to decline.

We may become subject to unanticipated tax liabilities and higher effective tax rates.

Our wholly owned subsidiary, Immunovant Sciences Ltd. ("ISL"), is incorporated under the laws of Bermuda, where it is not subject to any income or withholding taxes. Further, ISL is centrally managed and controlled in the U.K., and, under current U. K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. for taxation purposes. Accordingly, we expect ISL to be subject to U.K. taxation on its income and gains and subject to the U.K.'s controlled foreign company rules, except where an exemption applies. ISL may be treated as a dual resident company for U.K. tax purposes. As a result, ISL's right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the U.K. could result in the imposition of further restrictions on ISL's right to claim U.K. tax reliefs. ISL may also become subject to income, withholding or other taxes in certain jurisdictions by reason of its activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that ISL is subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations.

The intended tax effects of our corporate structure and intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

Our wholly owned subsidiary, ISL, and our controlling stockholder, RSL, are incorporated under the laws of Bermuda and are tax residents of the U.K. Further, we currently have other subsidiaries that are domiciled in the U.K., Switzerland and the U.S. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between us, our parent company and our subsidiaries. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views for instance with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. Moreover, certain relevant tax, accounting and other laws have special application with respect to "affiliated," "combined" or similar groups, which may include RSL, ISL and their respective subsidiaries and which may impact the tax liabilities of the companies. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice or tax positions are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could harm our financial condition, results of operations and cash flows.

Changes in tax laws or our effective tax rate may reduce our net income in future periods.

New income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect us. Further, our tax position could be adversely impacted by changes in existing tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the U.K. and Switzerland), the U.S., Bermuda and other jurisdictions as well as being affected by certain international tax developments, including certain changes currently proposed by the Organization for Economic Co-operation and Development ("OECD") and their action plan on Base Erosion and Profit Shifting ("BEPS"), as well as other initiatives led by the OECD and the European Commission. For example, the OECD is leading work on proposals, commonly referred to as "BEPS 2.0", which, if implemented, would make important changes to the international tax system. These proposals are based on two "pillars", involving the allocation of taxing rights in respect of certain multinational enterprises above a fixed profit margin to the jurisdictions in which they carry on business (referred to as the Pillar One proposal) and imposing a minimum effective tax rate on certain multinational enterprises (referred to as the Pillar Two proposal). The E.U. has adopted a Council Directive requiring aspects of the Pillar Two proposal to be transposed into the national laws of E.U. Member States by December 31, 2023, and a number of other countries (including, the U.K. and Switzerland) are also planning to enact (or are in the process of enacting) such rules, which could increase our tax obligations in the countries where we do business.

Failure to manage the risks associated with international tax changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of our operations and our financial condition. In addition, changes to the U.S. Internal Revenue Code, U.S. Treasury Regulations or other U.S. Internal Revenue Service guidance thereunder could adversely affect our effective tax rate. For example, the recently enacted Inflation Reduction Act of 2022 includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including the jurisdictions in which profits are determined to be earned and taxed, the resolution of issues arising from any future tax audits with various tax authorities, changes in the valuation of our deferred tax assets and liabilities, increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions, changes in the taxation of stock-based compensation, changes in tax laws or the interpretation of such tax laws and changes in generally accepted accounting principles and challenges to the transfer pricing policies related to our structure.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

Under current U.S. federal income tax law, U.S. federal net operating loss, or NOLs, generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs is generally limited to 80% of taxable income. In addition, our research and development credit carryforwards in the U.S. will begin to expire in the fiscal year ending March 31, 2039. It is uncertain if and to what extent various states will conform to the current U.S. federal income tax law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage-point cumulative change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. It is possible that we have experienced one or more ownership changes in the past. In addition, we may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income (if we earned net taxable income) and any other pre-ownership change tax attributes may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our Certificate of Incorporation and amended and restated bylaws (our "Bylaws") may have the effect of delaying or preventing a change of control or changes in our management. Our Certificate of Incorporation and Bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- specify that the holder of our Series A preferred stock, RSL, has the right to appoint a certain number of Series A Preferred Directors to our board of directors;
- require that, from and after such time as we are no longer a "controlled company" within the meaning of Nasdaq rules, any action to be taken by our holders of common stock be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by the chairperson of our board of directors, our chief executive officer or our board of directors;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- provide that, subject to the rights of our Series A preferred stockholder, our directors may be removed only upon the vote of at least 66 2/3% of our outstanding shares of voting stock;
- require the approval of our board of directors or, from and after such time as we are no longer a "controlled company" within the meaning of Nasdaq rules, the holders of at least 66 2/3% of our outstanding shares of voting stock to amend our Bylaws and certain provisions of our Certificate of Incorporation;
- provide that the number of directors is set at seven and may only be changed by resolution of the board of directors, including a majority of Series A Preferred Directors then serving;
- prohibit cumulative voting in the election of directors; and
- provide that, subject to the rights of our Series A preferred stockholder, vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock and they could deter potential acquirers of our company, thereby reducing the likelihood that you would receive a premium for your shares of our common stock in an acquisition.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the U.S. as the exclusive forums for substantially all disputes between us and our stockholders, which will restrict our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law (the "DGCL"), our Certificate of Incorporation or our Bylaws; any action as to which DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our Certificate of Incorporation. This may require significant additional costs and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive forum provision in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We maintain our headquarters at 320 West 37th Street, New York, New York 10018 and also conduct business operations at 1000 Park Forty Plaza, Suite 210, Durham, North Carolina 27713. ISL's registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda and ISL's principal office is located at 7th Floor, 50 Broadway, London, SW1H 0DB. ISG maintains its headquarters at Viaduktstrasse 8, 4051 Basel, Switzerland. In June 2020, we entered into two sublease agreements for our headquarters in New York, New York which expire in February 2024 and April 2024, respectively.

We could add new facilities or expand our existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

From time to time, we have been and may become involved in legal or regulatory proceedings arising in the ordinary course of our business. We do not currently, however, expect such legal proceedings to have a material adverse effect on our business, operating results or financial condition. However, depending on the nature and timing of a given dispute, an unfavorable resolution could materially affect our current or future results of operations or cash flows.

For a description of our legal proceedings, see Part II, Item 8. Financial Statements and Supplementary Data, Note 10 – Commitments and Contingencies for more information.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock currently trades on The Nasdaq Global Select Market under the ticker symbol "IMVT".

Holders of Record

Continental Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on May 17, 2023, we had three holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any dividends on shares of our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

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, results of operations, and cash flows together with the audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our fiscal year ends on March 31.

Overview

We are a clinical-stage biopharmaceutical company dedicated to enabling normal lives for people with autoimmune diseases. Our innovative product pipeline includes batoclimab, formerly referred to as IMVT-1401, and IMVT-1402, both of which are novel, fully human monoclonal antibodies that target the neonatal fragment crystallizable receptor ("FcRn"). Batoclimab and IMVT-1402 are the result of a multi-step, multi-year research program conducted by us and HanAll Biopharma Co., Ltd., ("HanAll") to design highly potent anti-FcRn antibodies that may be optimized as a simple, subcutaneous injection with dosing that we believe can be tailored based on disease severity and stage.

Batoclimab, our first product candidate, has been dosed in small volumes (e.g., 2 mL) and with a 27-gauge needle, while still generating therapeutically relevant pharmacodynamic activity, important attributes that we believe will drive patient preference and market adoption. In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce immunoglobulin G ("IgG") antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in these disease areas.

Likewise, IMVT-1402, our second product candidate, has also been observed in nonclinical studies to reduce IgG antibody levels. Importantly, based on the anticipated human effective dose levels, the human equivalent doses of IMVT-1402 have demonstrated minimal or no impact on levels of albumin and low-density lipoprotein ("LDL") cholesterol in cynomolgus monkeys. This is a key attribute for IMVT-1402, which we believe could potentially allow its use as a treatment of chronic conditions requiring maintenance doses that achieve high degrees of IgG suppression. We are developing batoclimab and IMVT-1402 in autoimmune diseases for which there is robust evidence that pathogenic IgG antibodies drive disease manifestation and for which reduction of IgG antibodies should lead to clinical benefit.

Based on third-party patient prevalence estimates, for the 22 indications that have been announced by multiple companies for clinical development with anti-FcRn assets, we estimate the total potential opportunity for our FcRn franchise to be greater than two million patients in the U.S. and Europe (includes all European Union countries, Norway, Lichtenstein, Iceland, the United Kingdom, and Switzerland). We are currently developing batoclimab for myasthenia gravis ("MG"), thyroid eye disease ("TED"), chronic inflammatory demyelinating polyneuropathy ("CIDP") and Graves' disease ("GD"). As a result of our rational design and current outlook on potential opportunities, we believe that batoclimab and IMVT-1402, if developed and approved for commercial sale, would be differentiated from currently available treatments for advanced IgG-mediated autoimmune diseases.

To the extent we choose to develop batoclimab and IMVT-1402 as potential treatments for certain of these and other rare diseases, we plan to seek orphan drug designation in the U.S. and Europe, where applicable. Such designations would primarily provide financial and exclusivity incentives intended to make the development of orphan drugs financially viable. In August 2022, we were granted orphan drug designation from the European Commission for batoclimab for the treatment of MG. Previously, batoclimab received orphan drug designation by the U.S. Food and Drug Administration ("FDA") for the treatment of MG. We plan to seek orphan drug designation in the U.S. and Europe for batoclimab and/or IMVT-1402 in other indications where there is a medically plausible basis for batoclimab and/or IMVT-1402's use.

Recent Developments in Our Clinical Programs

For IMVT-1402, our next generation FcRn inhibitor, in the second quarter of calendar year 2023, the FDA cleared our IND application for IMVT-1402 and we initiated a Phase 1 clinical trial in in healthy volunteers in New Zealand after approval of the CTA by the regulatory authority, MEDSAFE. Initial data from single-ascending dose cohorts are expected in August or September 2023, while initial data from multiple-ascending dose cohorts are expected in October or November 2023.

For batoclimab, in the second quarter of calendar year 2023, we initiated a proof-of-concept Phase 2 clinical trial in GD in Germany. We expect initial results from this trial to be available in the fourth quarter of calendar year 2023.

In the fourth quarter of calendar year 2022, we initiated a pivotal Phase 2b trial of batoclimab as a treatment for CIDP. We expect initial data from the open-label period of this trial (where one of two blinded doses of batoclimab are delivered) to be available in the first half of calendar year 2024. Also in the fourth quarter of calendar year 2022, we initiated our Phase 3 clinical program to evaluate batoclimab as a treatment for TED. We expect top-line results from this program to be available in the first half of calendar year 2025. In the second quarter of calendar year 2022, we initiated our Phase 3 pivotal trial of batoclimab as a treatment for MG. We expect top-line data from this trial to be available in the second half of calendar year 2024.

Macroeconomic Considerations

Unfavorable conditions in the economy in the U.S., Canada and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including the COVID-19 pandemic, rising inflation, the U.S. Federal Reserve raising interest rates, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and the Russia-Ukraine war, have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

For additional information about risks and uncertainties related to the macroeconomic that may impact our business, financial condition and results of operations, see the section titled “Risk Factors” under Part I, Item 1A in this Annual Report.

Our Key Agreements

License Agreement with HanAll (“HanAll Agreement”)

In December 2017, Roivant Sciences GmbH (“RSG”) entered into the HanAll Agreement. Under the HanAll Agreement, RSG, a wholly owned subsidiary of Roivant Sciences Ltd. (“RSL”), received (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to develop, import and use the antibody referred to as batoclimab and certain back-up and next-generation antibodies (including IMVT-1402), and products containing such antibodies, and to commercialize such products, in the U.S., Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America (the “Licensed Territory”), for all human and animal uses, during the term of the agreement.

In December 2018, we obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to batoclimab and IMVT-1402 in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and our wholly owned subsidiary, Immunovant Sciences GmbH (“ISG”), for an aggregate purchase price of $37.8 million.

Under the HanAll Agreement, the parties may choose to collaborate on a research program directed to the research and development of next generation FcRn inhibitors in accordance with an agreed plan and budget. Each party has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory. We are obligated to reimburse HanAll for half of such research and development expenses incurred by HanAll, up to an aggregate reimbursement amount of $20.0 million. Intellectual property created by HanAll pursuant to this research program will be included in our license; intellectual property created by us pursuant to this research program will be included in HanAll’s license. As of March 31, 2023, we do not have any additional amounts payable to HanAll for research and development costs incurred and reported to us pursuant to the HanAll Agreement. As of March 31, 2022, $0.4 million was payable to HanAll for research and development costs incurred and reported to us pursuant to the HanAll Agreement.

In the fourth quarter of calendar year 2022, we achieved our second development and regulatory milestone under the HanAll Agreement of $10.0 million, which was paid in the first quarter of calendar year 2023 and recorded as acquired in-process research and development expenses in the accompanying consolidated statement of operations for the year ended March 31, 2023. We will be responsible for future contingent payments and royalties, including up to an aggregate of $432.5 million (after an aggregate amount of $20.0 million of milestone achievements as of March 31, 2023) upon the achievement of certain development, regulatory and sales milestone events. We are also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens percentage of net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of: (A) the date on which the last valid claim of the licensed patents expire, (B) the date on which the data or market exclusivity expires or (C) 11 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country.

Product Service Agreement and Master Services Agreement

On November 17, 2021, Immunovant, Inc.'s wholly owned subsidiary, ISG, entered into a Product Service Agreement, ("PSA") with Samsung Biologics Co., Ltd., ("Samsung"), pursuant to which Samsung will manufacture and supply us with batoclimab drug substance for commercial, if approved, sale and perform other manufacturing-related services with respect to batoclimab. We previously entered in a Master Services Agreement, ("MSA") with Samsung, dated April 30, 2021, which governs certain terms of our relationship with Samsung. Upon execution of the PSA, we committed to purchase process performance qualification batches of batoclimab and pre-approval inspection batches of batoclimab which may be used for regulatory submissions and, pending regulatory approval, commercial sale. In addition to these, we are obligated to purchase additional batches of batoclimab in the four-year period of 2026 through 2029.

The PSA will continue until the later of December 31, 2029 or the completion of the services thereunder, unless the PSA is terminated earlier. If we make a final decision to stop all development of batoclimab and all attempts to obtain regulatory approval for batoclimab, then we will have the right to terminate the PSA with 30 days' written notice to Samsung as long as such notice is provided no later than January 2024. Upon such termination of the PSA, we will pay Samsung for non-cancellable service fees and costs that Samsung incurs and for all batches of batoclimab scheduled to be manufactured during the two-year period following such termination. In addition, either party may terminate the PSA on account of (i) the other party's material breach of the PSA that is not cured within a specified period after the termination notice, (ii) the other party's insolvency or bankruptcy, or (iii) certain force majeure events.

The remaining minimum purchase commitment related to this agreement was estimated to be approximately $33.3 million as of March 31, 2023. During the year ended March 31, 2023, we recorded $19.8 million of research and development expenses related to the PSA, of which $2.7 million was paid as of March 31, 2023.

Related Party Transactions

For a description of our transactions under agreements with related parties, refer to Part II, Item 8. Financial Statements and Supplementary Data, Note 5 – Related Party Transactions.

Financial Operations Overview

Revenue

We have not generated any revenue and have incurred significant operating losses since inception, and we do not expect to generate any revenue from the sale of any products unless or until we obtain regulatory approval of and commercialize batoclimab, IMVT-1402 or any future product candidates. Our ability to generate revenue sufficient to achieve profitability will depend completely on the successful development and eventual commercialization of batoclimab, IMVT-1402 and any future product candidates.

Research and Development Expenses

We have been primarily engaged in preparing for and conducting clinical trials. Research and development expenses include program-specific costs, as well as unallocated costs, and are net of costs reimbursable to the Company pursuant to cost-sharing arrangements with third parties.

Program-specific costs include direct third-party costs, which include expenses incurred under agreements with contract research organizations and the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, and any other third-party expenses directly attributable to the development of the product candidates. Program-specific costs also include contract manufacturing costs in connection with producing materials for use in conducting preclinical and clinical studies, including under our agreement with Samsung, to the extent they can be allocated to a specific program.

Unallocated costs include:

- personnel-related expenses for research and development personnel, which includes employee-related expenses such as salaries, benefits and other staff-related costs;
- stock-based compensation expenses for research and development personnel;
- costs allocated to us under our services agreements with RSI and RSG (the "Services Agreements"); and
- other expenses, which include the cost of consultants who assist with our research and development and costs related to contract manufacturing, but are not allocated to a specific program.

Research and development activities will continue to be central to our business model. We expect our research and development expenses to increase in the short term as we continue our ongoing Phase 3 pivotal trial of batoclimab as a treatment for MG, our Phase 3 clinical program to evaluate batoclimab for the treatment of TED and a pivotal Phase 2b trial of batoclimab as a treatment for CIDP. In addition, in the second quarter of calendar year 2023, the FDA cleared our IND application for IMVT-1402 and we initiated a Phase 1 clinical trial of IMVT-1402 in healthy volunteers in New Zealand after approval of the CTA by the regulatory authority, MEDSAFE. Finally, in the second quarter of calendar year 2023, we initiated a proof-of-concept Phase 2 clinical trial in GD with batoclimab in Germany. Our research and development expenses are expected to continue to increase over the next several years as we hire personnel and our compensation costs increase, commence additional clinical trials for batoclimab, increase manufacturing of batoclimab and IMVT-1402 substance and prepare to seek regulatory approval for our product candidates. It is not possible to determine with certainty the duration and completion costs of any clinical trial we may conduct.

The duration, costs and timing of clinical trials of batoclimab, IMVT-1402 and any future product candidates will depend on a variety of factors that include, but are not limited to:

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals;
- the potential impact of macroeconomic events, including the COVID-19 pandemic, rising inflation, the U.S. Federal Reserve raising interest rates, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and the Russia-Ukraine war;
- the efficacy and safety profile of the product candidate; and
- the cost of manufacturing.

In addition, the probability of success for batoclimab and IMVT-1402 will depend on numerous factors, including our product's efficacy, safety, ease of use, competition, manufacturing capability and commercial viability.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expenses include payments made or due upon the achievement of certain development and regulatory milestones under the HanAll Agreement.

General and Administrative Expenses

General and administrative expenses consist primarily of employee salaries and related benefits, stock-based compensation for general and administrative personnel, legal and accounting fees, consulting services, costs allocated under the Services Agreements and other operating costs relating to corporate matters and daily operations.

We anticipate that our general and administrative expenses will continue to increase in the future to support our continued research and development activities. These increases will likely include patent-related costs, including legal and professional fees for filing, prosecution and maintenance of our product candidates, increased costs related to the hiring of additional personnel and fees to outside consultants for professional services. In addition, if either batoclimab or IMVT-1402 obtains regulatory approval, we expect that we would incur significant additional expenses associated with further building medical affairs and commercial teams.

Results of Operations

Comparison of the Years Ended March 31, 2023 and 2022

The following table sets forth our results of operations for the years ended March 31, 2023 and 2022 (in thousands):

	Years Ended March 31,		Change
	2023	2022	$
Operating expenses:			
Research and development	$ 160,257	$ 101,808	$ 58,449
Acquired in-process research and development	10,000	—	10,000
General and administrative	48,019	54,225	(6,206)
Total operating expenses	218,276	156,033	62,243
Interest income, net	(7,578)	—	(7,578)
Other expense	253	781	(528)
Loss before provision (benefit) for income taxes	(210,951)	(156,814)	(54,137)
Provision (benefit) for income taxes	9	(84)	93
Net loss	**$ (210,960)**	**$ (156,730)**	**$ (54,230)**

Research and Development Expenses

The following table summarizes the year-over-year changes in research and development expenses for the years ended March 31, 2023 and 2022 (in thousands):

	Years Ended March 31,		Change
	2023	2022*	$
Batoclimab - Program-specific costs:			
Neurology diseases	$ 52,100	$ 14,341	$ 37,759
Endocrine diseases	26,377	20,818	5,559
Hematology diseases	—	6,935	(6,935)
Total Batoclimab - Program-specific costs	78,477	42,094	36,383
IMVT-1402	10,270	9,915	355
Unallocated costs:			
Personnel-related expenses including stock-based compensation	49,767	33,905	15,862
Other	21,743	15,894	5,849
Total research and development expenses	**$ 160,257**	**$ 101,808**	**$ 58,449**

* Certain prior year amounts have been reclassified to conform to current year presentation.

Research and development expenses increased by $58.4 million, from $101.8 million for the year ended March 31, 2022 to $160.3 million for the year ended March 31, 2023.

Batoclimab program-specific research and development costs increased by $36.4 million, from $42.1 million for the year ended March 31, 2023 to $78.5 million for the year ended March 31, 2023. This increase reflected $19.1 million of upfront and start-up costs related to our Phase 2b trial of batoclimab as a treatment for CIDP and $18.7 million of upfront and start-up costs related to our Phase 3 trial for batoclimab as a treatment for MG, including higher contract manufacturing costs for process development and drug substance manufacturing in preparation for process performance qualification activities for each indication. Also contributing to the increase were $4.8 million of start-up costs for TED due to the initiation of our Phase 3 clinical program. Partially offsetting these increases were lower contract manufacturing costs and clinical activities of $6.9 million in Warm Autoimmune Hemolytic Anemia, primarily as a result of our strategic decision not to pursue this indication for batoclimab.

For the year ended March 31, 2023 and 2022, we incurred $10.3 and $9.9 million, respectively, of research and development costs related to the development of IMVT-1402, primarily related to pre-clinical studies and contract manufacturing costs.

Unallocated research and development costs increased by $21.7 million, from $49.8 million for the year ended March 31, 2022 to $71.5 million for the year ended March 31, 2023. This increase reflected higher personnel-related expenses of $15.9 million, primarily reflecting higher headcount and enhancement of our capabilities to support our strategic objectives as we resumed our clinical activities and evaluated potential new indications. Also contributing to the increase were higher costs related to cross-indication clinical studies and clinical research costs of $5.8 million, primarily reflecting activities to advance the clinical development of batoclimab and IMVT-1402 in current and potentially new indications.

Acquired In-Process Research and Development Expenses for the Years Ended March 31, 2023 and 2022

During the year ended March 31, 2023, acquired in-process research and development expenses were $10.0 million related to the achievement of a development and regulatory milestone for batoclimab in MG as specified in the HanAll Agreement. There were no acquired in-process research and development expenses for year ended March 31, 2022.

General and Administrative Expenses

General and administrative expenses decreased by $6.2 million, from $54.2 million for the year ended March 31, 2022 to $48.0 million for the year ended March 31, 2023. Lower financial advisory, legal and other professional fees, as well as personnel-related expenses were partially offset by higher market research and information technology costs.

Liquidity and Capital Resources

Sources of Liquidity

We had cash and cash equivalents of $376.5 million and $493.8 million as of March 31, 2023 and 2022, respectively. For the years ended March 31, 2023 and 2022, we had net losses of $211.0 million and $156.7 million, respectively. We expect to continue to incur significant expenses and increasing operating losses at least for the next several years. We have never generated any revenue and we do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for batoclimab, IMVT-1402 or any future product candidate.

To date, we have financed our operations primarily from equity offerings and the sale of convertible promissory notes. Until such time, if ever, as we can generate substantial product revenue from sales of batoclimab, IMVT-1402 or any future product candidate, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the continuing disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide, including disruptions resulting from the ongoing military conflict between Russia and Ukraine, the COVID-19 pandemic, decades-high inflation, rising interest rates and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures.

We do not currently have any committed external source of funds. Debt financing and preferred equity financing, if available, 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.

In January 2021, we filed a shelf registration statement on Form S-3 with the SEC which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $900.0 million of our common stock, of which $150.0 million may be issued and sold pursuant to an at-the-market ("ATM") offering program for sales of our common stock under a sales agreement with SVB Leerink LLC, subject to certain conditions as specified in the sales agreement. We agreed to pay SVB Leerink up to 3% of the gross proceeds sold through the sale agreement. Our common stock would be sold at prevailing market prices at the time of the sale and, as a result, prices may vary. We have not issued or sold any securities pursuant to the ATM offering program.

In October 2022, we completed an underwritten offering of 12,500,000 shares of our common stock (including 416,667 shares of common stock purchased by RSL) at an offering price of $6.00 per share, for net proceeds to us of approximately $70.2 million after deducting underwriting discounts and commissions and offering expenses.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended March 31, 2023 and 2022 (in thousands):

	Years Ended March 31,	
	2023	2022
Net cash used in operating activities	$ (188,193)	$ (106,112)
Net cash used in investing activities	(197)	(254)
Net cash provided by financing activities	70,885	200,129

Operating Activities

For the year ended March 31, 2023, $188.2 million of cash was used in operating activities, primarily reflecting a net loss from operations of $211.0 million and a net change in operating assets and liabilities of $10.8 million, partially offset by non-cash charges of $33.6 million. The non-cash charges consisted mainly of stock-based compensation of $32.3 million. The change in our operating assets and liabilities was primarily due to a decrease of $17.1 million in accounts payable driven by the timing of payments related to contract manufacturing costs. The change in operating assets and liabilities also reflected $20.1 million of higher prepaid expenses and other current assets, driven by payments related to clinical research and contract manufacturing activities. These changes were partially offset by an increase in accrued expenses of $15.6 million primarily related to contract manufacturing costs, and a decrease in accounts receivable of $11.8 million reflecting the collection of amounts owed to us under research and development cost-sharing arrangements with third parties.

For the year ended March 31, 2022, $106.1 million of cash was used in operating activities, primarily reflecting a net loss from operations of $156.7 million, partially offset by non-cash charges of $35.5 million and a net change in operating assets and liabilities of $15.1 million. The non-cash charges consisted mainly of stock-based compensation of $34.2 million, reflecting the higher headcount and incentive equity awards as compared with the prior year. The change in our operating assets and liabilities was primarily due to an increase of $25.7 million in accounts payable and accrued expenses, driven by the timing and level of payments related to contract manufacturing and other research and development costs. The change in operating assets and liabilities also reflected $2.1 million of lower prepaid expenses and other current assets, driven by the timing of payments related to clinical research and contract manufacturing activities. Partially offsetting these changes was an increase in accounts receivable of $11.6 million reflecting amounts owed to us under research and development cost-sharing arrangements with a third party.

Investing Activities

For the years ended March 31, 2023 and 2022, cash used in investing activities was related to the purchase of computer equipment.

Financing Activities

For the year ended March 31, 2023, $70.9 million of cash provided by financing activities primarily consisted of proceeds from our October 2022 underwritten offering of approximately $70.2 million, after deducting underwriting discounts and commissions and offering expenses. Cash provided by financing activities also reflected $0.7 million of proceeds from the exercise of stock options.

For the year ended March 31, 2022, $200.1 million of cash provided by financing activities primarily consisted of $200.0 million in proceeds from the sale of 17,021,276 shares of common stock to RSL, at a per share price of $11.75 in August 2021.

Material Cash Requirements

Our primary uses of capital have been, and we expect will continue to be, for advancing our clinical and preclinical development programs. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our net losses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, timing of batoclimab or IMVT-1402 manufacturing, HanAll milestone payments and our expenditures on other research and development activities.

Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of product candidates.

Our short-term and long-term material cash requirements as of March 31, 2023 primarily consisted of those related to our clinical trials and clinical development activities, which we expect to fund primarily with our existing cash balance. Our most significant cash requirements are described below:

Product Service Agreement and Master Services Agreement

During the year ended March 31, 2022, we entered into an agreement with Samsung to manufacture a certain quantity of batoclimab drug substance for, among other things, commercial sale, if approved. In connection with this agreement, we have a remaining minimum long-term obligation to Samsung of approximately $33.3 million, of which $17.5 million, $0.3 million and $15.5 million is expected to be paid during the fiscal years ending March 31, 2024, 2025 and 2026, respectively. See Part II, Item 8. Financial Statements and Supplementary Data, Note 3 – Material Agreements for additional details.

HanAll Agreement

Potential future payments due under the HanAll Agreement are contingent upon future events. As of March 31, 2023, the aggregate maximum amount of milestone payments we could be required to make under the HanAll Agreement is $432.5 million (after an aggregate amount of $20.0 million of milestone achievements as of March 31, 2023) upon the achievement of certain development, regulatory and sales milestone events. In the fourth quarter of calendar year 2022, we achieved our second development and regulatory milestone under the HanAll Agreement and made a $10.0 million milestone payment in the first quarter of calendar year 2023 in accordance with the terms of the agreement.

We are also required to reimburse HanAll for half of budgeted research and development costs incurred by HanAll with respect to batoclimab and IMVT-1402, up to an aggregate of $20.0 million.

Lease Agreements

In June 2020, we entered into two sublease agreements with RSI, for the two floors of the building that serves as our headquarters in New York. The subleases will expire on February 27, 2024 and April 29, 2024, respectively, and have scheduled rent increases each year.

In March 2022, we entered into a lease agreement with an unrelated party for office space in a building in North Carolina. The lease will expire on March 31, 2024 and has scheduled rent increases each year. The lease agreement includes an option at the Company’s election to renew for an additional two years.

Our future minimum lease payments as of March 31, 2023 totaled $1.2 million related to short-term lease liabilities, and less than $0.1 million related to long-term lease liabilities.

For more information on our leases, see Part II, Item 8. Financial Statements and Supplementary Data, Note 9 – Leases.

Outlook

Based on our existing cash balance as of March 31, 2023 of $376.5 million, our research and development plans and our timing expectations related to our development programs for batoclimab and IMVT-1402, we expect to be able to fund our operating expenses and capital expenditure requirements into the second half of calendar year 2025. However, we have based this estimate on our current operating plan and assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Except as discussed above, we did not have any other ongoing material contractual obligations for which cash flows were fixed and determinable. We expect to enter into other commitments as the business further develops. In the normal course of business, we enter into agreements with CROs for clinical trials and with vendors for nonclinical studies, manufacturing and other services and products for operating purposes, which agreements are generally cancellable by us at any time, subject to payment of remaining obligations under binding purchase orders and, in certain cases, nominal early-termination fees. These commitments are not deemed significant. There are certain contracts wherein we have a minimum purchase commitment, however, most of it is due and payable within one year.

We anticipate that our short-term and long-term future capital requirements will increase substantially as we:

- fund our clinical development programs;
- launch any potential Phase 2 proof-of-concept studies of batoclimab or IMVT-1402 in additional indications;
- increase manufacturing of batoclimab and IMVT-1402 substance to support clinical trials;
- achieve milestones under our agreements with third parties, including the HanAll Agreement, that will require us to make substantial payments to those parties;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- commence the number of clinical trials required for approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to identify, acquire, develop and commercialize additional product candidates;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval; and
- incur insurance, legal and other regulatory compliance expenses to operate as a public company.

Our primary use of cash is to fund our clinical trials and clinical development activities. Our current funds will not be sufficient to enable us to complete all necessary development and, if approved, commercially launch batoclimab or IMVT-1402. We anticipate that we will continue to incur net losses for the foreseeable future.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet, and the reported amounts of expenses during the reporting period. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting estimates as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in "Note 2 — Summary of Significant Accounting Policies" to our consolidated financial statements in Part II, Item 8 of this Annual Report, we believe the following critical accounting estimate used in the preparation of our consolidated financial statements requires significant estimates and judgments. We did not make any material changes to these assumptions for the year ended March 31, 2023. We do not expect any material changes in the near term to the underlying assumptions during the year ended March 31, 2023.

Research and Development and Acquired In-Process Research and Development Expenses

Research and development costs with no alternative future use are expensed as incurred. We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by contract research organizations. In making these estimates, we consider various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as acquired in-process research and development expenses. Research and development costs are charged to expense when incurred and primarily consist of employee compensation and expenses from third parties who conduct research and development activities (including manufacturing) on our behalf.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Under SEC rules and regulations, because we are considered to be a "smaller reporting company", we are not required to provide the information required by this item in this report.

Item 8. Financial Statements and Supplementary Data

Immunovant, Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Immunovant, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Immunovant, Inc. (the Company) as of March 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended March 31, 2023, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 account or disclosure to which it relates.

Clinical Trial Accrual

Description of the Matter	As discussed in Note 2 to the consolidated financial statements, the Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by contract research organizations. In making these estimates, the Company considers various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment. Auditing the Company's accrual for clinical trial costs is especially complex due to the fact that information necessary to estimate the accruals is accumulated from clinical research organizations and the Company's assessment of that information is subject to variability and uncertainty. In addition, in certain circumstances, the determination of the nature and amount of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing does not correspond to the level of services provided and there may be delays in invoicing from clinical study sites and other vendors.
How We Addressed the Matter in Our Audit	We obtained an understanding and evaluated the design of internal controls that addressed the identified risks related to the information used in the Company's process for recording clinical trial accruals. To test the clinical trial accrual, our audit procedures included, among others, reading a sample of the Company's agreements with the service providers to understand key financial and contractual terms and testing the accuracy and completeness of the underlying data used in the accrual computations. We also evaluated management's estimates of the vendor's progress for a sample of clinical trials by making direct inquiries of the Company's operations personnel overseeing the clinical trials and obtaining information directly from certain service providers about the service providers' estimate of costs that had been incurred through March 31, 2023. We assessed the historical accuracy of the clinical trial accrual and analyzed the underlying data to evaluate changes in the clinical trial accrual that would result from reasonable changes in the underlying data. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

/s/ Ernst & Young LLP

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

Iselin, New Jersey

May 22, 2023

IMMUNOVANT, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	March 31, 2023	March 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 376,532	$ 493,817
Accounts receivable	700	12,229
Prepaid expenses and other current assets	26,916	6,253
Income tax receivable	185	632
Total current assets	404,333	512,931
Operating lease right-of-use assets	1,172	2,303
Property and equipment, net	333	330
Total assets	**$ 405,838**	**$ 515,564**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,353	$ 18,629
Accrued expenses	40,421	24,575
Current portion of operating lease liabilities	1,173	1,145
Due to Roivant Sciences Ltd.	350	171
Total current liabilities	43,297	44,520
Operating lease liabilities, net of current portion	47	1,219
Total liabilities	43,344	45,739
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Series A preferred stock, par value $0.0001 per share, 10,000 shares authorized, issued and outstanding at March 31, 2023 and March 31, 2022	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and March 31, 2022	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 130,329,863 shares issued and outstanding at March 31, 2023 and 500,000,000 shares authorized, 116,482,899 shares issued and outstanding at March 31, 2022	13	12
Additional paid-in capital	927,976	824,796
Accumulated other comprehensive income	852	404
Accumulated deficit	(566,347)	(355,387)
Total stockholders' equity	362,494	469,825
Total liabilities and stockholders' equity	**$ 405,838**	**$ 515,564**

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

IMMUNOVANT, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Years Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 160,257	$ 101,808
Acquired in-process research and development	10,000	—
General and administrative	48,019	54,225
Total operating expenses	218,276	156,033
Interest income, net	(7,578)	—
Other expense	253	781
Loss before provision (benefit) for income taxes	(210,951)	(156,814)
Provision (benefit) for income taxes	9	(84)
Net loss	**$ (210,960)**	**$ (156,730)**
Net loss per common share — basic and diluted	$ (1.71)	$ (1.43)
Weighted average common shares outstanding — basic and diluted	123,075,329	109,679,256

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

IMMUNOVANT, INC.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Years Ended March 31,	
	2023	**2022**
Net loss	$ (210,960)	$ (156,730)
Other comprehensive income:		
Foreign currency translation adjustments	448	702
Total other comprehensive income	448	702
Comprehensive loss	**$ (210,512)**	**$ (156,028)**

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

IMMUNOVANT, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except share data)

	Series A preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at March 31, 2021	**10,000**	**$ —**	**97,971,243**	**$ 10**	**$ 590,425**	**$ (298)**	**$ (198,657)**	**$ 391,480**
Issuance of common stock upon investment by Roivant Sciences Ltd.	—	—	17,021,276	2	199,998	—	—	200,000
Restricted stock units vested and settled	—	—	1,490,380	—	—	—	—	—
Capital contribution – stock-based compensation	—	—	—	—	1,101	—	—	1,101
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	129	—	—	129
Stock-based compensation	—	—	—	—	33,143	—	—	33,143
Foreign currency translation adjustments	—	—	—	—	—	702	—	702
Net loss	—	—	—	—	—	—	(156,730)	(156,730)
Balance at March 31, 2022	**10,000**	**$ —**	**116,482,899**	**$ 12**	**$ 824,796**	**$ 404**	**$ (355,387)**	**$ 469,825**
Issuance of common stock upon underwritten offering	—	—	12,500,000	1	70,227	—	—	70,228
Stock options exercised and restricted stock units vested and settled	—	—	1,346,964	—	657	—	—	657
Capital contribution – stock-based compensation	—	—	—	—	330	—	—	330
Stock-based compensation	—	—	—	—	31,966	—	—	31,966
Foreign currency translation adjustments	—	—	—	—	—	448	—	448
Net loss	—	—	—	—	—	—	(210,960)	(210,960)
Balance at March 31, 2023	**10,000**	**$ —**	**130,329,863**	**$ 13**	**$ 927,976**	**$ 852**	**$ (566,347)**	**$ 362,494**

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

IMMUNOVANT, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Years Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (210,960)	$ (156,730)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	32,296	34,244
Depreciation on property and equipment	193	126
Non-cash lease expense	1,131	1,106
Changes in operating assets and liabilities:		
Accounts receivable	11,764	(11,633)
Prepaid expenses and other current assets	(20,533)	2,137
Income tax receivable	461	(85)
Accounts payable	(17,124)	16,254
Accrued expenses	15,568	9,472
Operating lease liabilities	(1,145)	(1,179)
Due to Roivant Sciences Ltd.	156	176
Net cash used in operating activities	**(188,193)**	**(106,112)**
Cash flows from investing activities		
Purchases of property and equipment	(197)	(254)
Net cash used in investing activities	**(197)**	**(254)**
Cash flows from financing activities		
Proceeds from issuance of common stock upon underwritten offering	70,500	—
Payment of offering costs	(272)	—
Proceeds from stock options exercised	657	—
Proceeds from investment by Roivant Sciences Ltd.	—	200,000
Capital contributions	—	129
Net cash provided by financing activities	**70,885**	**200,129**
Effect of exchange rate changes on cash and cash equivalents	**220**	**(92)**
Net change in cash and cash equivalents	(117,285)	93,671
Cash and cash equivalents – beginning of period	493,817	400,146
Cash and cash equivalents – end of period	**$ 376,532**	**$ 493,817**
Non-cash operating activity		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	**$ —**	**$ 127**

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

IMMUNOVANT, INC.
Notes to Consolidated Financial Statements

Note 1 — Organization and Nature of Business

[A] Description of Business

Immunovant, Inc. (together with its wholly owned subsidiaries, the "Company" or "Immunovant") is a clinical-stage biopharmaceutical company dedicated to enabling normal lives for people with autoimmune diseases. The Company's innovative product pipeline includes batoclimab, formerly referred to as IMVT-1401, and IMVT-1402, both of which are novel, fully human, monoclonal antibodies that target the neonatal fragment crystallizable receptor ("FcRn"). Designed to be optimized as a simple, subcutaneous injection with dosing that the Company believes can be tailored based on disease severity and stage, batoclimab has been observed to reduce immunoglobulin G ("IgG") antibodies that cause inflammation and disease. IMVT-1402 has also demonstrated deep IgG antibody reduction in animal studies.

Immunovant, Inc.'s wholly owned subsidiaries include Immunovant Treasury Inc. a Delaware corporation based in the United States ("U.S") and Immunovant Sciences Ltd. ("ISL"), a Bermuda exempted limited company. Incorporated by ISL are its wholly owned subsidiaries, Immunovant Sciences Holdings Ltd. ("ISHL"), a private limited company incorporated in the United Kingdom under the laws of England and Wales, IMVT Corporation, a Delaware corporation based in the U.S., and Immunovant Sciences GmbH ("ISG"), a limited liability company formed under the laws of Switzerland. ISG holds all of the Company's intellectual property rights.

The Company has determined that it has one operating and reporting segment.

[B] Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of March 31, 2023, the Company's cash and cash equivalents totaled $376.5 million and its accumulated deficit was $566.3 million.

The Company has not generated any revenues to date and does not anticipate generating any revenues unless and until it successfully completes development and obtains regulatory approval for batoclimab, IMVT-1402 or any future product candidate. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates. The Company currently expects that its existing cash and cash equivalents as of March 31, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date these consolidated financial statements are issued.

Note 2 — Summary of Significant Accounting Policies

[A] Basis of Presentation

The Company's fiscal year ends on March 31, and its first three fiscal quarters end on June 30, September 30, and December 31. The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

[B] Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based compensation, litigation accruals, clinical trial accruals, operating leases, research and development costs and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be 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. Actual results could differ from those estimates.

Additionally, the Company assessed the impact that the COVID-19 pandemic, geopolitical tensions and global slowdown of economic activity, decades-high inflation, rising interest rates and a potential recession in the U.S. has had on its operations and financial results as of March 31, 2023 and through the issuance of this report. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact that these uncertainties may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

[C] Risks and Uncertainties

The Company is subject to risks common to early-stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to clinical effectiveness of the product, commercialization of products, regulatory approvals, dependence on key products, key personnel and third-party service providers such as contract research organizations ("CROs"), protection of intellectual property rights and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

[D] Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents. As of March 31, 2023, the cash balances are kept in banking institutions that the Company believes are of high credit quality and are in excess of federally insured levels. The Company maintains its cash with accredited financial institutions and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses on its cash.

[E] Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. At March 31, 2023, cash and cash equivalents included $346.2 million of money market funds invested in high-quality, short-term securities that are issued and guaranteed by the U.S. government and its agencies that are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. There were no cash equivalents as of March 31, 2022.

[F] Property and Equipment

Property and equipment, consisting of computers, is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Depreciation is recorded using the straight-line method over the estimated useful life of three years. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations.

[G] Impairment of Long-lived Assets

Long-lived assets, such as right-of-use assets due to operating leases, property and equipment, are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by an asset to the carrying value of the asset. If the carrying value of the long-lived asset is not recoverable on an undiscounted cash flow basis, impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary.

[H] Contingencies

The Company, from time to time, has been and may be a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible. Legal defense costs associated with loss contingencies are expensed in the period incurred. Additionally, the Company records a receivable for rights to insurance recoveries, limited to the extent of incurred or probable losses, when such recoveries have been agreed to with third-party insurers and when receipt is deemed probable. This includes instances when the third-party insurers have agreed to pay, on the Company's behalf, certain legal defense costs and settlement amounts directly to applicable law firms and settlement funds.

[I] Research and Development Expenses

Research and development costs with no alternative future use are expensed as incurred. Research and development expenses primarily consist of employee-related costs and expenses from third parties who conduct research and development activities (including manufacturing) on behalf of the Company. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by CROs. In making these estimates, the Company considers various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment. The Company accrues costs for non-clinical studies and contract manufacturing activities over the service periods specified in the contracts and are adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. The estimate of the work completed is developed through discussions with internal personnel and external services providers as to the progress toward completion of the services and the agreed-upon fee to be paid for such services. As actual costs become known, the accrued estimates are adjusted. Such estimates are not expected to be materially different from amounts actually incurred.

The Company participates in cost-sharing arrangements with third parties whereas the third parties have agreed to share a portion of the costs incurred by the Company, related to batoclimab drug manufacturing and clinical trials. The Company records the third parties' share of the costs as a reduction of research and development expenses and an increase to accounts receivable in the accompanying consolidated financial statements based on actual amounts incurred by the Company and billable to the third parties. These cost-sharing arrangements do not contemplate any future revenue-generating activity or global commercialization efforts of batoclimab benefiting any of the parties.

[J] Acquired In-Process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expenses include payments made or due in connection with license agreements upon the achievement of development and regulatory milestones.

The Company evaluates in-licensed agreements for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as acquired in-process research and development expenses in its consolidated statements of operations. Payments for milestones achieved and payments for a product license prior to regulatory approval of the product are expensed in the period incurred. Payments made in connection with regulatory and sales-based milestones will be capitalized and amortized to cost of product sales over the remaining useful life of the asset.

[K] Leases

Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and lease liabilities are initially recognized based on the present value of the future fixed lease payments over the expected lease term at commencement date calculated using the Company's incremental borrowing rate applicable to the lease asset, unless the implicit rate is readily determinable. Operating lease ROU assets also include any lease payments made at or before lease commencement, adjusted by any initial direct costs and exclude any lease incentives received. The Company determines the lease term as the non-cancelable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Variable lease costs such as common area costs and other operating costs are expensed as incurred.

The Company accounts for lease and non-lease components as a single lease component for its leases.

[L] Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between amounts in the consolidated financial statements and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income tax (benefit) expense in the accompanying consolidated statements of operations in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company's policy is to recognize interest and/or penalties related to income tax matters in provision for income taxes.

[M] Stock-based Compensation

Stock-based awards to employees and directors are valued at fair value on the date of the grant and that fair value is recognized as stock-based compensation expense over the requisite service period. The grant date fair value of the stock-based awards with graded vesting is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The Company values its stock options that only have service vesting requirements using the Black-Scholes option pricing model. Stock-based compensation related to restricted stock awards is based on the fair value of the Company's common stock on the grant date. When determining the grant-date fair value of stock-based awards, management further considers whether an adjustment is required to the observable market price or volatility of the Company's common stock that is used in the valuation as a result of material non-public information, if that information is expected to result in a material increase in share price.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate, expected dividend yield and the fair value of the Company's common stock. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. The expected share price volatility for the Company's common stock is estimated by taking the average historical price volatility for the Company's peers. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. As the Company has never paid and does not anticipate paying cash dividends on its common stock, the expected dividend yield is assumed to be zero. The Company accounts for pre-vesting award forfeitures when they occur.

[N] Fair Value of Financial Instruments

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. 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. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and amounts due to Roivant Sciences Ltd. ("RSL"). These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. There were no Level 2 or Level 3 financial instruments as of March 31, 2023 or 2022.

[O] Foreign Currency

The Company has operations in the U.S., the United Kingdom, Bermuda, and Switzerland. The results of its non-U.S. dollar based functional currency operations are translated to U.S. dollars at the average exchange rates during the period. The Company's assets and liabilities are translated using the current exchange rate as of the consolidated balance sheet date and equity is translated using historical rates. Adjustments resulting from the translation of the consolidated financial statements of the Company's foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are recognized in accumulated other comprehensive income (loss). Foreign exchange transaction gains and losses are included in other expense (income), net in the consolidated statements of operations.

[P] Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted-average number of common stock outstanding during the period. Diluted net loss per common share is computed by dividing the net loss applicable to common stockholders by the diluted weighted-average number of common stock outstanding during the period. In periods in which the Company reports a net loss, all common stock equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equivalent. Potentially dilutive common stock has been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total common stock outstanding for basic and diluted net loss per common share data.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Years Ended March 31,	
	2023	2022
Preferred stock as converted	10,000	10,000
Stock options	11,682,481	8,018,731
Restricted stock units	3,692,979	2,670,864
Total	**15,385,460**	**10,699,595**

[Q] Recent Accounting Pronouncements

Recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the U.S. Securities and Exchange Commission did not, or are not expected to, have a material impact on the Company's consolidated financial statements and related disclosures.

Note 3 — Material Agreements

License Agreement

On December 19, 2017, Roivant Sciences GmbH ("RSG"), a wholly owned subsidiary of RSL, entered into a license agreement (the "HanAll Agreement") with HanAll Biopharma Co., Ltd. ("HanAll"). Under the HanAll Agreement, RSG received (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to develop, import, use and commercialize the antibody referred to as batoclimab and certain back-up and next-generation antibodies (including IMVT-1402), and products containing such antibodies, in the U.S., Canada, Mexico, the European Union, the United Kingdom, Switzerland, the Middle East, North Africa and Latin America (the "Licensed Territory").

In exchange for this license, RSG provided or agreed to provide the following consideration:

- Upfront, non-refundable payment of $30.0 million;
- Up to $20.0 million in shared (50%) research, development, and out-of-pocket costs incurred by HanAll;
- Up to an aggregate of $432.5 million (after an aggregate amount of $20.0 million of milestone achievements as of March 31, 2023) upon the achievement of certain development, regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens percentage of net sales of licensed products subject to standard offsets and reduction on a product-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 11th anniversary of the first commercial sale of such product in such country.

On August 18, 2018, RSG entered into a sublicense agreement (the "Sublicense Agreement") with ISG to sublicense this technology, as well as RSG's know how and patents necessary for the development, manufacture or commercialization of any compound or product that pertains to immunology. On December 7, 2018, RSG issued a notice to terminate the Sublicense Agreement with ISG and entered into an assignment and assumption agreement to assign to ISG all the rights, title, interest, and future obligations under the HanAll Agreement from RSG, including all rights to batoclimab and IMVT-1402 in the Licensed Territory, for an aggregate purchase price of $37.8 million.

Under the HanAll Agreement, the parties may choose to collaborate on a research program directed to the research and development of next generation FcRn inhibitors in accordance with an agreed plan and budget. Each party has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory.

In the fiscal 2023 third quarter, the Company achieved its second development and regulatory milestone under the HanAll Agreement of $10.0 million, which was paid in the fiscal 2023 fourth quarter and recorded as acquired in-process research and development expenses in the accompanying consolidated statement of operations for the year ended March 31, 2023.

As of March 31, 2023, the Company does not have any additional amounts payable to HanAll for research and development costs incurred and reported to the Company pursuant to the HanAll Agreement. As of March 31, 2022, $0.4 million was payable to HanAll for research and development costs incurred and reported to the Company pursuant to the HanAll Agreement.

Product Service Agreement and Master Services Agreement

On November 17, 2021, ISG entered into a Product Service Agreement, ("PSA"), with Samsung Biologics Co., Ltd., ("Samsung"), pursuant to which Samsung will manufacture and supply the Company with batoclimab drug substance for commercial sale, if approved, and perform other manufacturing-related services with respect to batoclimab. The Company previously entered in a Master Services Agreement, ("MSA") with Samsung, dated April 30, 2021, which governs certain terms of the Company's relationship with Samsung. Upon execution of the PSA, the Company committed to purchase process performance qualification batches of batoclimab and pre-approval inspection batches of batoclimab which may be used for regulatory submissions and, pending regulatory approval, commercial sale. In addition to these, the Company is obligated to purchase additional batches of batoclimab in the four-year period of 2026 through 2029.

The PSA will continue until the later of December 31, 2029 or the completion of the services thereunder, unless the PSA is terminated earlier. If the Company makes a final decision to stop all development of batoclimab and all attempts to obtain regulatory approval for batoclimab, then the Company will have the right to terminate the PSA with 30 days' written notice to Samsung as long as such notice is provided no later than January 2024. Upon such termination of the PSA, the Company will pay Samsung for non-cancellable service fees and costs that Samsung incurs and for all batches of batoclimab scheduled to be manufactured during the two-year period following such termination. In addition, either party may terminate the PSA on account of (i) the other party's material breach of the PSA that is not cured within a specified period after the termination notice, (ii) the other party's insolvency or bankruptcy, or (iii) certain force majeure events.

As of March 31, 2023, the remaining minimum purchase commitment related to this agreement was estimated to be approximately $33.3 million.

Note 4 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31,	
	2023	2022
Research and development expenses	$ 31,321	$ 18,196
Accrued bonuses	7,530	4,456
Legal and professional fees	572	679
Other expenses	998	1,244
Total accrued expenses	**$ 40,421**	**$ 24,575**

Note 5 — Related Party Transactions

Roivant Sciences Inc. ("RSI") and RSG Services Agreements

In August 2018, the Company entered into amended and restated services agreements (the "Services Agreements") with RSI and RSG, under which RSI and RSG agreed to provide services related to development, administrative and financial activities to the Company. Under each Services Agreement, the Company will pay or reimburse RSI or RSG, as applicable, for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI or RSG employees, RSI or RSG, as applicable, will charge back the employee compensation expense plus a pre-determined mark-up. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost. The term of the Services Agreements will continue until terminated by the Company, RSI or RSG, as applicable, upon 90 days' written notice.

For the year ended March 31, 2023, the Company was charged $0.4 million under the Services Agreements, included in the accompanying consolidated statement of operations and amounts due to RSL in the accompanying consolidated balance sheet. For the year ended March 31, 2022, the Company was charged $0.5 million under the Services Agreements, included in the accompanying consolidated statement of operations, of which $0.1 million and $0.4 million were treated as capital contributions and amounts due to RSL, respectively, in the accompanying consolidated balance sheet.

RSL Information Sharing and Cooperation Agreement

In December 2018, the Company entered into an amended and restated information sharing and cooperation agreement (the "Cooperation Agreement") with RSL. The Cooperation Agreement, among other things: (1) obligates the Company to deliver to RSL periodic financial statements and other information upon reasonable request and to comply with other specified financial reporting requirements; (2) requires the Company to supply certain material information to RSL to assist it in preparing any future SEC filings; and (3) requires the Company to implement and observe certain policies and procedures related to applicable laws and regulations. The Company has agreed to indemnify RSL and its affiliates and their respective officers, employees and directors against all losses arising out of, due to or in connection with RSL's status as a stockholder under the Cooperation Agreement and the operations of or services provided by RSL or its affiliates or their respective officers, employees or directors to the Company or any of its subsidiaries, subject to certain limitations set forth in the Cooperation Agreement. No amounts have been paid or received under this agreement.

Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of (1) the mutual written consent of the parties or (2) the later of when RSL no longer (a) is required by U.S. GAAP to consolidate the Company's results of operations and financial position, account for its investment in the Company under the equity method of accounting or, by any rule of the SEC, include the Company's separate financial statements in any filings it may make with the SEC and (b) has the right to elect directors constituting a majority of the Company's board of directors.

RSI Subleases

See Note 9 – Leases for a discussion of the subleases the Company has entered into with RSI.

RSL Share Purchases

See Note 7 – Stockholders' Equity for a discussion of the RSL share purchases as part of the Company's underwritten offering in October 2022 and share purchase agreement in August 2021.

Note 6 — Income Taxes

The loss before income taxes and the related tax (benefit) provision are as follows (in thousands):

	Years Ended March 31,	
	2023	**2022**
(Loss) income before income taxes		
United States	$ (27,708)	$ (43,949)
Switzerland	(183,187)	(112,786)
Bermuda	(58)	(77)
United Kingdom	2	(2)
Total loss before income taxes	**$ (210,951)**	**$ (156,814)**
Current taxes		
United States – Federal	$ —	$ (85)
United States – State	9	1
Total current tax (benefit) expense	9	(84)
Deferred tax expense	—	—
Total benefit for income taxes	**$ 9**	**$ (84)**

A reconciliation of the benefit for income taxes computed at the U.S. statutory rate of 21% for the years ended March 31, 2023 and 2022 to the benefit for income taxes reflected in the consolidated statements of operations is as follows (in thousands):

	Years Ended March 31,	
	2023	2022
Income tax benefit at statutory rate	$ (44,300)	$ (32,931)
Foreign rate differential	14,569	8,978
Research and development credits	(4,798)	(2,493)
Valuation allowance	31,944	23,283
Non-deductible expense	3,632	3,121
Tax deficiencies (excess tax benefits) from stock-based compensation	(1,960)	439
Other	922	(481)
Total benefit for income taxes	**$ 9**	**$ (84)**

The Company's effective tax rate was 0% and 0.05% for the years ended March 31, 2023 and March 31, 2022, respectively, primarily driven by the Company's jurisdictional earnings by location, certain non-deductible expenditures, research and development credits, and a valuation allowance that eliminates the Company's global net deferred tax assets.

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2023 and 2022 are as follows (in thousands):

	March 31,	
	2023	2022
Deferred tax assets		
Intangible assets	$ 8,112	$ 6,726
Net operating losses	64,418	40,297
Stock-based compensation	7,120	5,581
Research and development credits	10,798	6,010
Lease liability	260	501
Others	1,782	219
Total deferred tax assets	**92,490**	**59,334**
Valuation allowance	(91,988)	(58,704)
Deferred tax assets, net of valuation allowance	**$ 502**	**$ 630**
Deferred tax liabilities		
Depreciation	$ (69)	$ (69)
Right-of-use assets	(250)	(489)
Others	(183)	(72)
Total deferred tax liabilities	**(502)**	**(630)**
Total net deferred taxes	**$ —**	**$ —**

As of March 31, 2023, the Company has gross net operating loss carryforwards in the following jurisdictions: Switzerland of approximately $447.6 million, which will begin to expire as of March 31, 2027, the United Kingdom of approximately $0.8 million, which can be carried forward indefinitely with an annual usage limitation, and the U.S. of approximately $27.7 million, which can be carried forward indefinitely with utilization limited to 80% of future taxable income for tax years beginning on or after January 1, 2021. The Company has research and development and orphan drug credit carryforwards in the U.S. of approximately $10.8 million, which will begin to expire in the fiscal year ending March 31, 2039, and approximately $2.2 million is subject to an annual usage limitation.

The Company assesses the realizability of the net deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and record a valuation allowance as necessary. Due to the Company's cumulative loss position which provides significant negative evidence difficult to overcome, the Company has recorded a valuation allowance of $92.0 million and $58.7 million for the years ended March 31, 2023 and 2022, respectively, representing the portion of the net deferred tax assets that is not expected to be realized. The amount of the net deferred tax assets considered realizable could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. The Company will continue to assess the realizability of net deferred tax assets at each balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

As of March 31, 2023, the Company does not have undistributed earnings from foreign subsidiaries. The Company regularly evaluates whether foreign earnings are expected to be indefinitely reinvested. This evaluation requires judgment about the future operating and liquidity needs of the Company. Changes in economic and business conditions, foreign or U.S. tax laws, or the Company's financial situation could result in a change to the Company's position.

The Company is subject to tax and files income tax returns in the United Kingdom, Switzerland, and U.S. federal, state, and local jurisdictions. The Company's March 31, 2023, 2022, 2021, 2020 and 2019 tax returns remain open for tax examinations in most applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the consolidated results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. The Company had unrecognized tax benefit activity during the years ended March 31, 2023 and 2022 and related liabilities were not material to the Company's consolidated financial statements as of March 31, 2023 and 2022. The Company does not expect the amount of unrecognized tax benefits to significantly increase or decrease within the next 12 months.

Note 7 — Stockholders' Equity

Series A Preferred Stock

As of March 31, 2023, 10,000 shares of Series A preferred stock, par value $0.0001 per share, were outstanding and held by RSL.

The holder(s) of the Series A preferred stock are entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series A preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter, and do not have cumulative voting rights.

The holder(s) of a majority of outstanding shares of Series A preferred stock, exclusively and as a separate class, are entitled to elect: (i) four Series A preferred directors, as long as the holder(s) of Series A preferred stock hold 50% or more of the voting power of all then-outstanding shares of capital stock entitled to vote generally at an election of directors, (ii) three Series A preferred directors, as long as the holder(s) of Series A preferred stock hold 40% or more but less than 50% of the voting power of all then-outstanding shares of capital stock entitled to vote generally at an election of directors, and (iii) two Series A preferred directors, as long as the holder(s) of Series A preferred stock hold 25% or more but less than 40% of the voting power of all then-outstanding shares of capital stock entitled to vote generally at an election of directors. Any Series A preferred director so elected may be removed without cause by, and only by, the affirmative vote of the holder(s) of Series A preferred stock given either at a special meeting of the holder(s) of Series A preferred stock duly called for that purpose or pursuant to a written consent of the holder(s) of Series A preferred stock.

Each share of Series A preferred stock is convertible at any time at the option of the holder into one share of common stock. On any transfer of shares of Series A preferred stock, whether or not for value, each such transferred share will automatically convert into one share of common stock, except for certain transfers described in the amended and restated certificate of incorporation.

Each share of Series A preferred stock will automatically convert into one share of common stock at such time as the holder(s) of Series A preferred stock hold less than 25% of the total voting power of the Company's outstanding shares.

The Company shall not, without the consent of the holder(s) of at least a majority of Series A preferred stock, alter or repeal any provisions of the Company's amended and restated certificate of incorporation or bylaws that adversely affect the powers, preferences or rights of the Series A preferred stock.

In the event of the Company's liquidation, dissolution, or winding up, the holder(s) of the Series A preferred stock will receive first an amount per share equal to $0.01 and then will be entitled to share ratably in the assets legally available for distribution to all stockholders.

Preferred Stock

As of March 31, 2023, the Company has authorized 10,010,000 shares of preferred stock par value $0.0001 per share. The board of directors has the authority, without further action by the stockholders to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, voting, and other rights, preferences and privileges of the shares. Other than the 10,000 shares of preferred stock designated as Series A preferred stock, there were no issued and outstanding shares of preferred stock as of March 31, 2023.

Common Stock

As of March 31, 2023, the Company authorized 500,000,000 shares of common stock, par value $0.0001 per share.

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared by the board of directors since the Company's inception.

In January 2021, the Company filed a shelf registration statement on Form S-3 with the SEC which permits the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $900.0 million of its common stock, of which $150.0 million may be issued and sold pursuant to an at-the-market (ATM) offering program for sales of the Company's common stock under a sales agreement with SVB Leerink LLC, subject to certain conditions as specified in the sales agreement. The Company agreed to pay SVB Leerink up to 3% of the gross proceeds sold through the sale agreement. The Company's common stock would be sold at prevailing market prices at the time of the sale and, as a result, prices may vary. The Company has not issued or sold any securities pursuant to the shelf registration statement or ATM offering program.

On August 2, 2021, the Company and RSL entered into a share purchase agreement pursuant to which the Company issued 17,021,276 shares of the Company's common stock, par value $0.0001 per share, to RSL at a per share price of $11.75 and received aggregate net proceeds of $200.0 million. Prior to the share issuance, the Company and RSL explored alternative potential transactions whereby the Company incurred additional costs, including $5.0 million in financial advisory fees, which are included in general and administrative expenses in the accompanying statement of operations for the year ended March 31, 2022.

In October 2022, the Company completed an underwritten offering of 12,500,000 shares of its common stock (including 416,667 shares of common stock purchased by RSL) at an offering price of $6.00 per share, for net proceeds to the Company of approximately $70.2 million after deducting underwriting discounts and commissions and offering expenses.

As of March 31, 2023, the Company had 130,329,863 shares of common stock outstanding, which include the above share issuances during the year and the issuance of shares of common stock from the exercise of stock options and vesting of restricted stock units. See Note 8 – Stock-Based Compensation for additional details about stock options and restricted stock units.

The Company has reserved the following shares of common stock for issuance:

	March 31,	
	2023	2022
Conversion of Series A preferred stock	10,000	10,000
Stock options outstanding	11,682,481	8,018,731
Restricted stock units outstanding	4,057,778	2,816,197
Equity awards available for future grants	590,317	2,188,860
Total	**16,340,576**	**13,033,788**

The reserved shares underlying restricted stock units above include 364,799 restricted stock units that vested but were not settled as of March 31, 2023. In addition, the Company has reserved 5,000,000 shares of its common stock that may be issued under its 2023 Inducement Plan as of March 31, 2023. See Note 8 – Stock-Based Compensation for further details.

Note 8 — Stock-Based Compensation

2019 Equity Incentive Plan

In December 2019, the Company's stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") and reserved 5,500,000 shares of common stock for issuance thereunder. The number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on April 1 of each year, beginning on April 1, 2020 and continuing through April 1, 2029, by 4.0% of the total number of shares of common stock outstanding on the last day of the preceding month, or a lesser number of shares as may be determined by the board of directors. The maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options under the 2019 Plan is 16,500,000. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards under the plan. Generally, each option will have an exercise price equal to the fair market value of the Company's common stock on the date of grant and a ten-year contractual term. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common stock on the date of grant and the option will have a five-year contractual term. Stock options that are forfeited, cancelled or have expired are available for future grants.

On April 1, 2022, 4,659,315 shares of common stock were added to the 2019 Plan pool in accordance with the 4.0% evergreen provision of the 2019 Plan . As of March 31, 2023, options to purchase 8,760,866 shares of common stock and 3,692,979 restricted stock units ("RSUs") were outstanding under the 2019 Plan and 590,317 shares of common stock remained available for future grant under the 2019 Plan.

Stock Option Repricing

Effective September 11, 2021, the Company's board of directors repriced certain previously granted and still outstanding vested and unvested stock option awards under the 2019 Plan held by eligible employees and executive officers. As a result, the exercise price for these awards was lowered to $8.62 per share, which was the closing price of the Company's common stock as reported on the Nasdaq Global Select Market on September 10, 2021. No other terms of the repriced stock options were modified, and the repriced stock options will continue to vest according to their original vesting schedules and will retain their original expiration dates. As a result of the repricing, 2,548,636 vested and unvested stock options outstanding as of September 11, 2021, with original exercise prices ranging from $10.71 to $50.67, were repriced.

The repricing on September 11, 2021 resulted in incremental stock-based compensation expense of $2.6 million, of which $0.4 million related to vested stock option awards was expensed on the repricing date, and $2.2 million related to unvested stock option awards is being amortized on a straight-line basis over the weighted-average vesting period of those awards of approximately 3.2 years.

2018 Equity Incentive Plan

As of the effective date of the 2019 Plan, no further stock awards have been or will be made under 2018 Equity Incentive Plan (the "2018 Plan"). As of March 31, 2023, 2,921,615 stock options were outstanding under the Company's 2018 Plan.

2023 Inducement Plan

On February 1, 2023, the Company's Board of Directors approved the adoption of the 2023 Inducement Plan (the "Inducement Plan"), which is to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company (or following a bona fide period of non-employment) as a material inducement to such individuals' entry into employment with the Company, pursuant to Nasdaq Listing Rule 5635(c)(4). The Company has reserved 5,000,000 shares of its common stock that may be issued under the Inducement Plan. The terms and conditions of the Inducement Plan are substantially similar to those of the 2019 Plan. As of March 31, 2023, no awards were granted or outstanding under the Inducement Plan.

Stock Option Activity

A summary of the stock option activity under the Company's equity incentive plans is as follows:

	Number of Stock Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance – March 31, 2022	8,018,731	$ 8.48	8.52	$ 60
Granted	4,173,345	7.08		
Exercised	(85,084)	7.72		
Forfeited	(393,102)	6.63		
Expired	(31,409)	8.69		
Balance – March 31, 2023	**11,682,481**	**$ 8.05**	**8.16**	**$ 88,919**
Exercisable – March 31, 2023	**5,214,517**	**$ 8.70**	**7.14**	**$ 36,383**

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable stock options and the fair value of the Company's common stock at March 31, 2023. The intrinsic value of stock options exercised during the year ended March 31, 2023 was $0.5 million. There were no stock options exercised during the year ended March 31, 2022. The stock options granted during the years ended March 31, 2023 and March 31, 2022 had a weighted-average fair value of $5.39 per share and $5.89 per share, respectively, at the grant date. The total grant-date fair value of stock options vested during the years ended March 31, 2023 and March 31, 2022 was $17.3 million and $17.9 million, respectively. The Company estimated the fair value of each option on the date of grant using the Black-Scholes option pricing model applying the weighted-average assumptions in the following table:

	Years Ended March 31,	
	2023	2022
Risk-free interest rate	2.74% - 4.21%	0.80% – 2.35%
Expected term, in years	6.11	5.56 – 6.11
Expected volatility	87.12% - 93.78%	82.92% – 91.15%
Expected dividend yield	—%	—%

Restricted Stock Unit Awards

A summary of RSUs activity under the Company's equity incentive plans is as follows:

	Number of RSUs	Weighted- Average Grant Date Fair Value
Nonvested as of March 31, 2022	2,670,864	$ 9.12
Issued	2,799,018	6.79
Vested	(1,482,354)	8.68
Forfeited	(294,549)	7.85
Nonvested as of March 31, 2023	**3,692,979**	**$ 7.63**

The RSUs granted during the years ended March 31, 2023 and March 31, 2022 had a weighted-average fair value of $6.79 per share and $7.42 per share, respectively, at the grant date. The total grant-date fair value of RSUs vested during the years ended March 31, 2023 and March 31, 2022 was $12.9 million and $16.3 million, respectively.

Stock-based Compensation Expense

For the years ended March 31, 2023 and 2022, stock-based compensation expense under the Company's equity incentive plans was as follows (in thousands):

	Years Ended March 31,	
	2023	2022
Research and development expenses	$ 14,779	$ 14,194
General and administrative expenses	17,187	18,949
Total stock-based compensation	**$ 31,966**	**$ 33,143**

As of March 31, 2023, total unrecognized compensation expense related to nonvested stock options and RSUs was $39.6 million and $23.2 million, respectively, which is expected to be recognized over the remaining weighted-average service period of 2.65 years and 2.70 years, respectively.

Stock-based Compensation Allocated to the Company by RSL

In relation to the RSL common share awards and options issued by RSL to employees of Roivant and the Company, stock-based compensation expense of $0.1 million and $0.4 million was recorded for the years ended March 31, 2023 and 2022, respectively, in the accompanying consolidated statements of operations.

The RSL common share awards are valued at fair value on the date of grant and stock-based compensation expense is recognized and allocated to the Company over the required service period. The allocation of stock-based compensation for Roivant employees is based upon the relative percentage of time utilized by Roivant employees on Company matters.

RSL RSUs

The Company's Chief Executive Officer was granted 73,155 RSUs of RSL in January 2021, which are vesting over a period of four years. For the years ended March 31, 2023 and 2022, the Company recorded $0.2 million and $0.7 million, respectively, of stock-based compensation expense related to these RSUs. As of March 31, 2023, there was $0.1 million of unrecognized compensation expense related to unvested RSL RSUs.

Note 9 — Leases

In June 2020, the Company entered into two sublease agreements with RSI for two floors of the building the Company currently occupies as its headquarters in New York. The subleases will expire on February 27, 2024 and April 29, 2024, respectively, and have scheduled rent increases each year. In March 2022, the Company entered into a lease agreement with an unrelated party for office space in a building in North Carolina, expiring on March 31, 2024 with scheduled rent increases each year. The lease agreement includes an option at the Company's election to renew for an additional two years. The Company had a previous sublease in this building that expired on February 28, 2022.

These leases are classified as operating leases. The aggregate weighted-average remaining lease term was 1.0 years and 2.0 years as of March 31, 2023 and 2022, respectively. As the Company's operating leases do not provide an implicit rate, estimated incremental borrowing rates based on the information available at the time of execution of each lease agreement were used in determining the present value of lease payments. The weighted-average incremental borrowing rate for the Company's operating leases was 3.9% for each of the years ended March 31, 2023 and 2022. Variable lease costs such as common area costs and other operating costs are expensed as incurred and were minimal for the years ended March 31, 2023 and 2022.

During the year ended March 31, 2023, the Company incurred $1.2 million in rent expense and paid $1.2 million in cash related to contractual rent obligations under the operating leases. The following table provides a reconciliation of the Company's remaining undiscounted contractual rent obligations due within each respective fiscal year ending March 31 to the operating lease liabilities recognized as of March 31, 2023 (in thousands):

Years Ending March 31,	Operating Leases
2024	$ 1,198
2025	47
Total undiscounted payments	1,245
Less: present value adjustment	(25)
Present value of future payments	1,220
Less: current portion of operating lease liabilities	(1,173)
Operating lease liabilities, net of current portion	**$ 47**

Note 10 — Commitments and Contingencies

Indemnification Agreements

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. The Company also indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance.

Litigation

The Company is involved in various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable.

In February 2021, a putative securities class action complaint was filed against the Company and certain of its current and former officers in the U.S. District Court for the Eastern District of New York on behalf of a class consisting of those who acquired the Company's securities between October 2, 2019 and February 1, 2021. The complaint alleges that the Company and certain of its officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by making false and misleading statements regarding the safety of batoclimab and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys' fees. On December 29, 2021, the U.S. District Court appointed a lead plaintiff. On February 1, 2022, the lead plaintiff filed an amended complaint adding RSL and the Company's directors and underwriters as defendants (collectively, "Defendants"), and asserting additional claims under Section 11, 12(a)(2), and 15 of the Securities Act of 1933 on behalf of a putative class consisting of those who purchased or otherwise acquired the Company's securities pursuant and/or traceable to the Company's follow-on public offering on or about September 2, 2020. On March 15, 2022, the lead plaintiff filed a further amended complaint. On February 14, 2023, the Court granted lead plaintiffs leave to amend. On March 17, 2023, the lead plaintiff filed a second amended complaint. The Company and other Defendants filed a motion to dismiss the second amended complaint on April 28, 2023. Plaintiff's opposition is due on June 9, 2023, and Defendants' replies are due on June 30, 2023, at which point Defendants intend to file the fully briefed motions to dismiss. No hearing date has been set on the motion to dismiss. The Company intends to continue to vigorously defend the case and has not recorded a liability related to this lawsuit because, at this time, the Company is unable to reasonably estimate possible losses or determine whether an unfavorable outcome is either probable or remote.

Commitments

During the year ended March 31, 2023, ISG entered into the PSA with Samsung to manufacture a certain quantity of batoclimab drug substance for, among other things, commercial sale, if approved. As of March 31, 2023, in connection with this agreement, the Company has a remaining minimum obligation to Samsung of approximately $33.3 million, of which $17.5 million, $0.3 million and $15.5 million is expected to be paid during the fiscal years ending March 31, 2024, 2025 and 2026, respectively. During the year ended March 31, 2023, the Company recorded $19.8 million of research and development expenses related to the PSA, of which $2.7 million was paid as of March 31, 2023. See Note 3 - Material Agreements for additional details.

As of March 31, 2023, the Company did not have any other ongoing material contractual obligations for which cash flows were fixed and determinable. In the normal course of business, the Company enters into agreements with CROs for clinical trials and with vendors for nonclinical studies, manufacturing and other services and products for operating purposes, which agreements are generally cancellable by the Company at any time, subject to payment of remaining obligations under binding purchase orders and, in certain cases, nominal early-termination fees. These commitments are not deemed significant. There are certain contracts wherein the Company has a minimum purchase commitment, however, most of it is due and payable within one year.

Contingencies

The extent of the impact of COVID-19, geopolitical tensions and global slowdown of economic activity, decades-high inflation, rising interest rates and a potential recession in the U.S. on the Company's future operational and financial performance will depend on certain developments, including the duration and spread of the pandemic, including its variants, impact on employees and vendors, and impact on clinical trial sites and patients, all of which are uncertain and cannot be predicted. At this point, the extent to which these events may impact the Company's future financial condition or results of operations is uncertain.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023, the end of the period covered by this Annual Report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2023 at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting.

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined under Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is designed 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.

A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Our management has assessed the effectiveness of our internal control over financial reporting as of March 31, 2023. In making this assessment, management used the criteria set forth in the Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of March 31, 2023, our internal control over financial reporting was effective based on those criteria.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to our status as a smaller reporting company and a non-accelerated filer.

Changes in Internal Control Over Financial Reporting.

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

We will file a definitive proxy statement for our 2023 Annual Meeting of Stockholders ("2023 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year, or March 31, 2023. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2023 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in our 2023 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Meetings of the Board and its Committees" and "Executive Officers" and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that is applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.immunovant.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to the principal executive officer, principal financial officer and principal accounting officer or controller or persons performing similar functions, we will promptly disclose the nature of the amendment or waiver on our website. Information 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.

Item 11. Executive Compensation

The information required by this item will be contained in our 2023 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Executive Compensation" and "Director Compensation" and is incorporated herein by reference.

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

The information required by this item will be contained in our 2023 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plans at March 31, 2023" and is incorporated herein by reference.

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

The information required by this item will be contained in our 2023 Proxy Statement under the captions "Certain Relationships and Related Party Transactions" and "Information Regarding the Board of Directors and Corporate Governance" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in our 2023 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a) Documents filed as part of this report

(1) All financial statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report or the notes thereto or is not applicable or required.

(3) Exhibits

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
2.1+	Share Exchange Agreement, dated September 29, 2019, by and among Immunovant Sciences Ltd., the stockholders of Immunovant Sciences Ltd., Roivant Sciences Ltd., and Health Sciences Acquisitions Corporation.	8-K	001-38906	2.1	October 2, 2019
3.1	Amended and Restated Certificate of Incorporation of Immunovant, Inc.	8-K	001-38906	3.1	December 20, 2019
3.2	Amended and Restated Bylaws of Immunovant, Inc.	8-K	001-38906	3.2	December 20, 2019
4.1	Specimen Warrant Certificate.	S-1/A	333-230893	4.3	April 29, 2019
4.2	Form of Warrant Agreement by and between Continental Stock Transfer & Trust Company and Health Sciences Acquisitions Corporation.	S-1/A	333-230893	4.4	April 29, 2019
4.3	Description of Securities.	10-K	001-38906	4.3	June 29, 2020
10.1	UK Sub-Plan to the Immunovant, Inc. 2019 Equity Incentive Plan	10-Q	001-38906	10.1	February 3, 2023
10.2	Form of Stock Option Grant Notice and Agreement for the UK Sub-Plan	10-Q	001-38906	10.2	February 3, 2023
10.3	Form of Restricted Stock Unit Grant Notice and Agreement for the UK Sub-Plan	10-Q	001-38906	10.3	February 3, 2023
10.4	Immunovant, Inc. 2023 Inducement Plan	10-Q	001-38906	10.4	February 3, 2023
10.5	Form of Stock Option Grant Notice and Option Agreement for the Immunovant, Inc. 2023 Inducement Plan	10-Q	001-38906	10.5	February 3, 2023
10.6	Form of Restricted Stock Unit Grant Notice and Award Agreement for the Immunovant, Inc. 2023 Inducement Plan	10-Q	001-38906	10.6	February 3, 2023
10.7	Amended and Restated Registration Rights Agreement, dated September 29, 2019, by and among Health Sciences Acquisitions Corporation and the Investors party thereto.	8-K	001-38906	10.1	December 20, 2019
10.8	Restricted Stock Agreement, dated September 29, 2019, by and between Health Sciences Acquisitions Corporation and Health Sciences Holdings, LLC.	8-K	001-38906	10.2	December 20, 2019
10.9†	2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3	June 29, 2020
10.10.1†	Forms of Option Grant Notices and Option Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3.1	June 29, 2020

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
10.10.2†	Forms of Restricted Stock Unit Grant Notices and Award Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3.2	June 29, 2020
10.11†	2018 Equity Incentive Plan of Immunovant Sciences Ltd., and forms of award agreements thereunder.	8-K	001-38906	10.4	December 20, 2019
10.12†	Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan.	S-4	333-256165	10.25	May 14, 2021
10.13†	Form of Indemnification Agreement.	8-K	001-38906	10.5	December 20, 2019
10.14††	License Agreement, dated December 19, 2017, by and between Roivant Sciences GmbH and HanAll BioPharma Co., Ltd.	8-K	001-38906	10.6	December 20, 2019
10.15	Assignment and Assumption Agreement, dated as of December 7, 2018, by and between Immunovant Sciences GmbH and Roivant Sciences GmbH, relating to the License Agreement by and between Roivant Sciences GmbH and HanAll BioPharma Co., Ltd.	8-K	001-38906	10.7	December 20, 2019
10.16	Services Agreement, effective as of August 20, 2018, by and between Roivant Sciences, Inc., Immunovant Sciences GmbH, IMVT Corporation (formerly Immunovant, Inc.) and Immunovant Sciences Ltd.	8-K	001-38906	10.8	December 20, 2019
10.17	Services Agreement, effective as of August 20, 2018, by and between Roivant Sciences GmbH and Immunovant Sciences GmbH.	8-K	001-38906	10.9	December 20, 2019
10.18	Amended and Restated Information Sharing and Cooperation Agreement, effective as of December 28, 2018, by and between Immunovant Sciences Ltd. and Roivant Sciences Ltd.	8-K	001-38906	10.10	December 20, 2019
10.19†	Employment Agreement with Peter Salzmann, dated as of May 30, 2019.	8-K	001-38906	10.11	December 20, 2019
10.20†	Employment Agreement with Julia G. Butchko, dated as of October 9, 2019.	8-K	001-38906	10.13	December 20, 2019
10.21†	Employment Agreement with William Macias, dated as of October 25, 2021, as amended.	10-Q	001-38906	10.1	February 4, 2022
10.22†	Employment Agreement with Renee Barnett, dated as of September 14, 2021.	8-K	001-38906	10.1	September 15, 2021
10.23†	Employment Agreement with Mark Levine, dated as of January 19, 2022.	10-K	001-38906	10.16	June 8, 2022
10.24†	Employment Agreement with Jay Stout, dated as of April 11, 2023.				
10.25††	Master Services Agreement, between Samsung Biologics Co., Ltd. and Immunovant Sciences GmbH, dated April 30, 2021.	10-Q	001-38906	10.2	February 4, 2022
10.26††	Product Service Agreement, between Samsung Biologics Co., Ltd. and Immunovant Sciences GmbH, dated November 17, 2021.	10-Q	001-38906	10.3	February 4, 2022
10.27	Share Purchase Agreement, dated as of August 2, 2021, by and between Immunovant, Inc. and Roivant Sciences Ltd.	8-K	001-38906	10.1	August 2, 2021
21.1	List of Subsidiaries.	10-K	001-38906	21.1	June 8, 2022

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.				
24.1	Power of Attorney (included on signature page to this Annual Report)				
31.1	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1#	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2#	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
99.1	Notice of Redemption of Warrants	8-K	001-38906	99.2	May 14, 2020
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				
104	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101)				

+ The annexes, schedules, and certain exhibits to the Share Exchange Agreement have been omitted pursuant to Item 601 of Regulation S-K.

† Indicates a management contract or compensatory plan, contract or arrangement.

†† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type that Immunovant, Inc. treats as private or confidential.

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Date: May 22, 2023

IMMUNOVANT, INC.

By: /s/ Peter Salzmann
Peter Salzmann, M.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter Salzmann, M.D. and Eva Renee Barnett, and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign 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 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 requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

SIGNATURE	TITLE	DATE
/s/ Peter Salzmann Peter Salzmann, M.D.	Chief Executive Officer and Director (*Principal Executive Officer*)	May 22, 2023
/s/ Eva Renee Barnett Eva Renee Barnett	Chief Financial Officer *(Principal Financial and Accounting Officer)*	May 22, 2023
/s/ Frank M. Torti Frank M. Torti, M.D.	Executive Chairperson of the Board of Directors	May 22, 2023
/s/ Andrew Fromkin Andrew Fromkin	Director	May 22, 2023
/s/ Douglas Hughes Douglas Hughes	Director	May 22, 2023
/s/ George Migausky George Migausky	Director	May 22, 2023
/s/ Atul Pande Atul Pande, M.D.	Director	May 22, 2023
/s/ Eric Venker Eric Venker, M.D., Pharm.D.	Director	May 22, 2023