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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, 2020

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

**(State or other jurisdiction of
incorporation or organization)**

83-2771572

**(I.R.S. Employer
Identification No.)**

320 West 37th Street

New York, NY

(Address of principal executive offices)

10018

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

The aggregate market value of the Registrant’s common stock held by non-affiliates of the Registrant, based on the closing price of the Registrant’s common stock on the Nasdaq Capital Market as of September 30, 2019, the last business day of the Registrant’s most recently completed second fiscal quarter, was approximately \$115.3 million, based on the closing price of the Registrant’s common stock on the Nasdaq Capital Market of \$10.02 per share.

As of June 29, 2020, the Registrant had 81,811,727 shares of common Stock, \$0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s Proxy Statement for its 2020 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, 2020.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended March 31, 2020 (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,” “continue,” “could,” “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:

- future operating or financial results;
- the effect of the COVID-19 pandemic 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;
- future acquisitions, business strategy and expected capital spending;
- the timing, progress, costs and results of our clinical trials for IMVT-1401, including its ASCEND MG, ASCEND GO and ASCEND WAIHA trials;
- the timing of meetings with and feedback from regulatory authorities as well as any submission of filings for regulatory approval of IMVT-1401;
- the potential advantages and differentiated profile of IMVT-1401 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 IMVT-1401, if approved;
- the rate and degree of market acceptance of IMVT-1401, if approved;
- our expectations regarding the size of the patient populations for and opportunity for and clinical utility of IMVT-1401, 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 IMVT-1401;
- 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 IMVT-1401;
- 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.

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You should refer to “Item 1A. Risk Factors” 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.

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 subsidiaries. Prior to December 18, 2019, we were known as Health Sciences Acquisitions Corporation (“HSAC”). On December 18, 2019, HSAC completed the acquisition of 100% of the outstanding shares of Immunovant Sciences Ltd. (“ISL”), which we refer to as the “Business Combination.” References herein to “we,” “our” and “us” may refer, as context requires, to ISL and its subsidiaries prior to the Business Combination.

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PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits the neonatal fragment crystallizable receptor (“FcRn”). IMVT-1401 is the product of a multi-step, multi-year research program conducted by HanAll Biopharma Co., Ltd. (“HanAll”) to design a highly potent anti-FcRn antibody optimized for subcutaneous delivery. These efforts have resulted in a product candidate that 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, IMVT-1401 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 IMVT-1401 has the potential for broad application in related disease areas. We intend to develop IMVT-1401 for the treatment of 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 a 2012 study by the American Autoimmune Related Diseases Association, approximately 50 million people in the United States 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 many 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 autoimmune diseases are lacking. Currently 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.

FcRn plays a pivotal role in preventing the degradation of IgG antibodies. The physiologic function of FcRn is to modulate the catabolism of IgG antibodies, and inhibition of FcRn, such as through use of an anti-FcRn antibody, has been shown to reduce levels of pathogenic IgG antibodies. Completed clinical trials of Immunovant and other anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results, suggesting that FcRn is a therapeutically important pharmacologic target to reduce levels of these disease-causing IgG antibodies.

In several nonclinical studies and a multi-part Phase 1 clinical trial in healthy volunteers, intravenous and subcutaneous delivery of IMVT-1401 demonstrated dose-dependent IgG antibody reductions and was observed to be well tolerated. In the highest dose cohort from the multiple-ascending dose portion of the Phase 1 clinical trial, four weekly subcutaneous administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, with a standard deviation of 2%. IMVT-1401 was generally well-tolerated in this study, and the majority of adverse events reported were mild or moderate. Injection site reactions were similar between IMVT-1401 and placebo arms.

We are developing IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule. As a result of our rational design, we believe that IMVT-1401, if approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases, (e.g., myasthenia gravis (“MG”), thyroid eye disease (“TED”, also known as Graves’ ophthalmopathy, or “GO”), warm autoimmune hemolytic anemia (“WAIHA”), idiopathic thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, bullous pemphigoid, neuromyelitis optica, pemphigus foliaceus, Guillain-Barré syndrome and PLA2R+ membranous nephropathy). In 2019, these diseases had an aggregate prevalence of approximately 243,000 patients in the United States and 388,000 patients in Europe. To the extent we choose to develop IMVT-1401 for certain of these rare diseases, we plan to seek orphan drug designation in the United States and Europe. Such designations would primarily provide financial and exclusivity incentives intended to make the development of orphan drugs financially viable. However, we have not yet sought such designation for any of our three target indications, and there is no certainty that we would obtain such designation, or maintain the benefits associated with such designation, if or when we do.

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We are developing IMVT-1401 as a fixed-dose subcutaneous injection, with an initial focus on the treatment of MG, TED and WAIHA. MG is an autoimmune disease associated with muscle weakness with an estimated prevalence of one in 5,000, with up to 66,000 cases in the United States. In MG, patients develop pathogenic IgG antibodies that attack critical signaling proteins at the junction between nerve and muscle cells. The majority of MG patients suffer from progressive muscle weakness, with maximum weakness occurring within six months of disease onset in most patients. In severe cases, MG patients can experience myasthenic crisis, in which respiratory function is weakened to the point where it becomes life-threatening, requiring intubation and mechanical ventilation. In August 2019, we initiated dosing in our ASCEND MG trial, a Phase 2a clinical trial in patients with MG. We expect to report results from the placebo-controlled treatment phase of this trial in the late third quarter or early fourth quarter of calendar year 2020.

TED is an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes, which can be sight-threatening. TED has an estimated annual incidence of 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe. 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.

In May 2019, we initiated dosing in our ASCEND GO-1 trial, a Phase 2a clinical trial in Canada in patients with TED. On March 30, 2020, we announced initial results from this trial. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, four of seven patients (57%) improved by ≥ 2 points on the Clinical Activity Score (“CAS”). Clinicians use CAS to measure disease activity in TED patients. CAS is based on seven parameters, including spontaneous pain behind the eye, pain with eye movement, redness of the eyelids, redness of the conjunctiva, swelling of the eyelids, swelling of the caruncle and swelling of the conjunctiva. A score is calculated based on the number of parameters that are positive with scores of four or above considered to be cases of active disease. Of six patients with baseline diplopia, four patients (67%) demonstrated improvement in diplopia. Three of seven patients (43%) were proptosis responders. The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. All AEs were mild or moderate and there were no headaches reported. Enrollment is ongoing in our ASCEND GO-2 trial, a Phase 2b clinical trial for TED in the United States, Canada and Europe. As previously communicated, results from this trial are still possible in the first half of calendar year 2021. We intend to provide an update on the timing for this trial in the third quarter of calendar year 2020.

WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of red blood cells (“RBCs”). Based on published estimates, we believe that there are approximately 42,000 patients in the United States and 66,000 patients in Europe living with WAIHA. The clinical presentation is variable and most commonly includes symptoms of anemia, such as fatigue, weakness, skin paleness and shortness of breath. In severe cases, hemoglobin levels are unable to meet the body’s oxygen demand, which can lead to heart attacks, heart failure and even death. In November 2019, we submitted our investigational new drug application (“IND”) to the U.S. Food and Drug Administration (“FDA”) for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. As previously communicated, results from this trial are still possible by the end of second half of calendar year 2020. We intend to provide an update on the timing for this trial in the third quarter of calendar year 2020.

We obtained rights to IMVT-1401 pursuant to our license agreement (the “HanAll Agreement”) with HanAll. Pursuant to the HanAll Agreement, we will be responsible for future contingent payments and royalties, including up to an aggregate of \$442.5 million 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 on net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement.

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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 IMVT-1401.* We plan to leverage IMVT-1401's differentiated profile in target indications where the anti-FcRn mechanism has already established clinical proof-of-concept. We intend to identify and target a variety of IgG-mediated autoimmune indications based on the following factors:
 - Inadequacy of the standard of care;
 - Disease severity that warrants novel therapies;
 - Ability to rapidly establish proof-of-concept through comparatively short duration clinical trials using validated clinical endpoints; and
 - Ability to rapidly initiate pivotal trial programs and potentially receive regulatory approval.
- *Select new indications for IMVT-1401 in areas of high unmet needs.* We intend to be the first to study FcRn inhibition in autoimmune indications with clear biologic rationale and no known in-class competitors in clinical development.
- *Rapidly advance development of IMVT-1401 for the treatment of MG, TED and WAIHA.* We are currently developing IMVT-1401 for the treatment of MG, TED and WAIHA by leveraging the strong biologic rationale of targeting FcRn to reduce IgG antibody levels and the clinical and regulatory insights gained from other FcRn-targeted therapies in MG.
- *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.

The prevalence of certain IgG-mediated autoimmune diseases are set forth in the following table:

Indication	Estimated Prevalence (2019)	
	U.S.	Europe*
Myasthenia Gravis	66,000	104,000
Warm Autoimmune Hemolytic Anemia	42,000	67,000
Thyroid Eye Disease	33,000	52,000
Idiopathic Thrombocytopenic Purpura	31,000	50,000
Pemphigus Vulgaris	28,000	45,000
Chronic Inflammatory Demyelinating Polyneuropathy	16,000	25,000
Bullous Pemphigoid	8,000	13,000
Neuromyelitis Optica	7,000	12,000
Pemphigus Foliaceus	7,000	11,000
Guillain-Barré Syndrome	3,000	5,000
PLA2R+ Membranous Nephropathy	2,000	4,000
Total	243,000	388,000

* Europe includes all E.U. countries, the U.K. and Switzerland

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FcRn, IgG Antibody Recycling and IMVT-1401 Mechanism of Action

The neonatal fragment crystallizable receptor is a cellular receptor that can bind IgG antibodies and guide their transport through cells. FcRn is named as such given its critical role in transferring maternal IgG antibodies contained in breast milk across the gut into the neonate's bloodstream, providing passive immunity until such time as the child is sufficiently mature to produce its own antibodies. FcRn is also involved in the transfer of maternal IgG antibodies across the placenta in the developing fetus.

In adults, FcRn is the primary protein responsible for preventing the degradation of IgG antibodies and albumin, the most abundant protein found in the blood. IgG antibodies are constantly being removed from circulation and internalized in cellular organelles called endosomes. The role of FcRn is to bind to the IgG antibodies under the more acidic conditions of the endosome and transport them to the cell surface, where the neutral pH causes them to be released back into circulation. This FcRn mechanism of action and IgG antibody recycling is depicted in the graphic below.

FcRn and IgG Antibody Recycling



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Our product candidate, IMVT-1401, is designed to block the recycling of IgG antibodies, resulting in their removal from circulation. IMVT-1401 binds to FcRn, blocking the ability of FcRn to bind to IgG antibodies under the more acidic conditions of the endosome. As a result, the bound IMVT-1401 and FcRn are transported to the cell surface, where FcRn is prevented from further recycling IgG antibodies as IMVT-1401 remains bound to FcRn even in the pH neutral environment outside the endosome. Meanwhile, the unbound IgG antibodies are degraded in the lysosome rather than being transported by FcRn for release back into circulation. This IMVT-1401 mechanism of action is depicted in the graphic below.

IMVT-1401's Mechanism of Action



IMVT-1401

Overview

IMVT-1401 (formerly referred to as RVT-1401) is a novel, fully human monoclonal antibody that selectively binds to and inhibits FcRn. In a Phase 1 clinical trial, IMVT-1401 has demonstrated dose-dependent reductions in serum levels of IgG antibodies and was well-tolerated following subcutaneous and intravenous administration to healthy volunteers. In addition, completed clinical trials of other anti-FcRn antibodies have produced positive proof-of-concept activity in multiple IgG-mediated autoimmune diseases. We believe that these data support FcRn as a viable pharmacologic target with the potential to address multiple IgG-mediated autoimmune diseases. We intend to develop IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule.

IMVT-1401 has been assigned the nonproprietary name batoclimab on the World Health Organization's Recommended International Nonproprietary Names List.

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Generation of IMVT-1401 and In Vitro Properties

IMVT-1401 is the result of a multi-step, multi-year research program conducted by our partner, HanAll, to engineer an antibody with the potency, specificity, safety, and pharmacokinetic (“PK”) properties optimized for subcutaneous administration. The selection of initial candidates was the result of screening a library of nearly 10,000 antibodies generated from both transgenic animal systems as well as phage-display libraries. These initial candidates were prioritized based on:

- Potency and specificity for FcRn;
- Ability to block the IgG-FcRn interaction;
- Ability to remain bound to FcRn regardless of pH;
- High production and stability in standard antibody production cell lines;
- Ability to achieve high concentrations appropriate for subcutaneous delivery; and
- Lack of immunogenicity.

IMVT-1401 was generated using the OmniAb transgenic rat platform from Open Monoclonal Technology (“OMT”). OMT was later acquired by Ligand Pharmaceuticals in 2015.

IMVT-1401 has been engineered to express specific known mutations that eliminate effector function. Traditional antibodies contain amino acid sequences that can trigger antibody-dependent cell-mediated cytotoxicity (“ADCC”) or complement-dependent cytotoxicity (“CDC”) in which bound antibodies are recognized by effector components of the immune system which leads to inflammation. While this is an important mechanism for elimination of pathogens, triggering ADCC or CDC can lead to unintended immune activation and side effects. For this reason, IMVT-1401 was engineered with specific and validated mutations known to reduce ADCC and CDC.

Potential Benefits of IMVT-1401

As a result of the rational design of IMVT-1401, we believe that IMVT-1401, if approved for use, could provide the following benefits:

- *Subcutaneous delivery.* Based on clinical data, we believe that we will be able to obtain therapeutically relevant levels of IgG reduction using 2-mL volume subcutaneous injections. Our current formulation is concentrated at 170 mg/mL.
- *Simple dosing schedule.* We are developing IMVT-1401 as a fixed-dose subcutaneously administered regimen without the need for preceding intravenous induction doses or lengthy subcutaneous infusions. If approved, we intend to market IMVT-1401 as a fixed-dose pre-filled syringe or auto-injector, which would allow for convenient self-administration, eliminating the need for frequent and costly clinic visits, and reduce complexity and errors associated with calculating individual doses.
- *Low immunogenicity risk.* IMVT-1401 is a fully human monoclonal antibody, and therefore contains only amino acid sequences native to humans.
- *Low effector function.* IMVT-1401 has been engineered to prevent activation of other components of the immune system, and, as a result, unintended immune response to IMVT-1401 is not expected. Specifically, well-characterized and validated mutations introduced into the fragment crystallizable domain of IMVT-1401 have reduced its ability to cause ADCC and CDC. There have been no reports of severe systemic allergic reactions to study therapy reported to-date.

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Clinical Development of IMVT-1401

We are developing IMVT-1401 as a fixed-dose subcutaneous injection for a variety of IgG-mediated autoimmune diseases, with an initial focus on the treatment of MG, TED and WAIHA. In light of the COVID-19 pandemic, we have taken several actions designed to protect the safety and well-being of our patients and ensure quality trial execution. Our very experienced clinical development team has successfully maintained robust communication with our sites. New patients enrolled in our programs from March to June 2020 did not miss any in-person clinic visits during the initial treatment period. We have also been working with our partners to ensure that backup services are in place, which has enabled some virtual visits to replace in-person visits during the follow-up period after initial treatment. As always, we continue to stay abreast of evolving guidance from regulatory agencies emphasizing patient safety, flexibility within certain guardrails and very good documentation. While we continue to evaluate the impact of the COVID-19 pandemic, we intend to provide an update on our anticipated clinical development timelines for TED and WAIHA in the third quarter of calendar year 2020.

Phase 1 Clinical Trials of IMVT-1401 in Healthy Volunteers

We have completed a multi-part, placebo-controlled Phase 1 clinical trial involving 99 healthy volunteers in Australia and Canada, administering IMVT-1401 both as an intravenous infusion and as a subcutaneous injection. In this trial, 77 subjects received at least one dose of IMVT-1401 and 22 subjects received placebo. The results of our Phase 1 trial are presented below:

Trial Design of Multi-Part Phase 1 Clinical Trial of IMVT-1401



Australian Trial data is not presented

Pharmacokinetic Data

In the single-ascending dose portion of our Phase 1 clinical trial, IMVT-1401 demonstrated a PK profile that varies with increase in dose, consistent with the characteristics expected of a drug exhibiting target-mediated disposition. Following subcutaneous administration of IMVT-1401, the median time to peak concentrations ranged from less than a day for the lowest dose administered to approximately three days for the highest dose of 765 mg. Following subcutaneous ("SC") administration of single doses of IMVT-1401, C_{max} and AUC increased in a greater than dose proportional manner. Following four-weekly SC doses of IMVT-1401, accumulation for C_{max} and $AUC_{0-\infty}$ were dose-dependent.

Pharmacodynamic Data

We tested single administrations of fixed intravenous doses of IMVT-1401, ranging from 0.1 mg/kg to 1530 mg as a fixed dose. The 1530 mg fixed intravenous dose resulted in mean maximum reduction of serum IgG levels of 67%. Maximal reductions were observed between 10 and 14 days after dose administration. In addition, single subcutaneous doses of IMVT-1401, ranging from 0.5 to 5 mg/kg and 340 mg to 765 mg led to dose-dependent mean maximum reductions in serum IgG levels of between 14% and 48%. Maximal reductions were observed between seven and 14 days after dose administration. Following four-weekly SC doses of IMVT-1401 at 340 mg and 680 mg, mean maximum reduction of serum IgG levels were 63% and 78%, respectively, compared with 11% for placebo. Maximal reductions were observed between 21 and 28 days after the first dose of IMVT-1401.

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Total Mean Reduction of IgG Levels in Phase 1 Clinical Trial of IMVT-1401 After Single Dose in Healthy Volunteers



In the multiple-ascending dose portion of our Phase 1 clinical trial, two dose levels were tested. After four weekly subcutaneous administrations of 340 mg, a mean maximum reduction of serum IgG levels of 63% was observed during the treatment period, and the standard deviation of the reduction was 11%. In the second and final multiple-dose cohort, four weekly subcutaneous administrations resulted in a mean maximum reduction of serum IgG levels of 78% during the treatment period, and the standard deviation of the reduction was 2%.

Total Mean Reduction of IgG Levels in Phase 1 Clinical Trial of IMVT-1401 After Four Weekly Doses in Healthy Volunteers



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In this Phase 1 clinical trial, we also analyzed reductions in IgG antibodies by subclasses. The IgG class of antibodies is composed of four different subtypes of IgG molecules, called the IgG subclasses, which are designated IgG1, IgG2, IgG3 and IgG4. In the multiple-dose cohorts, administration of IMVT-1401 resulted in dose-dependent reductions across all IgG subclasses. We observed mean maximal reductions of greater than 78% and 63% for the IgG1, IgG3 and IgG4 subclasses in subjects receiving the 680 mg and 340 mg fixed subcutaneous doses, respectively. IgG2 was reduced from baseline following 680 mg and 340 mg fixed subcutaneous doses with observed mean maximum reductions of 70% and 50%, respectively.



The IgG reductions we observed in this multi-part, placebo-controlled Phase 1 clinical trial support the continued development of IMVT-1401, however, this trial did not include pre-specified endpoints for IgG reduction, and we cannot be certain that similar IgG reductions will be observed in any future clinical trials.

Safety Data

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment-emergent AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo. These reactions at the injection site were not considered dose-related and did not increase with multiple administrations of IMVT-1401 in the multiple-dose cohorts. To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. There have been no treatment-related serious AEs reported.

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A summary of the most commonly reported AEs, meaning the AE reported occurred in more than one subject, is set forth in the table below:

Most Common Adverse Events Reported in Phase 1 Clinical Trial of IMVT-1401

Number of Subjects MedDRA Preferred Term	Single Ascending Dose												Multiple Ascending Dose Subcutaneous Injection				
	Intravenous Infusion						Subcutaneous Injection										
	0.1 MG/ KG N=4	100 MG N=6	340 MG N=6	765 MG N=6	1530 MG N=6	Placebo N=8	0.5 MG/KG N=3	1.5 MG/KG N=6	5 MG/KG N=6	340 MG N=6	500 MG N=6	765 MG N=6	Placebo N=10	340 MG N=8	680 MG N=8	Placebo N=4	
Abdominal pain										1					1		
Abdominal pain upper														2	1		
Abnormal sensation in eye						1				1							
Back pain							2				1			1	1		
Constipation							1								1		
Cough											1			2			
Diarrhea														2			
Dizziness						1								1		1	
Dry skin														1	1		
Erythema							1								1		
Fatigue	1		1	1	1	1				1					1		
Headache	1	1	1	1	1			1	1	4	1			1	2		
Injection site erythema									5	1	5	6		7	8	7	4
Injection site pain										1					2		1
Injection site swelling								3		2	4		3	7	6	2	
Insomnia									1					4			
Myalgia														1	1		
Nasal congestion									1		1			1	1		
Nausea									1	1				1	1	1	
Ocular hyperaemia															2		
Oropharyngeal pain	1			1	2					1		1			1	2	
Pain in extremity							1								1		
Procedural complication									1		1						
Procedural dizziness					2									1			
Pyrexia		1	1							1							
Rash					2					2					2	1	
Rhinorrhoea										1					2		
Sinusitis			1												1		
Somnolence		1									1						
Upper respiratory tract infection	1	1	1					3		1	1				1		
Vision blurred					1							1					

In November 2018, one serious AE (malpighian carcinoma) occurred in a 51-year-old subject who had received a single 765 mg subcutaneous administration of IMVT-1401. Fifty-five days after study drug administration, the subject presented to his personal physician with a left-sided neck mass. Biopsy results determined the mass to be a poorly differentiated malpighian carcinoma, which was assessed as unrelated to IMVT-1401 by the study investigator. In February 2019, a 25-year-old subject who received a single dose 1530 mg of IMVT-1401 by intravenous infusion presented five days later with uncomplicated acute appendicitis and the presence of an appendiceal stone. The subject underwent laparoscopic appendectomy and recovered with an uneventful post-operative course. The event was considered unrelated to study drug by the study investigator.

While headaches, some of which have been considered severe, have been reported in third-party clinical trials of some other anti-FcRn antibodies, no headaches have been noted in any of the subjects receiving IMVT-1401 in the 680 mg multiple-dose cohort. In the 340 mg cohort, two of eight subjects experienced headaches, one mild and one moderate. The moderate headache occurred six days after the final dose of IMVT-1401 was administered.

Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts. In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). These reductions were not associated with any AEs or clinical symptoms and did not lead to any study discontinuations. The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia). In this syndrome, despite extremely low or absent levels of albumin, those affected have only mild symptoms, including fatigue, low blood pressure and edema. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

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Immunogenicity Data

The development of anti-drug antibodies (ADA) to IMVT-1401 was assessed across all dosed cohorts following single (IV and SC formulations) and multiple (SC formulation) administrations of IMVT-1401. Preliminary data show a similar frequency of treatment-emergent ADA development among subjects who received at least one administration of IMVT-1401 or placebo (8% and 6%, respectively). The antibody titers were low ($\leq 1:16$) consistent with the high sensitivity of the ADA assay. No subjects in either the 340 mg or 680 mg multiple ascending dose (MAD) cohorts developed ADAs with treatment. ADAs will continue to be monitored throughout the development program.

Nonclinical Studies of IMVT-1401

Cynomolgus monkeys were selected as the primary species for nonclinical testing, given the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn. Our partner, HanAll, completed five nonclinical studies of IMVT-1401 (referred as HL161BKN for the purposes of these studies) in cynomolgus monkeys. We have conducted two additional studies in cynomolgus monkeys. These studies are listed in the table below:

<u>Name of Study</u>	<u>Duration</u>	<u>Animals Tested</u>	<u>Route of Administration Dose (Frequency)</u>
Evaluation of IgG Catabolism and PK of HL161 Candidates (HL161AN and HL161BKN) in Cynomolgus Monkey (Study TR-127-161)	4 weeks	N = 20 ^a	IV: 5, 20 mg/kg/dose (Days 0, 7, 14, 21)
Evaluation of IgG Catabolism and PK of HL161AN and HL161BKN Following IV and SC Administration (Study TR-140-161)	2 weeks	N = 36 ^a	IV: 5, 10 mg/kg/dose; SC: 5, 10 mg/kg/dose (Days 0, 3, 7, 10)
Evaluation of Low-dose PK-PD Cynomolgus Monkey for Selection of Maximum Recommended Start Dose (MRSD) of HL161BKN in Humans (Study TR-166-161)	2 weeks	N = 12	IV: 0.5, 1.5, 5 mg/kg/dose (Days 0, 3, 7, 10)
HL161BKN 1-Week Repeat-Dose Range-Finding Toxicity, PK, and PD Study in the Cynomolgus Monkey (Study 8348379)	1 week	N = 16 ^a	SC: 25, 100 mg/kg/dose IV: 100 mg/kg/dose (Days 1, 4, 8)
HL161BKN A Six-Week Subcutaneous and Intravenous Administration Toxicity Study in Cynomolgus Monkeys with a Nine-Week Treatment-Free Period (Study 8348381)	6 weeks	N = 48 ^a	SC: 25, 50, 100 mg/kg/dose; IV: 25, 100 mg/kg/dose (twice weekly)
12-Week Subcutaneous Injection and Intravenous Infusion Toxicity and Toxicokinetic Study with RVT-1401 in Cynomolgus Monkeys Followed by a 10-Week Recovery Period (Study 8386882)	12 weeks	N = 60 ^a	SC: 10, 25, 100 mg/kg/dose; IV: 10, 100 mg/kg/dose
26-Week Subcutaneous Injection and Intravenous Infusion Toxicity and Toxicokinetic Study with RVT-1401 in Cynomolgus Monkeys Followed by a 10-Week Recovery Phase (Study 8391434)	26 weeks	N = 40 ^a	SC: 100 mg/kg/dose (twice weekly); IV: 50, 100 mg/kg/dose

a: includes vehicle control group animals.

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Three pharmacology studies were performed to screen molecules and to define the efficacious dose based on the PK and pharmacodynamics (“PD”), profile, and two toxicology studies were performed. In the pharmacology studies, IMVT-1401 demonstrated a consistent PD response of reduced IgG levels that correlated with the PK of IMVT-1401 with observed IgG reductions ranging between approximately 53%, and 78% across all three studies. The following chart sets forth the range of trough IgG levels from percentage of baseline:

Pharmacology Studies

Evaluation of IgG Catabolism and PK of HL161 Candidates (HL161AN and HL161BKN) in Cynomolgus Monkey (Study TR-127-161)
Evaluation of IgG Catabolism and PK of HL161AN and HL161BKN Following IV and SC Administration (Study TR-140-161)

Evaluation of Low-dose PK-PD Cynomolgus Monkey for Selection of Maximum Recommended Start Dose (MRSD) of HL161BKN in Humans (Study TR-166-161)

Trough IgG % of Baseline (Mean ± SD)
IV 5 mg/kg: -57 ± 5
IV 20 mg/kg: -74 ± 7
IV 5 mg/kg: -78 ± 7
IV 10 mg/kg: -73 ± 10
SC 5 mg/kg: -74 ± 4
SC 10 mg/kg: -77 ± 10
IV 0.5 mg/kg: -53 ± 16
IV 1.5 mg/kg: -58 ± 9
IV 5 mg/kg: -75 ± 13

In the 6-week and 12-week toxicology studies (Study 8348381, Study 8386882, respectively), exposure to IMVT-1401, a fully human monoclonal antibody, resulted in the development of an ADA response that led to immune complex formation in isolated animals. In the six-week study, at least one sampling point tested positive for ADA in 37 of the 38 animals that received IMVT-1401 twice weekly by subcutaneous or intravenous administration. Some animals with ADA had reduced TK and PD responses. However, the majority of animals still had measurable circulating levels of IMVT-1401 that translated to reduced IgG levels. In the 12-week toxicology study all animals developed ADA by Day 22 of the treatment phase of the study, and IMVT-1401 exposures on Days 43 and 78 were generally lower compared to Day 1, particularly with low subcutaneous doses. An abrogation of the PD response was observed following development of ADA in the lower dose cohorts but was maintained in the higher dose cohorts. In the 26-week toxicology study (Study 8391434), animals administered by IV infusion resulted in higher incidence of ADA positive responses compared to animals dosed by SC injections. Over the course of the study, PD effect of total IgG reductions was observed in all animals. The decrease in total IgG was more pronounced in animals administered with 100 mg/kg/week IV compared to animals administered 200 mg/kg/week SC. Reversibility of the total IgG reduction in the SC animals was evident by Day 64 in the recovery phase. Importantly from the subchronic 26-week toxicity study, based on the overall toxicity profile following 26 weeks of SC injections (200 mg/kg/week), the No-Observed-Adverse-Effect-Level (NOAEL) of IMVT-1401 following SC injection was concluded to be 100 mg/kg/dose or 200 mg/kg/week; this represents a 3-fold safety margin (100 mg/kg/dose) when compared to the clinical dose of 680 mg/dose taking into account allometric corrections between monkeys and humans. Moreover, the safety margin is increased to 6-fold when considering IMVT-1401 was administered twice per week at 200 mg/kg/week. Overall, in these nonclinical studies, there was a robust PK/TK and PD correlation in cynomolgus monkeys after removing the confounding element of ADA.

The immunogenicity response to human proteins generated in nonclinical species is generally not predictive of that in the human. Nevertheless, subjects in clinical trials with IMVT-1401 will be carefully monitored for any AEs, including those related to immunogenicity.

IMVT-1401 for the Treatment of 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 to 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 one in 5,000, with up to 66,000 cases expected in the United States. MG can occur at any age; however, the age of onset tends to follow a bimodal distribution. Early onset disease usually occurs in individuals between 10 to 30 years old and predominantly affects females. Later onset disease usually occurs in individuals 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.

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These broad classes of MG severity are often referred to by a clinical classification system described by the Myasthenia Gravis Foundation of America (“MGFA”) the only national volunteer health agency in the United States dedicated solely to the fight against MG. The MGFA clinical classification divides MG patients into five classes: Class I represents patients with weakness restricted to ocular muscles, while Classes II through V represent generalized MG with severity of symptoms increasing in each Class.

Class	MGFA Clinical Classification	
	Symptoms	
I	Weakness in ocular muscles	
II	Mild weakness in limb, head and trunk, or respiratory muscles	
III	Moderate weakness in limb, head and trunk, or respiratory muscles	
IVa	Severe weakness in non-ocular muscles, predominantly affecting muscles in limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles	
IVb	Severe weakness in non-ocular muscles, predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.	
V	Requires intubation	

Clinicians have developed a quantitative examination-based scoring system to follow a patient’s disease severity called the Quantitative Myasthenia Gravis (“QMG score”), which measures muscle weakness. The QMG score is divided into 13 sections, each measuring the weakness of different sets of muscles such as that of outstretched limbs, grip strength, breathing, swallowing, eye movement, speech and neck strength. Each item is assessed on a four-point scale where a score of zero represents no weakness and a score of three represents severe weakness for a maximum total score of 39. Clinicians also use the MG Activities of Daily Living (“MG-ADL”) score, a clinically validated, patient-reported measurement of the severity of MG symptoms. The MG-ADL score measures the effect of MG symptoms on eight functions as reported by the patient, including talking, chewing, swallowing, breathing and vision. Each item is assessed on a three-point scale where a score of zero represents no symptoms and a score of three represents severe symptoms for a maximum total of 24.

Previously completed clinical trials of anti-FcRn antibodies have generated promising results. In a recently completed Phase 3 clinical trial conducted by argenx SE to evaluate efgartigimod, an anti-FcRn antibody fragment for the treatment of MG, patients dosed with intravenous drug product demonstrated clinically meaningful and statistically significant responder rate in MG-ADL score compared to those receiving placebo after four weeks of treatment. Note that detailed and longer term safety data has not yet been reported.

The most common target of autoimmune antibodies in MG are the AChR protein within the neuromuscular junction that binds to the acetylcholine neurotransmitter released by the nerve fiber terminal, and muscle-specific kinase (“MuSK”), a tyrosine kinase, which is involved in propagating neuronal signals. Anti-AChR and anti-MuSK antibodies are found in approximately 85% and 8% of MG patients, respectively. The presence of these autoimmune antibodies blocks the signaling from neurons to muscles which results in an impaired ability for the muscle to contract or sustain contraction and results in outward signs of muscle weakness and fatigue.

Current Treatment Paradigm

Very early stage MG is symptomatically treated with acetylcholinesterase inhibitors such as pyridostigmine, which block the breakdown of acetylcholine at the neuromuscular junction, thereby increasing its concentration and capacity to activate the muscle. 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. However, IVIg requires recurrent, burdensome infusions to obtain significant reductions in symptoms, and the large volumes of intravenous fluid associated with the administration of IVIg can lead to significant side effects, including pulmonary edema and renal complications and treatment can be complicated by events associated with intravascular thrombosis.

Physicians direct patients with more advanced chronic disease and patients in times of crisis to therapies that reduce levels of circulating IgG antibodies. One method of reducing IgG levels is to take blood from a patient and physically remove the patient’s plasma before returning the red blood cells as well as outside obtained albumin or plasma to the patient in a process called plasma exchange. This is a slow process that typically takes several hours. Furthermore, this process often requires multiple treatment sequences due to limited daily tolerance (a reported mean of 6 treatments in MG) over a number of days in order to achieve a significant reduction in IgG antibody levels. A variant of this procedure is immunoadsorption, in which bacterial proteins are used to selectively remove IgG antibodies from serum. The table below sets forth an overview of these treatments for MG. The most recent agent approved for MG is eculizumab, a complement C5 inhibitor, the use of which is limited to patients refractory to available therapy with anti-AChR-positive MG. Anti-MuSK antibodies have a low propensity to activate complement proteins, thus C5 inhibition may not be therapeutically relevant in anti-MuSK-positive patients. Studies indicating that patients with MuSK-positive disease are more likely to become treatment refractory thus present an additional unmet need. Approximately 10% of MG patients are refractory to current treatments, while up to 80% fail to achieve complete stable remission.

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Overview of Current Treatment Options for Advanced Myasthenia Gravis

	IVIg	Immunoadsorption	Plasma Exchange	Eculizumab
Mechanism of Action	Not fully known	Removal of autoantibodies	Removal of autoantibodies	Complement inhibition (only approved in anti-AChR MG)
Pathogenic IgG Reduction*	~30% to 70%	~55% to 90%	~65% to 75%	N/A
Mode of Administration	Intravenous or subcutaneous	Intravenous	Intravenous	Intravenous
Typical Regimen	Each session requires 2-4 hours over 2-5 consecutive days Subcutaneous options require ~ 1 hour	Each session requires 3-4 hours over 2-4 consecutive days Repeat every 2-4 weeks	Each session requires ~2 hours Repeat daily, weekly or monthly	Weekly for the first five weeks, then every other week
Setting	Home or clinic administration	Clinic	Clinic	Clinic

* Company estimates based on literature review across autoimmune indications.

ASCEND MG Trial

In August 2019, we initiated dosing in a randomized, blinded, placebo-controlled Phase 2a clinical trial of IMVT-1401 for the treatment of MG. The ASCEND MG trial assesses safety and efficacy of IMVT-1401 in an anticipated 21 patients with MG symptoms, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12. In the ASCEND MG trial, patients with MG who have confirmed anti-AChR antibodies will receive one of two dose levels of IMVT-1401 (680 mg or 340 mg) or placebo delivered by subcutaneous injection on a weekly schedule for six weeks followed by a six-week open-label extension period, in which patients will be able to receive up to three further injections of IMVT-1401 administered every other week. There are then three follow-up visits during a six-week post-dosing period. The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401 and measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG. Secondary endpoints include PK and changes from baseline in various clinical scores such as QMG, MG-ADL and quality of life measures. Exploratory endpoints include assessment of multiple biomarkers including gene expression profiles, pro-inflammatory markers and receptor occupancy. We expect to report results from the placebo-controlled treatment phase of this trial in the late third quarter or early fourth quarter of calendar year 2020.

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Trial Design of ASCEND MG Trial



On June 29, 2020, we announced that we have begun preparation to initiate a Phase 3 registrational trial of IMVT-1401 in MG. We expect to engage the FDA on the design and conduct of this pivotal program and expect the FDA's feedback to be an important part of the final plan.

IMVT-1401 for the Treatment of Thyroid Eye Disease

Thyroid Eye Disease Overview

TED, also referred to as GO, is an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes, which can be sight-threatening. 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. By the time that TED is clinically diagnosed, many patients have retraction of their upper eyelids, swelling and redness surrounding the eyes and protrusion of the eyes. In some cases, swelling and stiffness of the muscles that move the eyes cause the eyes to no longer line up with each other or for the eyelids to no longer be able to close. Approximately 3% to 5% of TED patients have a severe manifestation of the disease, with intense pain, inflammation and sight-threatening corneal ulcers or optic neuropathy that requires 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 thyroid-stimulating hormone receptor ("TSHR"). These antibodies activate certain cell types, such as fibroblasts and adipocytes, present in the extraocular space, which are known to highly express TSHR. The activation of these fibroblasts causes them to proliferate and to produce 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 and extensive tissue inflammation and remodeling. Exposure to other inflammatory agents, such as cigarette smoke, lead to exacerbation of the disease resulting in more severe symptoms. Anti-TSHR antibodies also increase the proliferation of adipose or fat cells as well as myofibroblasts, smooth muscle-like cells. Levels of anti-TSHR autoantibodies correlate positively with clinical features of TED and influence its prognosis.

In addition to anti-TSHR autoantibodies, antibodies that activate the insulin-like growth factor 1 receptor ("IGF1R") have been described in the literature. TSHR and IGF1R have functional overlaps and stimulation of either receptor may lead to activation of similar biochemical pathways in certain cell types, including the ones implicated in TED. Published studies investing 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 suggest 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 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe. 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. 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 United States have active inflammatory TED and are eligible for treatment.

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Clinicians use the CAS to measure disease activity in TED patients. CAS is based on seven parameters, including spontaneous pain behind the eye, pain with eye movement, redness of the eyelids, redness of the conjunctiva, swelling of the eyelids, swelling of the caruncle and swelling of the conjunctiva. A score is calculated based on the number of parameters that are positive with scores of four or above considered to be cases of active disease. Changes in disease severity over time are determined by changes in proptosis, or protrusion of the eyeball, eye movements and visual acuity.

Relationship between TED and Graves' Disease

TED often develops in parallel with Graves' disease, a related but clinically distinct autoimmune disease. In Graves' disease, anti-TSHR autoantibodies cause the thyroid to become overactive, resulting in a condition called hyperthyroidism, in which the thyroid overproduces thyroid hormone. If left untreated, hyperthyroidism can cause serious problems with the heart, bones, muscles, menstrual cycle and fertility.

A close temporal relationship exists between the onset of Graves' disease and the onset of TED. Regardless of which condition occurs first, in 80% of patients, the other condition develops within 18 months. Approximately one in 20 patients with Graves' disease present with moderate-to-severe TED, which is characterized by swelling and redness of eyelids, proptosis, double vision and, in severe cases, corneal ulceration and decreased visual acuity. Graves' disease can be treated with antithyroid drugs or removal of the thyroid through a procedure called a thyroidectomy. While some studies of these treatments have shown autoimmune antibodies decreasing or disappearing with treatment, others have shown no change in antibody levels after treatment.

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 which is still in the active stage and who do not respond adequately to corticosteroids can be treated with cyclosporine or mycophenolate mofetil, two broad immunosuppressive drugs. These powerful 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 high CAS 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.

We believe that a therapy for TED focused on addressing the cause of the disease, namely the presence of autoimmune antibodies, represents an attractive approach that has the potential to avoid many of the serious side effects of current therapies. In previously conducted third-party studies, levels of autoimmune antibodies were reduced through plasmapheresis and IVIg and resulted in therapeutic benefit. We expect that IMVT-1401 has the potential to deliver similar benefits. Because the mode of action of IMVT-1401 is independent of the antigen recognized by the autoimmune antibodies, we believe that IMVT-1401 can address TED that arises through any IgG autoantibody mechanism whether it be anti-TSHR, anti-IGF1R, or any other IgG autoantibodies.

ASCEND GO-1 Trial

In May 2019, we initiated dosing in our ASCEND GO-1 trial, an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with TED. We announced initial results from this trial in March 2020. Patients recruited for this trial have moderate-to-severe active TED with confirmed autoantibodies to TSHR. A total of seven patients were dosed weekly with subcutaneous injections for six weeks. The trial utilized an induction and maintenance strategy, using only subcutaneous injections. Patients received a 680 mg dose for the first two administrations of study followed by a 340 mg dose for the final four administrations. The primary endpoints of this trial are safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses. Secondary clinical endpoints include mean changes in proptosis, or protrusion of the eyeball, the proptosis responder rate, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, PK and anti-drug antibodies. Exploratory endpoints include assessment of change from baseline in the CAS, change from baseline in the Gorman diplopia score, multiple biomarkers including gene expression profiles, pro-inflammatory markers, receptor occupancy and changes as measured by computerized tomography (CT) scans.

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Trial Design of ASCEND GO-1 Trial



All seven patients have completed the six-week treatment phase of the trial and have entered the 12-week follow-up phase. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, four of seven patients (57%) improved by ≥ 2 points on the CAS. Of six patients with baseline diplopia, four patients (67%) demonstrated improvement in diplopia. Three of seven patients (43%) were proptosis responders. The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. Mean albumin reduction from baseline to end of treatment was 24%. All AEs were mild or moderate and there were no headaches reported.

ASCEND GO-2 Trial

In October 2019, we initiated dosing in our ASCEND GO-2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active TED with confirmed autoantibodies to TSHR. The ASCEND GO-2 trial explores the potential of IMVT-1401 to improve proptosis and assesses the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of three doses of IMVT-1401 (680 mg, 340 mg or 255 mg) or placebo administered weekly by subcutaneous injection for 12 weeks. The primary endpoints of this trial are the proptosis responder rate measured at week 13, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, and safety and tolerability. Secondary endpoints include the proptosis responder rate measured at weeks 2, 3, 4, 5, 6, 8, 10, 12, 14, 16 and 20, the proportion of patients with a CAS of 0 or 1, the mean change from baseline in proptosis, CAS, diplopia, ophthalmic improvement and GO-QOL and PK, PD, defined as anti-TSHR antibodies and total IgG and IgG antibodies by subclasses, and anti-drug antibodies. Exploratory endpoints include assessment of CT-measured muscle volume, fat volume, total orbital volume and proptosis, as well as multiple biomarkers including gene expression profiles, pro-inflammatory markers and receptor occupancy. As previously communicated, results from this trial are still possible in the first half of calendar year 2021. We intend to provide an update on the timing for this trial in the third quarter of calendar year 2020.

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Trial Design of ASCEND GO-2 Trial



IMVT-1401 for the Treatment of Warm Autoimmune Hemolytic Anemia

Warm Autoimmune Hemolytic Anemia Overview

WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of RBCs. The clinical presentation is variable and most commonly includes non-specific symptoms of anemia such as fatigue, weakness, skin paleness and shortness of breath. Symptoms typically develop chronically over several weeks to months, however rapid progression over a span of days has also been observed.

In severe cases, hemoglobin levels are unable to meet the body's oxygen demand, which can lead to heart attacks, heart failure and even death. Though the exact causes of WAIHA are unknown, roughly half of cases occur in patients with an underlying lymphoproliferative or autoimmune disease, most commonly chronic lymphocytic leukemia, rheumatoid arthritis or systemic lupus erythematosus.

In WAIHA, autoantibodies react with surface proteins on RBCs at temperatures at or above 37° Celsius, or normal body temperature. These antibodies are of the IgG subtype in the majority of patients. WAIHA is differentiated from cold autoimmune hemolytic anemia, or cold agglutinin disease, which shares a similar clinical presentation but is triggered by autoantibodies that react at temperatures below 37° Celsius. In WAIHA, antibody-coated RBCs are removed from circulation primarily in the spleen, where they are destroyed by macrophages. Studies have suggested the severity of WAIHA correlates with the amount and potency of autoantibodies present.

The laboratory evaluation of WAIHA begins with a peripheral blood analysis revealing evidence of extravascular hemolysis (spherocytes, low haptoglobin, elevated bilirubin and elevated LDH). In over 97% of cases, patients have a positive direct antiglobulin test, which detects the presence of IgG or complement proteins bound to the surface of RBCs.

The annual incidence of WAIHA in the United States and Europe is estimated at one to three in 100,000 persons. Based on published estimates, we believe that there are approximately 42,000 patients in the United States and 66,000 patients in Europe living with WAIHA. The disease may be more common in females, with some sources suggesting a 2:1 female predominance. Peak incidence occurs during the sixth and seventh decades of life, however, WAIHA can occur in children as well.

Current Treatment Paradigm

High doses of corticosteroids (>1 mg/kg of prednisone) are typically the first-line treatment option for WAIHA and lead to initial disease control in approximately 70-85% of cases. Once initial disease control is achieved, doses of steroids are tapered. However, only 33% of patients maintain sustained disease control once steroids are discontinued and, as a result, the majority of patients will require either long-term steroid treatment or additional therapies.

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There are few studies to guide which treatment options to use in patients failing corticosteroids. Until recently, splenectomy had been a common second-line treatment option for patients not responding adequately to corticosteroids. The therapeutic benefit of splenectomy is thought to be twofold: first, it eliminates the major site of RBC destruction in WAIHA; second, removal of the spleen reduces the total lymphoid tissue capable of producing autoantibodies. However, because of the lack of reliable predictors of the outcome, morbidity and potential operative complications of splenectomy, rituximab has become the default second-line option despite not being approved for use in WAIHA. In case studies looking at patients with relapsed disease after treatment with steroids, single-agent rituximab led to responses in 65% to 90% of patients. In such a course of treatment, maximal therapeutic effect is not immediate.

Patients with persistent disease despite use of corticosteroids and rituximab may be offered a course of other immunosuppressive drugs, such as cyclophosphamide, mycophenolate mofetil or azathioprine sirolimus.

IVIg is not routinely used alone for the treatment of WAIHA, however, small case series have suggested some evidence for a therapeutic effect in patients suffering from life-threatening complications of the disease. In these reports, IVIg has been given at high doses (greater than or equal to 1 g/kg per day), and the results have been inconsistent, requiring repeated courses of treatment in at least one case.

RBC transfusions are indicated in patients who require immediate stabilization. Such patients are monitored closely for evidence of a transfusion reaction. In contrast to other treatment modalities that lead to nonspecific suppression of the immune system, IMVT-1401 may offer a more targeted approach for reducing levels of the causative IgG species responsible for most cases of WAIHA. We believe this could provide a favorable therapeutic window and avoid the significant side effects associated with less targeted immunosuppression.

ASCEND WAIHA Trial

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. The ASCEND WAIHA trial will explore the potential of IMVT-1401 to increase hemoglobin levels and assess the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of two doses of IMVT-1401 (680 mg or 340 mg) administered weekly by subcutaneous injection for 12 weeks. The primary endpoint of this trial is the proportion of responders, defined as patients achieving a hemoglobin level of at least 10 g/dL and at least a 2 g/dL increase from baseline. Secondary endpoints include change from baseline in other hematologic and chemistry parameters, time to response, patient reported outcome measures, total IgG antibodies and IgG antibodies by subclasses. As previously communicated, results from this trial are still possible by the end of second half of calendar year 2020. We intend to provide an update on the timing for this trial in the third quarter of calendar year 2020.

Trial Design of ASCEND WAIHA Trial



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Key Agreements

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, Roivant Sciences GmbH (“RSG”), a wholly owned subsidiary of RSL, entered into the HanAll Agreement. Under the HanAll Agreement, RSG 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 IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, and to commercialize such products, in the United States, 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. 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 United States and E.U.; (2) an affiliate of RSG in any country in the Licensed Territory; and (3) a third party in the United States and E.U. only after submission of a biologics license application (“BLA”) in the United States 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 IMVT-1401 antibody, and certain back-up and next-generation antibodies, 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 IMVT-1401 from RSG 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 plus Swiss value-added tax of \$2.9 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.

Pursuant to the HanAll Agreement, RSG made an upfront payment of \$30.0 million to HanAll. In May 2019, we achieved our first development and regulatory milestone, which resulted in a \$10.0 million milestone payment that we subsequently paid in August 2019. We will be responsible for future contingent payments and royalties, including up to an aggregate of \$442.5 million 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 on 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.

Services Agreements with RSI and RSG

In August 2018, we entered into services agreements (the “Services Agreements”) with Roivant Sciences Inc. (“RSI”) and RSG, under which RSI and RSG agreed to provide services related to development, administrative and financial activities to us during our formative period. Under each Services Agreement, we will pay or reimburse RSI or RSG, as applicable, for any expenses they, or third parties acting on our behalf, incur. 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 markup. RSI and RSG also provided such services prior to the formalization of the Services Agreements, and such costs have been recognized by us in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on our matters. All other costs will be billed back at cost. The term of the Services Agreements will continue until terminated by us, RSI or RSG, as applicable, upon 90 days’ written notice.

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RSL Information Sharing and Cooperation Agreement

In December 2018, we entered into an amended and restated information sharing and cooperation agreement (the “Cooperation Agreement”) with RSL. The Cooperation Agreement, among other things: (1) obligates us to deliver to RSL periodic financial statements and other information upon reasonable request and to comply with other specified financial reporting requirements; (2) requires us to supply certain material information to RSL to assist it in preparing any future SEC filings; and (3) requires us to implement and observe certain policies and procedures related to applicable laws and regulations. We have 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 us or any of our subsidiaries, subject to certain limitations set forth in the Cooperation Agreement. No amounts have been paid or received under this agreement; however, we believe this agreement is material to our business and operations.

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 accounting principles generally accepted in the United States of America (“U.S. GAAP”) to consolidate our results of operations and financial position, account for its investment in us under the equity method of accounting or, by any rule of the SEC, include our separate financial statements in any filings it may make with the SEC and (b) has the right to elect directors constituting a majority of our board of directors.

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.

Sales and Marketing

We do not currently have our own marketing, sales or distribution capabilities. In order to commercialize IMVT-1401 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 United States, 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 IMVT-1401 or any future product candidates inside and outside the United States.

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Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of IMVT-1401, 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) of the FDA 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. Currently, we contract with two well-established third-party manufacturers, one for the manufacture of our drug substance and another for the manufacture of our drug product. We expect to engage additional third-party manufacturers to support any pivotal clinical trials for IMVT-1401 as well as commercialization of IMVT-1401, if approved, in the United States or other jurisdictions. In addition, we intend to recruit personnel with experience to manage the CMOs producing our product candidate 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 IMVT-1401. We are aware of several FcRn inhibitors that are in clinical development. These include efgartigimod (argenx SE), nipocalimab (Momenta Pharmaceuticals), rozanolixizumab (UCB) and ALXN1830 (Alexion Pharmaceuticals). Each of efgartigimod, nipocalimab, and rozanolixizumab is currently under development for the treatment of MG. In addition, for WAIHA, Alexion has announced plans to begin a Phase 2 trial for ALXN1830 in 2021 and Momenta is conducting an adaptive Phase 2/3 clinical study for nipocalimab. Momenta also announced that the FDA has granted Fast Track Designation for nipocalimab in WAIHA.

In a Phase 1 trial conducted by argenx SE, efgartigimod was observed to reduce mean IgG levels by approximately 50% after two 20 mg/kg intravenous induction doses followed by eight weekly 300 mg subcutaneous doses. 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. Momenta's nipocalimab is not yet in clinical development with a subcutaneous formulation and no clinical results for Alexion's subcutaneous formulation of ALXN1830 are available.

IMVT-1401, 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 Alexion), 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. The first line of treatment for TED and WAIHA 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, WAIHA and other IgG-mediated autoimmune diseases. Momenta 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, currently in a Phase 3 trial in a similar patient population; amifampridine (Catalyst Pharmaceuticals), a neuronal potassium channel blocker, for MG patients positive for the MuSK antibody, which is currently in Phase 3; and Myasterix (CuraVac), a therapeutic vaccine against B and T cells, which is being tested in early stage trials in MG patients. Moreover, Viela Bio has announced plans to initiate a pivotal trial in MG for inebilizumab, a CD19-targeted humanized monoclonal antibody, in 2020. Toleranzia has announced its intention to initiate Ph1/2a program in MG patients for its immunomodulating complex, TOL2, in 2020.

Numerous product candidates are currently in development for the treatment of WAIHA. Fostamatinib (Rigel Pharmaceuticals), a syk inhibitor, is currently in Phase 3 development. A Phase 2 investigator-initiated study of ibrutinib (AbbVie), a BTK inhibitor, in steroid-refractory WAIHA is ongoing. Kezar Life Sciences is running a Phase 2 trial including WAIHA patients for its immunoproteasome inhibitor, KZR-616.

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Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon its ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that it 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 United States 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 candidate 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 its ability to obtain and maintain proprietary protection for IMVT-1401 and any of its 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, we are the exclusive licensee of a patent family directed to IMVT-1401, and certain back-up and next-generation antibodies, and products containing such antibodies, in the Licensed Territory. As of May 14, 2020, this licensed patent family includes patent applications pending in the United States, Argentina, Brazil, Canada, European Patent Office, Egypt, Israel, Mexico and Saudi Arabia. These patent applications disclose the antibody, pharmaceutical composition thereof, methods of treating autoimmune disease using the same, polynucleotide encoding the antibody, expression vector including such polynucleotide, host cell transfected with such recombinant expression vector, methods of manufacturing the antibody and methods of detecting FcRn in vivo or in vitro using the antibody. Additionally, as of May 14, 2020, independent of the licensed patent family, ISG has a patent family that includes an internationally filed patent application and patent application pending in Argentina. This patent family is directed to methods of treating thyroid eye disease using anti-FcRn antibodies. Generally, the term of any patent granted from a patent application in the in-licensed HanAll patent family directed to the IMVT-1401 composition of matter and methods of use has a projected natural expiration and will expire on April 30, 2035 in the United States and in other jurisdictions, subject to such terms as may be modified by, for example, terminal disclaimer or any adjustment or extension of patent term that may be available in a particular jurisdiction. Notably, in this patent family, a U.S. patent in the patent family was issued on July 2, 2019, with claims directed to an isolated anti-FcRn antibody 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 patent family on January 28, 2020, with claims directed to an isolated anti-FcRn antibody 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 the antibody, polynucleotides and expression vectors encoding the antibody, host cells capable of expressing the antibody and methods of producing the antibody.

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In the United States, 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 14, 2020, this trademark portfolio included registration of the Immunovant trademark in the United States, Argentina, Brazil, Chile, China, Colombia, EU, Hong Kong Israel, the International Register, Japan, Mexico, Monaco, New Zealand, Norway, Philippines, Russian Federation, Saudi Arabia, Serbia, Singapore, South Korea and Switzerland, plus registration of the Immunovant logo trademark in Switzerland, and registration of the composite trademark in Chile, EU, the International Register, Monaco, Saudi Arabia, Switzerland and the United Kingdom. Additionally, trademark applications are pending for the Immunovant trademark in 22 foreign jurisdictions and for the composite trademark in the United States and 19 foreign jurisdictions. Under the HanAll Agreement, we have the right to market IMVT-1401 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 right, 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 its 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 it 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 its 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 it may require to develop or commercialize its future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States 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, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of IMVT-1401 or any future product candidate.

FDA Drug Approval Process

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

- completion of preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA’s current Good Laboratory Practices (“GLP”) regulations 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 annually or when significant changes are made;
- approval by an institutional review board (“IRB”) or ethics committee at each clinical site before the trial is commenced;

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- performance 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 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, and 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 United States.

Our product candidates are being developed as pre-filled syringes, 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, 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 (the “E.U.”), there are three existing regulatory procedures for a medicinal product to be authorized for use in the Member States of the E.U. and the European Economic Area under the E.U. pharmaceutical legislation that harmonizes the regulatory standards and requirements for assessing safety, quality and efficacy.

A medicinal product for human use may be authorized either by the European Commission through the centralized procedure or by national competent authorities through a mutual recognition, decentralized or national procedure.

The centralized procedure applies to a medicinal product for human use containing a new active substance which was not authorized in the E.U. for which the therapeutic indication is the treatment of any of the following diseases: acquired immune deficiency syndrome, cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases. In addition, the following product categories must also be centrally authorized: a medicinal product developed by means of recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells and hybridoma and monoclonal antibody methods. A medicinal product that has been designated as an orphan medicinal product must also be evaluated through the centralized procedure. A medicinal product that is considered as constituting a significant therapeutic, scientific or technical innovation or its approval is in the interests of E.U. patients is also eligible for the optional centralized assessment. The centralized procedure requires applicants to submit an application for marketing authorization to the European Medicines Agency (“EMA”) which is responsible for the coordinating the scientific assessment to be performed by its relevant advisory committees. Once a positive benefit/risk assessment is adopted by the EMA, the European Commission will issue a binding decision on granting the centralized marketing authorization which is valid throughout the Member States of the E.U. and the European Economic Area (Norway, Iceland and Liechtenstein).

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The mutual recognition procedure is applicable to the majority of conventional medicinal products. To be eligible for the mutual recognition procedure, a medicinal product must have already received a marketing authorization in one E.U. Member State which will become the Reference Member State. An application for mutual recognition may involve one or more E.U. Member States, known as Concerned Member States, for the medicinal product to be progressively authorized in these E.U. Member States. The decentralized procedure permits the common assessment of an application submitted simultaneously to two or more Member States. One of the Member States will take the lead in evaluating the application as the Reference Member State.

National authorization procedure is still available for medicinal products sold in an individual E.U. Member State only.

A reference medicinal product containing a new active substance enjoys a period of 10 years data and market protection or exclusivity upon grant of a marketing authorization. This period is divided into 8 years of data protection within which no generic applicant including a biosimilar applicant can cross-reference the non-clinical and clinical data contained in the file of the reference medicinal product. Even if an authorization is granted based on data cross-referencing, the follow-on manufacturer cannot market the product until the 10-year protection period expires. This period can be extended to a total period of 11 years if during the first 8 years of the protection period one or more new therapeutic indications which are held, during the regulatory review, to bring a significant clinical benefit in comparison with existing therapies.

On January 31, 2020, the United Kingdom (the “U.K.”) left the E.U. and accordingly is no longer a Member State. However, the U.K. primary legislation permits all E.U. law to continue being applied in the U.K. as part of the domestic law. The Withdrawal Agreement with the E.U. sets out a specific transition arrangement for the E.U. law to be applicable in the U.K. until the expiry of the transition period at the end of 2020 while the U.K. and E.U. negotiate additional future relationship arrangements.

As the U.K. is no longer an E.U. Member State, the U.K.’s participation in the European Medicines Regulatory Network would cease and the U.K. Medicines and Healthcare products Regulatory Agency (“MHRA”) would take on the functions currently undertaken by the E.U. for human medicines on the U.K. market. All existing centralized marketing authorizations are or will be converted into the U.K. marketing authorizations during the transition period.

The MHRA would offer the following new assessment procedures for applications for products containing new active substances and biosimilars alongside our existing 210-day national licensing route (which, for the time being, will continue to operate as now):

- A targeted assessment of new applications for products containing new active substances or biosimilars which have been submitted to the EMA and received a Committee for Medicinal Products for Human Use (“CHMP”) positive opinion, based on submission of all relevant information and the CHMP assessment reports to MHRA. The MHRA review will be completed within 67 days of submission of the application;
- A full accelerated assessment, that industry can choose for new active substances, with a timeline of no more than 150 days; and
- A ‘rolling review’, for new active substances and biosimilars, which would allow companies to make an application in stages, throughout the product’s development, to better manage development risk.

Nonclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, 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 central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes 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 safety concerns or questions about the proposed clinical trial. 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 suspend or terminate such studies.

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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. For new indications, a separate new IND may be 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, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing 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, dosage tolerance, 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 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 geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual 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. 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.

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. 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.

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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. 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 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 without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed, 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 to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

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). In addition, if a sponsor submits a BLA for a product intended to treat certain rare pediatric or tropical diseases or for use as a medical countermeasure for a material threat, and that meets other eligibility criteria, upon approval such sponsor may be granted a priority review voucher that can be used for a subsequent application or sold to another applicant.

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 provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete 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.

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In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act (“FDASIA”) passed in July 2012, 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. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must 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 will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial 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.

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 United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States 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. 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 United States 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.

Similarly, in the E.U., the European Commission grants binding decision on orphan designations after a satisfactory scientific assessment provided by the EMA’s Committee for Orphan Medicinal Products. To qualify for orphan designation, a medicinal product must meet the following criteria set out in E.U. Orphan Medicinal Products Regulation:

- it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating;
- the prevalence of the condition in the E.U. must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

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The orphan designation granted is re-assessed at the time when the marketing authorization is granted in order to confirm whether the statutory criteria continue to be met. If the criteria are no longer met, then the orphan designation is removed.

If the orphan designation is maintained when the marketing authorization is granted, then the orphan medicinal product will enjoy 10-year orphan market exclusivity in respect of the approved indication. This exclusivity period prevents a similar medicinal product being accepted by the E.U. regulatory authorities for approval. This exclusivity period can be extended to a total period of 12 years under the E.U. Pediatric Regulation in lieu of six-month extension of the supplementary protection certificate. The orphan exclusivity is run in parallel with the basic regulatory data/market protection or exclusivity period of 10 years in the E.U. However, this period can be reduced to six years if at the end of the fifth year, it is established that the criteria for orphan designation are no longer met where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

After its departure from the E.U., there will be a U.K. system for regulating medicinal products for treating rare diseases including granting of orphan status determined by the MHRA as is the case in the current E.U. system. Overall, the orphan criteria would still be based on the current E.U. criteria, but U.K.-specific considerations will be incorporated into the local system. These will be based on the prevalence of the rare disease in the U.K., the availability of satisfactory alternative treatment methods in the U.K. and the significant benefit of the product. The evaluation of compliance with orphan criteria would be conducted in parallel with the review of quality, safety and efficacy of the medicine at the time of the marketing authorization application.

Where a medicine receives orphan status the initial marketing authorization (“MA”) application fee will be refunded at 100% for SMEs and 10% for all other manufacturers. For these medicines small medium sized enterprises will also receive a fee waiver for variations in the first year after the MA is granted. The 10 years market exclusivity from competition from similar products in the approved orphan indication would be retained. If criteria for orphan status are met, this incentive would be awarded following grant of a U.K. marketing authorization.

According to the MHRA, the E.U. pre-marketing authorization orphan designation will not be replicated in the U.K., given that this will be available at E.U. level and that a separate U.K.-only designation is unlikely to further incentivize industry to warrant the investment required to resource a separate system. As it has been proposed to have a U.K.-specific criteria for determining whether a drug qualifies as ‘orphan’, it would not be possible simply to accept the E.U. designation for these high value drugs; however, the government has committed to monitor these incentives and will consider any further evidence to support this.

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.

In the E.U., a sponsor is required to obtain an agreed Pediatric Investigation Plan (“PIP”) which describes a program of pediatric studies to generate meaningful data to inform the use of the product in the pediatric population. The data derived from the PIP must be submitted with the marketing authorization application unless a waiver or a deferral is granted. Otherwise, the application will not be accepted by the EMA for review. If the pediatric data required by the PIP are submitted, irrespective of whether the data have led to approval of a pediatric indication, the orphan exclusivity period is extended to a total period of 12 years. For a product which is not an orphan medicinal product, the supplementary protection certificate can be extended to a further 6 months under the E.U. pediatric rules. For a medicinal product which is no longer protected by a subsisting patent, a pediatric use marketing authorization can be sought and upon approval, a period of 10 years regulatory data exclusivity or protection is granted.

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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, 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 agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. 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.

Biosimilars and Reference Product Exclusivity

The 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 United States. 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. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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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. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

On December 20, 2019, the Further Consolidated Appropriations Act, 2020 ("FCAA 2020") became law. Section 610, entitled "Actions for Delays of Generic Drugs and Biological Products", provides generic drug (ANDA and 505(b)(2)) and biosimilar developers with a private right of action to obtain sufficient quantities of reference product from the brand manufacturer, or a generic or biosimilar manufacturer, necessary for approval of the developers' generic or biosimilar product. If a generic drug or biosimilar developer is successful in its suit, the defendant manufacturer would be required to provide sufficient quantities of product on commercially-reasonable, market-based terms and may be required to pay the developer's reasonable attorney's fees and costs as well as financial compensation under certain circumstances. The purpose of section 610 is to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar products. We cannot determine what effect section 610 of the FCAA 2020 may have on manufacturers that may develop biosimilar or other competing versions of our products once approved.

In the E.U., a biosimilar product is approved under a different regulatory pathway, recognizing that a biosimilar product does not meet the conditions set out in 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. In view of these differences, a biosimilar is required to provide the results of appropriate pre-clinical tests or clinical trials. 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. The regulatory data/market protection or exclusivity period is the same as a conventional medicinal product as discussed above.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, 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 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 Department of Health and Human Services Office 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.

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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 civil monetary penalty laws, 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.

We may be subject to data privacy, security, and breach notification regulations administered by the federal government and the states in which we conduct our business. 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 clearinghouses”), we would be subject to the HHS regulations related 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.

Although the HIPAA privacy, security and breach notification regulations may not necessarily apply to us, a growing body of state privacy and data security laws and regulations governing the collection, use, disclosure, transfer, storage, disposal, and protection of personal information may apply and could create compliance, investigation, and other risks. The definition of “personal information” in these laws differs and in some cases can be quite broad. These laws and regulations may be more restrictive and not preempted by U.S. federal laws. To the extent we hold personally identifiable information, we may be at risk of data security breaches, which could require us to notify affected individuals, regulators, media, credit reporting agencies, and others, and might expose us to regulatory investigations or private claims of negligence or violation of state law standards for adequately protecting personal information. Relevant state laws include the California Consumer Privacy Act (“CCPA”), which contains significant privacy and data security obligations. The CCPA and other state privacy, security, and breach notification laws may impose substantial penalties for violations, as well as incurring costs associated with investigations, compliance, and private class-action litigation.

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, as defined by such law, 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. Failure to report accurately could result in penalties.

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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 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 or sell any of our products in foreign countries and jurisdictions, including Canada or the E.U., we may be subject to additional 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 its ability to operate our business and results of operations.

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 United States 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 United States, 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 United States, 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.

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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 its 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., governments influence the price of biopharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to establish their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

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 United States 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 United States 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 United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, 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;

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- a new Medicare Part D coverage gap discount program, in which manufacturers must 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 new 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." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act.

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 2029 unless additional Congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, 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 United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed 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

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programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biologic 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. It is possible that additional governmental action is taken to address the COVID-19 pandemic. 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 United States 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 United States 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 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.

Employees

As of June 29, 2020, we had no employees, and our wholly owned subsidiary, IMVT Corporation (formerly Immunovant, Inc.) had 42 employees, including 25 who are engaged in research and development activities. The employees of IMVT Corporation provide services to us and our subsidiaries pursuant to an intercompany services agreement by and among Immunovant Sciences Ltd. ("ISL"), IMVT Corporation and ISG.

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Corporate Information

Prior to December 18, 2019, we were known as Health Sciences Acquisitions Corporation (“HSAC”). HSAC was incorporated in Delaware on December 6, 2018 and formed as a blank check company for the purpose of effecting a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses. On December 18, 2019, HSAC completed the Business Combination, pursuant to which HSAC acquired 100% of the outstanding shares of ISL, a Bermuda exempted limited company. Subsequent to the acquisition, ISL became a wholly owned subsidiary of HSAC and we were renamed “Immunovant, Inc.”

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 Suite 1, 3rd Floor, 11-12 St. James’s Square, London, SW1Y 4LB, United Kingdom. ISG maintains its headquarters at Viaduktstrasse 8, 4051 Basel, Switzerland.

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 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.

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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 combined and 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 Our Business, Financial Position and Capital Requirements

Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, 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 have imposed, or in the future may impose, “shelter-in-place” orders, quarantines or similar orders or restrictions to control the spread of COVID-19. Our headquarters is located in New York City, we have business operations in North Carolina, and our contract manufacturers are located in the United States and in South Korea. At present, we have implemented work-from-home policies for all employees. The effects of the executive order and our work-from-home policies 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, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain. For example, any manufacturing supply interruption of IMVT-1401, which is currently manufactured at facilities in the United States and in South Korea, or any future product candidates, could adversely affect our ability to conduct ongoing and future clinical trials of IMVT-1401 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 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.”

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city, or state governments could adversely impact our clinical trial operations. We continue to evaluate the impact of the COVID-19 pandemic on our clinical development timelines previously provided. We will provide an update on our clinical development timelines in the third quarter of calendar year 2020 once we have more information about how the COVID-19 pandemic progressed.

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The spread of COVID-19 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 COVID-19. To the extent the COVID-19 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.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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, IMVT-1401 and any future product candidates. 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 IMVT-1401 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 IMVT-1401 or any future product candidate in the United States and in other jurisdictions;
- add operational, financial and management information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of IMVT-1401 or any future product candidate manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- attract and retain experienced management and advisory teams;
- raise additional funds when needed and on terms acceptable to us;
- commercially launch IMVT-1401 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 non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if IMVT-1401 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.

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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 gain 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 \$66.4 million and \$28.6 million for the fiscal years ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of \$91.2 million.

We expect to continue to incur substantial and increasing losses through the commercialization of IMVT-1401 or any future product candidate, if approved. 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 IMVT-1401 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 profitable even if we successfully commercialize IMVT-1401 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 gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidate, the reimbursement environment for our product candidate and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities for IMVT-1401 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. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of 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 IMVT-1401 to continue to be significant. In addition, if we obtain regulatory approval for IMVT-1401, 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.

Our business is heavily dependent on the successful development, regulatory approval and commercialization of our sole product candidate, IMVT-1401.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of IMVT-1401. Accordingly, our business currently depends heavily on the successful completion of our clinical trials for IMVT-1401 and subsequent regulatory approval and commercialization of this product candidate.

We cannot be certain that IMVT-1401 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products, including antibody-based products, are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market our product candidate in the United States until we receive approval of a BLA, or in any foreign country until we receive the requisite approvals from the appropriate 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 candidate.

We have not submitted a BLA for IMVT-1401 to the FDA or any comparable application to any other regulatory authority. Obtaining approval of a BLA or similar 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 IMVT-1401 for many reasons, including:

- we may not be able to demonstrate that our product candidate is safe and effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant 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 regulatory authorities for marketing approval;

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- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our clinical trials of IMVT-1401 for the treatment of MG, TED and WAIHA;
- the contract research organizations (“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 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 candidate outweigh its safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of our product candidate, or may require additional studies;
- the FDA or other relevant 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 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 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 regulatory authorities may require development of a REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidate;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Even if we do receive regulatory approval to market IMVT-1401, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market IMVT-1401. 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 candidate will be successfully developed or commercialized.

In addition, if our product candidate encounters safety or efficacy problems, developmental delays, regulatory issues, supply issues, or other problems in one of our target indications, our development plans for our product candidate 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 candidate that would potentially harm our business.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of IMVT-1401.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for, and commercialize IMVT-1401. 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 IMVT-1401 (up to an aggregate reimbursement amount of \$20.0 million), make payments in connection with the achievement of certain regulatory milestones prior to generating any product sales (including the initiation of certain clinical trials for IMVT-1401), make significant further payments upon the achievement of certain sales milestones and make tiered royalty payments in connection with the commercial sale of IMVT-1401, if approved.

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We will require additional capital to complete the development and potential commercialization of IMVT-1401. Because the length of time and activities associated with successful development of our product candidate 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 potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 IMVT-1401, including our clinical trials of IMVT-1401 for the treatment of MG, TED and WAIHA;
- 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 IMVT-1401 or any future product candidate in regions where we choose to commercialize such product candidate on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidate, 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 IMVT-1401 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 IMVT-1401, we are unable to estimate the associated amounts of increased capital outlays, operating expenditures and capital requirements.

Raising additional funds by issuing securities may 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 IMVT-1401 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 rights to the core intellectual property relating to IMVT-1401. Any termination or loss of significant rights under the HanAll Agreement would adversely affect our development or commercialization of IMVT-1401.

We have licensed our core intellectual property relating to IMVT-1401 from HanAll under the HanAll Agreement. See “Business—License Agreement with HanAll Biopharma Co., Ltd.” 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 IMVT-1401, 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 IMVT-1401, if approved.

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The HanAll Agreement obligates us to make certain milestone payments, some of which will be triggered prior to our commercialization of IMVT-1401.

We will be responsible for future contingent payments and royalties under the HanAll Agreement, including up to an aggregate of \$442.5 million upon the achievement of certain development and regulatory milestone events, which events will occur prior to our planned commercialization of IMVT-1401. 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 IMVT-1401. 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 currently have a limited number of employees who are employed by our wholly owned subsidiary and we rely on RSI and RSG to provide various administrative, business development, clinical development and other services.

As of June 29, 2020, we had no employees, and our wholly owned subsidiary, IMVT Corporation, had 42 employees, including 25 who are engaged in research and development activities. We rely on the administrative support, business development, clinical development and other services provided by RSI and RSG, wholly owned subsidiaries of RSL, which provide services to us pursuant to the Services Agreements, as further described under the section titled “Certain Relationships and Related Party Transactions—Affiliate Services Agreements.” For example, we currently rely and expect to continue to rely on RSI to support our nonclinical and clinical development programs. Personnel and support staff that provide services to us under the Services Agreements are not required to, and we do not expect that they will, have the management and administration of our business as their primary responsibility, or act exclusively for us. RSI and RSG have limited finance, accounting, clinical development and other resources. Furthermore, RSI and RSG engage in other business activities and provide support for other of our affiliates and subsidiaries of RSL. If their focus is diverted or their limited resources are otherwise employed, we could face potential delays or disruptions in the conduct of our ongoing clinical trial programs and the commercialization of our product candidate, if approved, which could harm our business.

In the event of a default under or termination of the Services Agreements, we may be unable to contract with substitute service providers on similar terms, in a timely fashion, or at all, and the costs of substituting service providers may be substantial. In addition, a substitute service provider may not be able to provide the same level of services due to a lack of pre-existing knowledge or synergies. Any termination of our relationship with RSI or RSG, or decrease in provision of services by RSI and RSG, and any delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our business and continue the clinical development and potential commercialization of IMVT-1401 or any future product candidate.

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 may terminate their positions with us at any time. If we lose one or more 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 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, gain 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 will need 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.

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We may have difficulties identifying, hiring and integrating 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. 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 IMVT-1401 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 IMVT-1401 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 bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; 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 ongoing 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 candidate 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, 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.

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;

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- 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 United States or other countries or territories of the world. We will 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, among other things, upon 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.

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

Part of our business strategy involves potentially expanding internationally with third-party collaborators to seek regulatory approval for IMVT-1401 and any future product candidates outside the United States. 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 candidates, 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 that may result from the ongoing 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 the COVID-19 pandemic 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 United Kingdom Bribery Act 2010 ("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.

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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.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union is a source of instability and uncertainty.

Following the result of a referendum in 2016, the United Kingdom (the “U.K.”) formally left the European Union (the “E.U.”) on January 31, 2020, commonly referred to as “Brexit.” Pursuant to the formal withdrawal arrangements agreed between the U.K. and E.U., the U.K. will be subject to a transition period until December 31, 2020 (the “Transition Period”) during which E.U. rules will continue to apply to the U.K. Pharmaceutical companies can continue to carry out activities in the U.K. until the end of the Transition Period. However, the U.K. no longer participates in EU institutions after the Transition Period. EMA’s public statement indicates that as of February 1, 2020, no U.K. representative will be appointed or nominated to participate in any EMA scientific committee meeting, working party meeting or the EMA’s management board. Negotiations between the U.K. and the E.U. are expected to continue in relation to the customs and trading relationship between the U.K. and the E.U. following the expiry of the Transition Period.

The uncertainty concerning the U.K.’s legal, political and economic relationship with the E.U. after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border cooperation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the E.U. are unable to negotiate acceptable trading and customs terms, barrier-free access under the single internal market principle between the U.K. and other E.U. Member States or among the European Economic Area (the “E.E.A.”) overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets after the Transition Period. Such a withdrawal from the E.U. is unprecedented, and it is unclear how the U.K. access to the European single market for goods, capital, services and labor within the E.U., or single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, the U.K. could lose the benefits of global trade agreements negotiated by the E.U. on behalf of its members, which may result in increased trade barriers that could make our doing business in the E.U., the E.E.A. and other territories more difficult. There may continue to be economic uncertainty surrounding the consequences of Brexit, which could adversely affect our financial condition, results of operations and the market price of our common stock.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Our computer systems, as well as those of various third parties on which we rely, including RSL and its affiliates, our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidate or any future product candidate that we may develop could be delayed.

The failure to successfully implement an enterprise resource planning system could adversely impact our business and results of operations.

We completed the implementation of a company-wide enterprise resource planning (“ERP”) system to upgrade certain existing business, operational, and financial processes, upon which we rely. ERP implementations are complex and time-consuming projects that require transformations of business and finance processes to reap the benefits of the ERP system. Any such transformation involves risk inherent in the conversion to a new system,

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including loss of information and potential disruption to normal operations. Additionally, if the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess those controls adequately could be delayed. Significant delays in documenting, reviewing and testing our internal control over financial reporting could cause us to fail to comply with the Securities and Exchange Commission (the “SEC”) reporting obligations related to our management’s assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business during or following the implementation of the ERP system, our business and results of operations could be harmed.

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 IMVT-1401 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 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:

- 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 IMVT-1401 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 agencies 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 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 ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

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Separately, in response to the global pandemic of Novel Coronavirus Disease 2019, or COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. The FDA is continuing to evaluate and utilize alternative regulatory tools while postponing non-critical inspections. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other 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 a material adverse effect on our business.

Risks Related to Development, Regulatory Approval and Commercialization

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

Our product candidate is still in clinical development and will require extensive clinical testing before we are prepared to submit a 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 candidate 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 regulatory authorities may not agree with our proposed analysis plans or trial design for any clinical trials for IMVT-1401, including our ASCEND MG, ASCEND GO and ASCEND WAIHA trials; and during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of an BLA or similar application. The FDA may also find that the benefits of IMVT-1401 in any of our target indications do not outweigh its risks 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 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 biopharmaceutical industry have suffered significant setbacks in, or the discontinuation of, advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, the results of early nonclinical studies and clinical trials of IMVT-1401, 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.

The commencement and completion of clinical trials may be delayed by several factors, including:

- failure to obtain regulatory authorization to commence a trial or reaching consensus with regulatory authorities regarding the design or implementation of our studies;
- unforeseen safety issues, or subjects experiencing severe or unexpected AEs;
- occurrence of serious AEs in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- resolving any dosing issues or limitations, including those raised by the FDA;
- 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 regulatory authorities;

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- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;
- an 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;
- premature discontinuation of study participants from clinical trials or missing data;
- failure to manufacture or release sufficient quantities of our product candidate or placebo or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unmasking of trial results.

In addition, disruptions caused by the COVID-19 pandemic increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Further, we, the FDA or another 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 GCP, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our 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 candidate could be harmed, and our ability to generate product revenue from our product candidate, 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, many of the factors that cause or lead to a termination or suspension of, or delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidate. We may make formulation or manufacturing changes to our product candidate, 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 candidate and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidate could be significantly reduced.

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 regulatory authorities. The FDA or other 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 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 regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidate.

In addition, we had no involvement with or control over the nonclinical or clinical development of IMVT-1401 prior to its in-license from HanAll. We are dependent on our licensing partner having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all nonclinical studies and clinical trials and other research they conducted prior to our acquisition of the rights to our product candidate, having correctly collected and interpreted the data from these studies, trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of this asset. Problems related to our predecessor could result in increased costs and delays in the development of our product candidate, which could adversely affect our ability to generate any future revenue from sales of our product candidate, if approved.

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The results of our nonclinical and clinical trials may not support our proposed claims for our product candidate, 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 particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our Phase 1 clinical trial of IMVT-1401, which did not include pre-specified endpoints for IgG reduction, will be observed in any future clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported AEs. The results of nonclinical studies and early clinical trials of our product candidate may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon our product candidate. 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 candidate, 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 claims for differentiation or the effectiveness or safety of our product candidate. 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 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 analyses 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 agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our 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 IMVT-1401 or any future product candidate, our business, operating results, prospects or financial condition may be harmed.

We are at an early stage in our development efforts for IMVT-1401 and we may not be able to successfully develop and commercialize our product candidate on a timely basis or at all.

IMVT-1401 is a novel therapeutic antibody and its potential therapeutic benefit is unproven. While several FcRn inhibitor candidates are under development by other companies, there is currently no approved therapy inhibiting FcRn for the treatment of autoimmune diseases, and, as a result, the regulatory pathway for IMVT-1401 may present novel issues that could cause delays in development or approval. While results from early clinical trials of IMVT-1401 have shown meaningful reductions in IgG antibody levels in healthy volunteers, IMVT-1401 may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for IMVT-1401 in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although we and our licensing partner have evaluated

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IMVT-1401 nonclinical studies and in early-stage clinical trials, we have not yet advanced IMVT-1401 into a large-scale, pivotal clinical trial for any indication. Positive results from our early-stage clinical trials are not necessarily predictive of the results of our planned clinical trials of IMVT-1401. If we cannot replicate the positive results from our Phase 1 clinical trial in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize IMVT-1401 for the treatment of MG, TED, WAIHA or any other autoimmune indication. As a result, our focus on exploring FcRn inhibition may fail to result in the identification of viable additional indications for IMVT-1401. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize IMVT-1401, raise capital, expand our business or continue our operations.

We have licensed the rights to IMVT-1401 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 IMVT-1401.

We have licensed the right to develop, manufacture and commercialize IMVT-1401 in the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America (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 IMVT-1401 in geographies outside of our Licensed Territory. If AEs occur with patients using IMVT-1401 or during any clinical trials of IMVT-1401 conducted by HanAll or third parties in other jurisdictions outside of our Licensed Territory, the FDA may delay, limit or deny approval of IMVT-1401 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 approval for IMVT-1401 and a new and serious safety issue is identified in connection with clinical trials of IMVT-1401 conducted by third parties in other jurisdictions outside of our Licensed Territory, the FDA may withdraw their approval of the product or otherwise restrict our ability to market and sell IMVT-1401. In addition, treating physicians may be less willing to administer our product candidate due to concerns over such AEs, which would limit our ability to commercialize IMVT-1401. In addition, issues may arise in connection with the manufacturing process for IMVT-1401 utilized by HanAll or any of its sublicensees or collaborators, which could affect our ability to obtain regulatory approval for, or commercialize, IMVT-1401.

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, 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 and WAIHA due to the existing alternative treatments available for the treatment of MG, TED and WAIHA, 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, delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, 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, our ability to successfully complete prerequisite studies before enrolling certain patient populations. Our product candidate is focused in part on addressing rare autoimmune indications, including MG, TED and WAIHA with limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. 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 candidate, 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.

We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune disease indications, and 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

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disease indications, including MG, TED and WAIHA. We anticipate that, if we obtain regulatory approval of our product candidate, 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 candidate may also compete with unregulated, unapproved and off-label treatments. Even if a biosimilar product is less effective than our product candidate, a less effective biosimilar may be more quickly adopted by physicians and patients than our competing product candidate based upon cost or convenience. Our product candidate, if approved, is expected to present a novel therapeutic approach for MG, TED and WAIHA 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, 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 candidate and contribute to downward pressure on the pricing of our product candidate, 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 IMVT-1401. We are aware of several FcRn inhibitors that are in clinical development. These include, efgartigimod (argenx SE), nipocalimab, (Momenta Pharmaceuticals), rozanolixizumab (UCB) and ALXN1830 (Alexion Pharmaceuticals). Each of efgartigimod, nipocalimab, rozanolixizumab and ALXN1830 is currently under development for the treatment of MG. In addition, for WAIHA, Alexion has announced plans to begin a Phase 2 trial for ALXN1830 in early 2020 and Momenta has announced the launch of an adaptive Phase 2/3 clinical study for nipocalimab. Momenta also announced that the FDA has granted Fast Track Designation for nipocalimab in WAIHA.

We also expect to face competition from agents with different mechanisms of action. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (tepotumumab), 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 Alexion Pharmaceuticals), an antibody inhibitor of the C5 protein, was recently approved in 2017 for the treatment of generalized MG in patients who are positive for anti-AChR antibodies. The first line of treatment for patients with TED or WAIHA 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, a monoclonal antibody that binds to an antigen specific to antibody-producing B cells, may also be used as a treatment for TED, WAIHA and other IgG-mediated autoimmune diseases. Momenta 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, currently in a Phase 3 trial in a similar patient population; amifampridine (Catalyst Pharmaceuticals), a neuronal potassium channel blocker, for MG patients with the MuSK form of the disease, which is currently in Phase 3; and Myasterix (CuraVac), a therapeutic vaccine against B and T cells, which is being tested in early stage trials in MG patients. Moreover, Viela Bio has announced plans to initiate a pivotal trial in MG for inebilizumab, a CD19-targeted humanized monoclonal antibody, in 2020. Toleranzia has announced its intention to initiate Ph1/2a program in MG patients for its immunomodulating complex, TOL2, in 2020.

Numerous product candidates are currently in development for the treatment of WAIHA. Fostamatinib (Rigel Pharmaceuticals), a syk inhibitor, is currently in Phase 3 development. A Phase 2 investigator-initiated study of ibrutinib (AbbVie), a BTK inhibitor, in steroid-refractory WAIHA is ongoing. Kezar Life Sciences is running a Phase 2 trial including WAIHA patients for its immunoproteasome inhibitor, KZR-616.

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 United States 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. 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 less stringent regulatory requirements in certain foreign countries, there are many more products and procedures available for use to treat autoimmune diseases in those international markets than are approved for use in the United States. 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 United States.

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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 IMVT-1401 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 IMVT-1401 and any future product candidates;
- obtain required regulatory approvals, including approvals to market IMVT-1401 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 IMVT-1401 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.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize IMVT-1401 or any future product candidate, and our ability to generate product revenue will be impaired.

IMVT-1401 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 United States and by similar regulatory authorities outside the United States. 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 candidate 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 candidate in the United States or any other jurisdiction until we receive regulatory approval of a BLA from the FDA or similar regulatory authorities outside of the United States.

The time required to obtain approval of a BLA by the FDA or similar regulatory authorities outside of the United States is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory 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 gain 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 nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of our product candidate for the specified indications. We expect to rely on third-party CROs, consultants, our collaborators and personnel from RSI and RSG to assist us in filing and supporting the applications necessary to gain 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 candidate and generate product revenue.

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Additional time may be required to obtain marketing authorizations for our IMVT-1401 pre-filled syringe product candidate 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. Our IMVT-1401 pre-filled syringe product candidate would be considered a combination product that requires coordination within the FDA and similar foreign regulatory agencies for review of its device and biologic components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidate due to uncertainties in the product development and approval process.

Our product candidate may cause adverse events or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

Adverse events associated with our product candidate in our clinical trials could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. 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. If an unacceptable frequency or severity of AEs or new safety signals are reported in our clinical trials for our product candidate, our ability to obtain regulatory approval for such product candidate may be negatively impacted. Treatment-related side effects arising from, or those perceived to arise from, our product candidate or those from other companies targeting similar autoimmune indications, including incidence of headache from other product candidates targeting IgG antibody reductions, could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

If our product candidate 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 or limit their approval of the product or require a REMS (or equivalent outside the United States) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- 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;
- 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 our product candidate, if approved.

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IMVT-1401 is an antibody protein 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 IMVT-1401.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidate, IMVT-1401, 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 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 or even clinical studies, and their detection or appearance is often delayed. As a result, neutralizing antibodies may be detected at a later date or upon longer exposure of patients with our product candidates, such as following more chronic administration in longer lasting clinical trials. In some cases, detection of such 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 our product candidate, the continued clinical development or receipt of marketing approval for our product candidate could be delayed or prevented and, even if our product candidate is approved, its commercial success could be limited, any of which would impair our ability to generate revenue and continue operations.

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 agencies, 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 promising, 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 United States. 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. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. 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.

Even if we obtain regulatory approval for a product candidate, we will still face extensive ongoing regulatory requirements and our product may face future development and regulatory 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 submission requirements, export, import, 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 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 the conditions of approval or the FDA or other 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. 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 United States and other comparable regulations in foreign jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, DOJ, State Attorneys General and other foreign regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

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In addition, later discovery of previously unknown AEs 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 equivalent outside the United States);
- Warning or Untitled Letters;
- withdrawal of the product from the market;
- recall of a product;
- fines, restitution or disgorgement of profits or revenues;
- suspension 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 regulatory authorities’ policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of IMVT-1401 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 United States 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. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders will be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions 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 IMVT-1401 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 IMVT-1401 subcutaneous delivery method, compared to alternative, competing or existing treatments, which physicians may perceive to be adequately effective for some or all patients;

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- limitations or warnings contained in the labeling approved for our product candidate by the FDA or other applicable 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 candidate;
- 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 IMVT-1401 for the treatment of MG, TED and WAIHA may also be affected by the perception that existing available treatments, such as pyridostigmine, corticosteroids and immunosuppressants, may be sufficient to treat the majority of these patients. In addition, IMVT-1401, if approved, may compete with other FcRn inhibitors under development that have demonstrated similar levels of IgG reductions as IMVT-1401 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 candidate, if approved, could be much slower than anticipated.

We cannot assure you that IMVT-1401 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 candidate, 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 candidate in the United States, 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

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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 our product candidate 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 candidate 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 plan to seek orphan drug designation for IMVT-1401, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted.

We plan to seek orphan drug designation from the FDA for IMVT-1401 for the treatment of MG, TED and WAIHA and potentially in other orphan indications in which there is a medically plausible basis for its use, and we may seek orphan drug designation for IMVT-1401 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 United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the E.U., the European Medicine Agency's Committee for Orphan Medicinal Products assesses orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the E.U. or a serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the E.U. would be sufficient to justify the necessary investment in developing the drug or biological product, and where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. In addition, if a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective, or makes a major contribution to patient care. In the E.U., orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval in respect of the approved therapeutic indication if the designation is maintained at the time of granting the EU product approval. The 10-year market exclusivity can be extended to 12 years under the E.U. pediatric regulation if the studies contained in an agreed pediatric investigation plan are completed with the data submitted for regulatory review as part of the compliance check. This period of exclusivity may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

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As indicated above, following the U.K.'s departure from the E.U., the U.K. will establish its own system for regulating medicinal products for rare diseases by granting orphan designations by MHRA as is the case in the current E.U. system. Overall, the orphan criteria would still be based on the current E.U. criteria, but U.K.-specific considerations will be incorporated.

Although we intend to seek orphan drug designation for IMVT-1401 from the FDA, we may never receive such designation. Moreover, obtaining orphan drug designation for IMVT-1401 for the treatment of MG, TED or WAIHA does not mean we will be able to obtain such designation for any other indications. Even if we were to obtain orphan drug designation for IMVT-1401 from the FDA, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of IMVT-1401 could be blocked for seven years if another company obtains approval and orphan drug exclusivity for the same drug and same condition before us. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA 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 advantage in, or shorten the duration of, the development or FDA review and approval process.

If we obtain approval to commercialize our product outside of the United States, a variety of risks associated with international operations could adversely affect our business.

If our product candidate is approved for commercialization outside of the United States, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- different 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;
- 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 reimbursement, pricing and insurance regimes;
- foreign taxes;
- 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;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the FCPA, 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.

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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 FCA;
- the federal criminal and civil false claims laws, including the FCA, which imposes criminal and civil penalties, including through civil whistleblower or “qui tam” actions, against individuals or entities for, among other things, causing false or fraudulent claims to be presented, for payment to the federal government;
- 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 government information related to payments or other “transfers of value” made to physicians, as defined by law, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the ownership and investment interests held by such physicians and their immediate family members and payments or other “transfers of value” to such physician owners (covered manufacturers are required to submit reports to the CMS by the 90th day of each calendar year);
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices;
- 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 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 require the registration of pharmaceutical sales representatives; and
- federal, state and foreign laws governing the privacy and security of personal information, including health information, 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 to 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, agency 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. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, 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.

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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, several executive, 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 our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States 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 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 United States pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced a new “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 new Medicare Part D coverage gap discount program, in which manufacturers currently must 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 the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. For example, the 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.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. 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 2029, unless additional Congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, 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. At the federal level, the Trump administration’s budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare

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Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a “Blueprint,” or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states in the United States 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. It is possible that additional governmental action is taken to address the COVID-19 pandemic. 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 candidate, 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 candidate, if approved, would achieve adequate coverage and reimbursement levels.

In the United States, 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 candidates 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. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. 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 candidates that we develop. Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. There can be no assurance that our product candidate, if approved, will be considered medically reasonable and necessary, that it will be considered 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 United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidate profitably, if approved for sale.

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Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical supplies and commercial supplies of our product candidate. The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production that may delay or prevent our ability to obtain marketing approval or commercialize our product candidates, 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. 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 a product candidate, 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 IMVT-1401 or any future product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for any product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, due to COVID-19 or otherwise, which would impair our ability to generate revenue from the sale of such product candidate. In addition, IMVT-1401 is a biologic and requires processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. 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.

The facilities used by our contract manufacturers to manufacture our product candidate must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. 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 candidates. 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 candidate 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 our product candidate, if approved. 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;

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- 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 potential product liability litigation, product recalls or product withdrawals. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

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 IMVT-1401 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. 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 IMVT-1401 or any future product candidate or jeopardize our ability to commence sales and generate revenue.

We are reliant 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, it may harm our business.

We currently do not have the ability to independently conduct nonclinical studies that comply with 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 are also required by the competent authorities of the member states of the European Economic Area and other comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for any of our 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 GLP nonclinical studies and GCP 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. 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 healthcare regulatory risks for us as sponsors of those studies.

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

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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.

Risks Related to Our Intellectual Property

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

In the United States, the 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 IMVT-1401, 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 nonclinical and 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 candidate, as a biological product, 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, or that the FDA will not consider our product candidate to be a reference product for competing products, 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 recent 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.

In addition, while we cannot determine what effect section 610 of the FCAA 2020 may have on manufacturers that may develop biosimilar or other competing versions of our products once approved, it may ultimately facilitate their entry to the market.

If we are unable to obtain and maintain patent protection for IMVT-1401 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 candidate. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to IMVT-1401 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad 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 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 agencies 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.

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The patent applications that we in-license in the United States or in other foreign countries may fail to result in issued patents with claims that protect our product candidate 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 candidate, uses of our product candidate or other aspects related to our product candidate, 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 candidate, 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 candidate, 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 candidate, and if we do not own or have exclusive rights to other enforceable patents protecting our product candidate, 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 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 candidate, it could dissuade companies from collaborating with us to develop our product candidate, 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 applications.

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 (the “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 United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Patent reform legislation in the United States 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 partes review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States 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 United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not until a patent issue. 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 IMVT-1401 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 United States 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 IMVT-1401 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 IMVT-1401 or any future product candidates.

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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 United States 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 United States, 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 IMVT-1401 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 IMVT-1401, can be challenged by third parties.

For biologics subject to approval by the FDA via a BLA, such as IMVT-1401, 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 does not require reference product sponsors to list patents in an Orange Book and does not include an automatic 30-month stay of FDA approval upon the timely filing of a lawsuit. The BPCIA, however, does require 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 IMVT-1401 or any future product candidates.

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

Filing, prosecuting and defending patents on our product candidate 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 United States. 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 United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may 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 United States. 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.

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

Patents have a limited lifespan. In the United States, 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 candidate 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 IMVT-1401 has a natural projected expiration date in 2035 in the United States and in foreign jurisdictions. 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.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for IMVT-1401 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 United States and other countries with respect to our proprietary technology, product candidate 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 candidate might expire before or shortly after such candidates begin to be commercialized. Depending upon the timing, duration and specifics of FDA marketing approval of IMVT-1401 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 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 United States 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 IMVT-1401 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 or enforce intellectual property rights in certain territories and jurisdictions.

We do not have rights to develop, manufacture, use or commercialize IMVT-1401 or file or enforce patents relating to these assets in territories other than the Licensed Territory, as such rights in other jurisdictions have been retained by HanAll or licensed by HanAll to third parties. One or more third parties may challenge the current patents, or patents that may issue in the future, in such territories for which HanAll retains rights or has licensed out rights to defend and enforce such patents. HanAll may not coordinate the defense and enforcement of such patents with us, which could impair our ability to defend or enforce corresponding patents in other jurisdictions.

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

We have licensed certain intellectual property rights covering IMVT-1401 from HanAll. We are heavily dependent on the HanAll Agreement for the development, manufacture and commercialization of our product candidate. 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.

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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 and 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 a material adverse effect on our business, financial condition, results of operations, and 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 the affected product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and 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. 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 our product candidate, 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 our product candidate. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize IMVT-1401 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.

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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 candidate.

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 United States, 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 United States 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 United States 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 a product candidate. 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 candidate 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 candidate. 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 candidate 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 candidate, 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 candidate. 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 candidate. 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 candidate, 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 candidate or any future product candidates. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material 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 a material 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 a material adverse effect on the price of shares of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

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We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidate 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 candidate 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 United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidate or any future product candidates in any jurisdiction. Patent applications in the United States 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 United States remain confidential until patents issue. Therefore, patent applications covering our product candidate 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 candidate or any future product candidates, the use thereof, provided such pending patent applications result in issued patents, our ability to develop and market our product candidate 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 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 United States 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 candidate 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 United States, 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

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proceedings outside the United States, 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 IMVT-1401 or any future product candidate. 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 United States. 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 the patents we own are owned by our wholly owned subsidiary, ISG, we may not be in a position to obtain a permanent injunction against a third party that is found to infringe our patents.

Any patents that we own are assigned to our wholly owned subsidiary, ISG. If a third party is found to be infringing such patents, we may not be able to permanently enjoin the third party from making, using, offering for sale or selling the infringing product or activity for the remaining life of such patent in the United States or foreign jurisdictions because the patent is assigned to our wholly owned subsidiary, ISG, which is not the entity that would be commercializing a potentially competitive product or service.

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 United States 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 our product candidate.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our product candidate, IMVT-1401, 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 United States or USPTO rules and regulations could increase the uncertainties and costs.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance 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.

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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 United States 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 would 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 United States 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 would 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 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 our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property.

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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. We are still in the process of obtaining certain assignments for some of our owned patent applications.

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 a material 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 a material 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 other 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 candidate 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, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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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 grant. 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 our product candidate, but that are not covered by the claims of the patents that we own;
- others may be able to make a product that is similar to our product candidate 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 or 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 advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States 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;

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- we may not develop additional proprietary technologies that are patentable;
- third parties performing manufacturing or testing for us using our product candidate 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, they could harm our business and results of operations.

Risks Related to Our Common Stock

The market price of shares of our common stock 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:

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- results of clinical trials for IMVT-1401 or any future product candidate or those of our competitors;
- any delay in filing a BLA or similar application for IMVT-1401 or any future product candidate and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that BLA or similar application, as the case may be;
- failure to successfully develop and commercialize IMVT-1401 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States or other countries or jurisdictions applicable to IMVT-1401 or any future product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for IMVT-1401 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;

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- 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 Section 16 officers;
- 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;
- 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, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including very recently in connection with the ongoing COVID-19 pandemic, 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 and other adverse effects or developments relating to the ongoing COVID-19 pandemic, 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.

Volatility in our share price could subject us to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We are a "controlled company" within the meaning of the applicable 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;

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- 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.

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

As of June 29, 2020, RSL beneficially owned approximately 57.7% 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. For example, 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's 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. Further, RSL is a privately held company whose ownership and governance structure is not transparent to 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 Directors to our board of directors, in accordance with our amended and restated 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.

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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.

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

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (the “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 devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. 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. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming 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.

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act (“Section 404”), to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the first fiscal year beginning after the effective date of the registration statement of which this Annual Report forms a part. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal controls procedures on a quarterly basis.

We have begun the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and finance staff and consultants with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal controls over financial reporting is effective, or if our independent registered public accounting firm 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.

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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 are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make shares of our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of HSAC’s initial public offering (“IPO”), (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of shares of our common stock that are held by non-affiliates exceeds \$700 million as of September 30 of such fiscal year, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements.

We cannot predict if investors will find shares of our common stock less attractive because we may rely on these exemptions. If some investors find shares of our common stock less attractive as a result, there may be a less active trading market for shares of our common stock and our share price may be more volatile.

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

Our wholly owned subsidiary, 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 United States. 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.

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

Our tax position could be adversely impacted by changes in 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 United States, Bermuda and other jurisdictions as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such 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.

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: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of stock-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

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 amended and restated certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated 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;

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- 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 amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America 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 amended and restated 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, our amended and restated certificate of incorporation, or our amended and restated bylaws; any action as to which Delaware General Corporation Law 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. The provisions would not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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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 Suite 1, 3rd Floor, 11-12 St. James's Square, London, SW1Y 4LB, United Kingdom. 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 intend to 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 may become involved in legal proceedings related to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market Information

Prior to the closing of the Business Combination, HSAC common stock, units and warrants were traded on The Nasdaq Capital Market under the ticker symbols “HSAC,” “HSACU” and “HSACW,” respectively. On December 19, 2019, the Company’s common stock, units and warrants began trading on The Nasdaq Capital Market under the ticker symbols “IMVT”, “IMVTU” and “IMVTW,” respectively. We no longer have any outstanding units or warrants.

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 June 19, 2020, we had 10 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.

Use of Proceeds

On May 14, 2019, HSAC consummated its IPO of 11,500,000 units, which included the full exercise by the underwriters of the over-allotment option. The units were sold at an offering price of \$10.00 per unit, generating total gross proceeds of \$115.0 million. Chardan Capital Markets LLC and UBS Securities LLC acted as joint book running managers. The securities sold in the IPO were registered under the Securities Act on a registration statement on Form S-1 (No. 333-230893) which was declared effective on May 9, 2019.

Simultaneously with the closing of the IPO, HSAC consummated a private placement of 10,000,000 private warrants to its sponsor at a price of \$0.50 per warrant, generating total proceeds of \$5.0 million. The private warrants were issued pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act. On December 18, 2019, upon the closing of the Business Combination pursuant to which HSAC acquired 100% of the issued and outstanding common shares of ISL, the private warrants were canceled.

Following the closing of the IPO, \$115.0 million in net proceeds from the sale of the units and the private warrants was placed in a trust account. HSAC paid a total of \$2.3 million in underwriting discounts and commissions and \$0.6 million for other costs and expenses related to the IPO. Upon the closing of the Business Combination, the underwriters were paid an additional \$4.0 million in deferred underwriting discounts and commissions. Following the closing of the Business Combination, \$116.5 million net of \$6.3 million in expenses related to Business Combination was released to us from the trust account.

We have been using and will continue to use these proceeds primarily (1) to fund our ASCEND MG trial, ASCEND GO-1 trial, ASCEND GO-2 trial, our planned ASCEND WAIHA trial, and other clinical development activities, (2) to expand our research and development capabilities, and (3) for general corporate purposes.

Issuer Purchases of Equity Securities

None.

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Item 6. Selected Financial Data

Because we are considered to be a “smaller reporting company” under SEC rules and regulations, we are not required to provide the information required by this item in this report.

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 combined and 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.

Prior to December 18, 2019, we were known as Health Sciences Acquisitions Corporation. On December 18, 2019, we completed the Business Combination, with Immunovant Sciences Ltd., a private company. For accounting purposes, Health Sciences Acquisitions Corporation was deemed to be the acquired entity.

Overview

We are a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits the FcRn. IMVT-1401 is the product of a multi-step, multi-year research program conducted by HanAll Biopharma Co., Ltd. to design a highly potent anti-FcRn antibody optimized for subcutaneous delivery. These efforts have resulted in a product candidate that 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, IMVT-1401 has been observed to reduce IgG antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe IMVT-1401 has the potential for broad application in these disease areas. We intend to develop IMVT-1401 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.

We are developing IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule. As a result of our rational design, we believe that IMVT-1401, if approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases, (e.g., MG, TED, WAIHA, idiopathic thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, bullous pemphigoid, neuromyelitis optica, pemphigus foliaceus, Guillain-Barré syndrome and PLA2R+ membranous nephropathy). In 2019, these diseases had an aggregate prevalence of approximately 243,000 patients in the United States and 388,000 patients in Europe. To the extent we choose to develop IMVT-1401 for certain of these rare diseases, we plan to seek orphan drug designation in the United States and Europe. Such designations would primarily provide financial and exclusivity incentives intended to make the development of orphan drugs financially viable. However, we have not yet sought such designation for any of our three target indications, and there is no certainty that it would obtain such designation, or maintain the benefits associated with such designation, if or when we do.

In August 2019, we initiated dosing in our ASCEND MG trial, a Phase 2a clinical trial in patients with MG. We expect to report results from the placebo-controlled treatment phase of this trial in the late third quarter or early fourth quarter of calendar year 2020. In May 2019, we initiated dosing in our ASCEND GO-1 trial, a Phase 2a clinical trial in Canada in patients with TED. We announced initial results from this trial in March 2020. Enrollment is ongoing in our ASCEND GO-2 trial, a Phase 2b clinical trial for TED in the United States, Canada and Europe. As previously communicated, results from this trial are still possible in the first half of calendar year 2021. We intend to provide an update on the timing for this trial in the third quarter of calendar year 2020. In November 2019, we submitted an IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. As previously communicated, results from this trial are still possible by the end of second half of calendar year 2020. We intend to provide an update on the timing for this trial in the third quarter of calendar year 2020.

ISL was incorporated in July 2018 and its operations prior to the closing of the Business Combination were limited to organizing and staffing ISL, acquiring the rights to IMVT-1401, and preparing for and conducting clinical trials. To date, we have not generated any revenue and have generated significant operating losses since our inception. As of March 31, 2020 and 2019, we had an accumulated deficit of \$91.2 million and \$24.8 million, respectively. For the years ended March 31, 2020 and 2019, we recorded net losses of \$66.4 million and \$28.6 million, respectively.

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Our financial statements are derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with IMVT-1401 that have been contributed to us by RSL, from RSL's financial statements and have been presented as if we had been a separate business since the acquisition of IMVT-1401 by RSG on December 19, 2017. Accordingly, the financial statements as of and for the year ended March 31, 2019 include reasonable allocations for assets and liabilities and expenses attributable to our operations. Beginning on July 6, 2018 (date of formation), the combined and consolidated financial statements include our accounts and those of our wholly owned subsidiaries.

COVID-19 Business Update

We have been actively monitoring the impact of the global COVID-19 pandemic on our employees and our business. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for our employees, effective mid-March 2020. Our operations continue as we seek to comply with guidance from governmental authorities and adjust our activities as appropriate.

The COVID-19 pandemic had a variable impact on our clinical trials from March through June 2020. Some sites closed enrollment for new patients in early March and remain closed today, whereas other sites remained partially open for new patient enrollment. At this time, we expect most sites globally to re-open for new enrollment in the coming months, but given the uncertain course of the pandemic this is impossible to predict with certainty.

In the conduct of our business activities, we are also taking actions designed to protect the safety and well-being of our patients and employees. For patients already enrolled in our clinical trials, we are working closely with clinical trial investigators and site staff to continue treatment in compliance with trial protocols and observe government and institutional guidelines designed to safeguard the health and safety of patients, clinical trial investigators and site staff. Our very experienced clinical development team has successfully maintained robust communication with our sites. New patients enrolled in our programs from March to June 2020 did not miss any in-person clinic visits during the initial treatment period. We have also been working with our partners to ensure that backup services are in place, which has enabled some virtual visits to replace in-person visits during the follow-up period after initial treatment. These internal and external efforts have allowed us to continue progress across our clinical development programs. While we continue to evaluate the impact of the COVID-19 pandemic, we intend to provide an update on our clinical development timelines for TED and WAIHA in the third quarter of calendar year 2020.

The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, the ultimate impact of the pandemic on financial markets and the global economy, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled "Risk Factors" under Part II, Item 1A in this Annual Report on Form 10-K.

Business Combination and Recapitalization

On December 18, 2019, HSAC completed its acquisition of ISL pursuant to that certain share exchange agreement dated as of September 29, 2019 (the "Share Exchange Agreement"), by and among HSAC, ISL, the stockholders of ISL (the "Sellers"), and RSL, as representative of the Sellers. At the closing, HSAC acquired 100% of the issued and outstanding common shares of ISL. The aggregate value of the consideration paid by HSAC in the Business Combination was \$420.9 million, consisting of 42,080,376 shares of HSAC's common stock and 10,000 shares of HSAC's Series A preferred stock, in each case, valued at \$10.00 per share (the deemed value of the shares issued pursuant to the Share Exchange Agreement). Upon the closing of the Business Combination, ISL became a wholly owned subsidiary of HSAC and HSAC was renamed "Immunovant, Inc."

ISL was founded on July 6, 2018 as a Bermuda exempted limited company and a wholly owned subsidiary of RSL. HSAC was incorporated in Delaware on December 6, 2018 and was formed as a blank check company for the purpose of effecting a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses.

The Business Combination was accounted for as a reverse recapitalization and HSAC was treated as the "acquired" company for accounting purposes. Accordingly, the Business Combination was accounted as the equivalent of ISL issuing stock for the net assets of HSAC, accompanied by a recapitalization. Reported amounts from operations included herein prior to the Business Combination are those of ISL.

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Our Key Agreements

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, RSG entered into the HanAll Agreement. Under the HanAll Agreement, RSG, a wholly owned subsidiary of 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 IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, and to commercialize such products, in the United States, 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 IMVT-1401 from RSG in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and its wholly owned subsidiary, ISG, for an aggregate purchase price of \$37.8 million plus Swiss value-added tax of \$2.9 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. Since the acquisition of IMVT-1401, we, along with RSL, have performed all the development associated with IMVT-1401 and no amounts were due to HanAll for further research or development of the technology for the years ended March 31, 2020 and 2019.

Pursuant to the HanAll Agreement, RSG made an upfront payment of \$30.0 million to HanAll. In May 2019, we achieved our first development and regulatory milestone which resulted in a \$10.0 million milestone payment that we subsequently paid in August 2019. We will be responsible for future contingent payments and royalties, including up to an aggregate of \$442.5 million 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 on 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. See “Business—License Agreement with HanAll Biopharma Co., Ltd.” for further information.

Services Agreements with RSI and RSG

In August 2018, we entered into Services Agreements with RSI and RSG, under which RSI and RSG agreed to provide services related to development, administrative and financial activities to us during our formative period. Under each Services Agreement, we will pay or reimburse RSI or RSG, as applicable, for any expenses they, or third parties acting on our behalf, incur. 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 markup. RSI and RSG also provided such services prior to the formalization of the Services Agreements, and such costs have been recognized by us in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on our matters. All other costs will be billed back at cost. The term of the Services Agreements will continue until terminated by us, RSI or RSG, as applicable, upon 90 days’ written notice.

RSL Information Sharing and Cooperation Agreement

In December 2018, we entered into an amended and restated information sharing and cooperation agreement (the “Cooperation Agreement”) with RSL. The Cooperation Agreement, among other things: (1) obligates us to deliver to RSL periodic financial statements and other information upon reasonable request and to comply with other specified financial reporting requirements; (2) requires us to supply certain material information to RSL to assist it in preparing any future SEC filings; and (3) requires us to implement and observe certain policies and procedures related to applicable laws and regulations. We have 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 us or any of our subsidiaries, subject to certain limitations set forth in the Cooperation Agreement. No amounts have been paid or received under this agreement; however, we believe this agreement is material to our business and operations.

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 accounting principles generally accepted in the U.S. GAAP to consolidate our results of operations and financial position, account for its investment in us under the equity method of accounting or, by any rule of the SEC, include our separate financial statements in any filings it may make with the SEC and (b) has the right to elect directors constituting a majority of our board of directors.

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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 IMVT-1401 or any future product candidates. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of IMVT-1401 and any future product candidates.

Research and Development Expenses

Since our incorporation, our operations have primarily been limited to organizing and staffing our company, acquiring rights to our product candidate, IMVT-1401, and preparing for and conducting clinical trials. Research and development expenses primarily consist of salaries, benefits, and other staff-related costs, including associated stock-based compensation, laboratory supplies, clinical studies and trials and related clinical manufacturing costs. Costs related to manufacturing preparation, fees paid to other entities that conduct certain research and development activities on our behalf, and facilities and allocated overhead and facility costs are also included within research and development. We expect to significantly increase our research and development efforts as we initiate and conduct our Phase 2 and Phase 3 clinical trials for IMVT-1401. Research and development expenses will include:

- employee-related expenses, such as salaries, stock-based compensation, benefits and travel expense for the research and development personnel that we plan to hire;
- expenses incurred under agreements with CROs, as well as consultants that conduct nonclinical studies designed to assist with the lead optimization of our product candidate;
- manufacturing costs in connection with conducting nonclinical studies and clinical trials;
- milestone payments and other costs associated with the HanAll Agreement;
- costs for sponsored research;
- cost incurred under patent, technology, and know-how sublicense agreements;
- upfront payments for the purchase of in-process research and development; and
- costs allocated to us under our Services Agreements with RSI and RSG.

Research and development activities will continue to be central to our business model. We expect our research and development expenses to be significant over the next several years as we increase personnel and compensation costs and commence additional expected clinical trials for IMVT-1401 and prepare to seek regulatory approval for our product candidate. It is difficult 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 IMVT-1401 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 the recent COVID-19 pandemic;
- the efficacy and safety profile of the product candidate; and
- the cost of manufacturing.

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In addition, the probability of success for IMVT-1401 and any other product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and increased costs of operating as a public company. These increases will likely include patent costs for our product candidates and increased costs related to the hiring of additional personnel and fees to outside consultants for professional services. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with Nasdaq rules and SEC requirements, insurance and investor relations costs. In addition, whenever IMVT-1401 obtains regulatory approval, we expect that we would incur expenses associated with building a sales and marketing team.

Interest Expense

Interest expense consisted of interest incurred on our convertible promissory notes that were settled through conversion upon the closing of the Business Combination.

Results of Operations

Comparison of the Years Ended March 31, 2020 and 2019

The following table sets forth our results of operations for the years ended March 31, 2020 and 2019 (in thousands):

	Years Ended March 31,		Change
	2020	2019	\$
Operating expenses:			
Research and development	\$ 47,927	\$ 25,733	\$ 22,194
General and administrative	18,151	2,692	15,459
Total operating expenses	66,078	28,425	37,653
Interest expense	625	—	625
Other (income) expense, net	(412)	155	(567)
Loss before provision for income taxes	(66,291)	(28,580)	(37,711)
Provision for income taxes	97	19	78
Net loss	<u>\$66,388</u>	<u>\$(28,599)</u>	<u>\$(37,789)</u>

Research and Development Expenses

Research and development expenses increased by \$22.2 million, from \$25.7 million for the year ended March 31, 2019 to \$47.9 million for the year ended March 31, 2020. This increase was primarily due to \$10.0 million related to the achievement of the first development and regulatory milestone under the HanAll Agreement in May 2019. Other increases mainly include higher clinical trial costs of \$7.5 million, contract manufacturing costs of \$5.7 million, and other costs of \$1.3 million, all of which were driven by the advancement of our clinical trials for the treatment of autoimmune disease, as well as higher personnel-related expenses of \$2.6 million and stock-based compensation expense of \$1.9 million, both of which were due to higher headcount to support our clinical operations. The overall increase was partially offset by decreases in costs billed to us under the Services Agreements of \$4.9 million, and nonclinical studies of \$1.9 million.

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General and Administrative Expenses

General and administrative expenses increased by \$15.5 million, from \$2.7 million for the year ended March 31, 2019 to \$18.2 million for the year ended March 31, 2020. This increase was primarily due to higher legal and professional fees of \$6.4 million, driven by advisory fees incurred in relation to the Business Combination and increased accounting and legal services to support our higher operating activities and SEC filings. Additional increases include higher stock-based compensation expense of \$3.7 million and higher personnel-related costs of \$3.8 million, both of which were due to higher headcount, and an increase in other costs of \$1.6 million.

Interest Expense

Interest expense was \$0.6 million for the year ended March 31, 2020 and was related to the interest accrued on our convertible promissory notes issued during the year that were settled through conversion upon the closing of the Business Combination.

Liquidity and Capital Resources

Overview

We had cash of \$100.6 million and \$7.0 million as of March 31, 2020 and 2019, respectively. For the years ended March 31, 2020 and 2019, we had net losses of \$66.4 million and \$28.6 million, respectively. Prior to the Business Combination, our operations were historically financed through capital contributions from RSL or its affiliates, the issuance of equity instruments, and the issuance of notes payable.

In April 2020, we completed an underwritten public offering of 9,613,365 shares of our common stock (including 1,034,483 shares of common stock purchased by RSL and the full exercise of the underwriters' option to purchase 1,253,917 additional shares of common stock) at a price to the public of \$14.50 per share, for net proceeds to us of approximately \$131.0 million, after deducting underwriting discounts and commissions and estimated offering expenses.

From May 14, 2020 through June 15, 2020, an aggregate of 11,438,290 outstanding warrants were exercised for an aggregate of 5,719,145 shares of our common stock at a price of \$11.50 per share, for net proceeds to us of approximately \$65.8 million.

Our cash balance as of June 29, 2020 is approximately \$280.4 million.

We expect to continue to incur significant 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 IMVT-1401 or any future product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- fund our ongoing ASCEND-MG trial;
- fund our ongoing ASCEND-GO 1 and ASCEND-GO 2 trials;
- fund our ongoing ASCEND-WAIHA trial;
- launch any potential Phase 2 proof-of-concept studies of IMVT-1401 in additional indications;
- achieve milestones under our agreements with third parties, including the HanAll Agreement, that will require us to make substantial payments to those parties;
- seek to identify, acquire, develop and commercialize additional product candidates;
- 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;

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- commence the number of trials required for approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- 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
- operate as a public company.

Our primary use of cash is to fund our ASCEND-MG trial, our ASCEND-GO 1 trial, our ASCEND-GO 2 trial, our planned ASCEND-WAIHA trial, and other clinical development activities. Our current funds will not be sufficient to enable us to complete all necessary development and commercially launch IMVT-1401. We anticipate that we will continue to incur net losses for the foreseeable future.

Until such time, if ever, as we can generate substantial product revenue from sales of IMVT-1401 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 potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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.

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, 2020 and 2019 (in thousands):

	Years Ended March 31,	
	2020	2019
Net cash used in operating activities	\$ (53,357)	\$(28,547)
Net cash used in investing activities	(31)	(52)
Net cash provided by financing activities	146,974	35,584

Operating Activities

Cash provided by operating activities represents the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for non-cash items and changes in operating assets and liabilities. For the year ended March 31, 2020, \$53.4 million of cash was used in operating activities. This was primarily attributable to a net loss from operations for the year of \$66.4 million, non-cash charges of \$8.2 million and a net change in operating assets and liabilities of \$4.8 million. The non-cash charges consisted mainly of stock-based compensation of \$7.0 million and \$1.6 million from the write-off of deferred offering costs. The change in our operating assets and liabilities was primarily due to an increase of \$7.5 million in accounts payable and accrued expenses, primarily driven by increased research and development efforts and general and administrative activities, partially offset by an increase of \$2.8 million in prepaid expenses.

For the year ended March 31, 2019, \$28.5 million of cash was used in operating activities. This was primarily attributable to a net loss from operations for the year of \$28.6 million and a net change in operating assets and liabilities of \$1.4 million, which were partially offset by stock-based compensation of \$1.3 million. The change in our operating assets and liabilities was due to an increase of \$2.5 million in prepaid expenses and an increase of \$2.9 million in the Swiss value-added tax receivable related to the assignment of the HanAll License Agreement, partially offset by a net increase in accounts payable and accrued expenses of \$4.0 million due to a ramp up in our research and development efforts.

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Investing Activities

For the years ended March 31, 2020 and 2019, cash used in investing activities was related to the purchase of property and equipment.

Financing Activities

For the year ended March 31, 2020, \$147.0 million of cash provided by financing activities consisted of \$111.0 million in cash received as a result of the Business Combination, \$35.0 million in proceeds from the issuance of convertible promissory notes, \$7.9 million from the issuance of promissory notes to RSL, and \$1.2 million in capital contributions by RSL, partially offset by \$5.0 million in repayments of convertible promissory notes and the payment of offering costs of \$3.1 million.

For the year ended March 31, 2019, \$35.6 million of cash provided by financing activities consisted of \$16.1 million in capital contributions by RSL, \$14.9 million of net proceeds from the issuance of common stock and \$5.1 million of investments made by RSL.

Outlook

Based on our existing cash balance as of June 29, 2020 of approximately \$280.4 million, our research and development plans and our timing expectations related to our development programs for IMVT-1401, we expect to be able to fund our operating expenses and capital expenditure requirements into the first half of 2022. However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Contractual Obligations and Commitments

As of March 31, 2020, other than contingent payments pursuant to the HanAll Agreement, we did not have any ongoing material financial commitments, such as lines of credit or guarantees, that we expect to affect our liquidity over the next several years.

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 cancelable 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.

We have not included potential future payments due under the HanAll Agreement in a table of contractual obligations because the payment obligations under this agreement are contingent upon future events. As of March 31, 2020, the aggregate maximum amount of milestone payments we could be required to make under the HanAll Agreement is \$442.5 million upon the achievement of certain development, regulatory and sales milestone events. In May 2019, we achieved our first development and regulatory milestone under the HanAll Agreement resulting in a \$10.0 million milestone payment that was paid by us in August 2019. We are also required to reimburse HanAll for half of budgeted research and development costs incurred by HanAll with respect to IMVT-1401, up to an aggregate of \$20.0 million.

Our office leases are short-term in nature and cancelable at any time. Subsequent to March 31, 2020, we entered into two sublease agreements with RSI for office space expiring in 2024. For more information on such subleases, see “Note 12 — Subsequent Events” to our combined and consolidated financial statements.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our combined and consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these combined and 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.

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Our combined and consolidated financial statements are derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with product candidate IMVT-1401, that have been contributed to us by RSL, from RSL's financial statements. Because the transfer of assets and liabilities in our formation on July 6, 2018 was between entities under the common control of RSL and/or its wholly owned subsidiaries, our combined and consolidated financial statements have been presented as if we had been a separate business when RSG acquired IMVT-1401 on December 19, 2017, and accordingly, the assets, liabilities and expenses relating to our operations have been separated from RSL in the combined and consolidated financial statements for periods prior to and after our formation through March 31, 2020.

We define our critical accounting policies 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 combined and consolidated financial statements included elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our combined and consolidated financial statements that require significant estimates and judgments.

Stock-Based Compensation

We recognize stock-based compensation expense related to stock options based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. 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. We account for forfeitures as they occur. The Black-Scholes option pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected Term. The expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility. Prior to the Business Combination, we were a privately-held company and did not have any trading history for our common stock. The expected volatility was estimated using weighted average measures of implied volatility and the historical volatility of our peer group of companies for a period equal to the expected life of the stock options. Our peer group of publicly-traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty. Because we do not have an extended trading history for our shares of common stock since the closing of the Business Combination, the method used to estimate the expected volatility remained unchanged.

Risk-Free Interest Rate. 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 stock options.

Expected Dividend. We have never paid, and do not anticipate paying, cash dividends on our common stock. Therefore, the expected dividend yield was assumed to be zero.

Prior to the closing of the Business Combination, the fair value of our common stock was estimated on each grant date by our board of directors. In order to determine the fair value of our common stock, our board of directors considered, among other things, timely valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including (1) our business, financial condition and results of operations, including related industry trends affecting our operations; (2) our forecasted operating performance and projected future cash flows; (3) the illiquid nature of our common stock; (4) the rights and privileges of our common stock; (5) market multiples of our most comparable public peers and (6) market conditions affecting our industry.

After the closing of the Business Combination, our board of directors determined the fair value of each share of common stock underlying stock-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant.

A component of total stock-based compensation expense relates to the RSL common stock awards and options issued by RSL to its employees. Stock-based compensation expense is allocated to us by RSL based upon the relative percentage of time utilized by RSL employees on our matters. The fair value of the RSL common stock awards is determined on the date of grant and that fair value is recognized over the requisite service period. Significant judgment and estimates were used to estimate the fair value of these awards and options, as they are not publicly traded. RSL common share awards and options are subject to specified vesting schedules and requirements (a combination of time-based, performance-based and corporate event-based vesting terms, including targets for post-IPO market capitalization and future financing events of RSL). The fair value of each RSL option is estimated on the date of grant using the Black-Scholes option pricing model.

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Research and Development Expense

Research and development costs with no alternative future use are expensed as incurred. Clinical trial costs are accrued over the service periods specified in the contracts and are adjusted as necessary based on an ongoing review of the level of effort and costs actually incurred. 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 research and development. Research and development costs are charged to expense when incurred and primarily consist of employee compensation, allocated costs from RSL and expenses from third parties who conduct research and development activities on our behalf.

Income Taxes

We account for income taxes in accordance with ASC 740, *Income Taxes*. Under the assets and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize 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. As of March 31, 2020, we did not have any significant uncertain tax positions.

Jumpstart Our Business Startups Act

In April 2012, the JOBS Act was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Recent Accounting Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our combined and consolidated financial statements, refer to “Note 2 — Summary of Significant Accounting Policies” in our combined and consolidated financial statements in Part II, Item 8 of this Annual Report.

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.

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Item 8. Financial Statements and Supplementary Data

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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 combined and consolidated balance sheets of Immunovant, Inc. (the Company) as of March 31, 2020 and 2019, the related combined and consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended March 31, 2020, and the related notes (collectively referred to as the "combined and consolidated financial statements"). In our opinion, the combined and consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

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

Iselin, New Jersey

June 29, 2020

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

	March 31,	
	2020	2019
Assets		
Current assets:		
Cash	\$100,571	\$ 6,985
Prepaid expenses	5,460	2,632
Income tax receivable	36	49
Value-added tax receivable	3,009	2,913
Total current assets	<u>109,076</u>	<u>12,579</u>
Property and equipment, net	65	54
Deferred offering costs	246	1,195
Total assets	<u>\$109,387</u>	<u>\$ 13,828</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,190	\$ 206
Accrued expenses	10,938	6,225
Due to Roivant Sciences Ltd.	3,190	58
Total liabilities	<u>15,318</u>	<u>6,489</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:(1)		
Series A preferred stock, par value \$0.0001 per share, 10,000 shares authorized, issued and outstanding at March 31, 2020 and no shares authorized at March 31, 2019	—	—
Preferred stock, par value \$0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2020 and no shares authorized at March 31, 2019	—	—
Common stock, par value \$0.0001 per share, 500,000,000 shares authorized, 56,455,376 shares issued and 54,655,376 shares outstanding at March 31, 2020 and 489,066,238 shares authorized, 38,590,381 shares issued and outstanding at March 31, 2019	5	4
Common stock subscribed	—	(3)
Additional paid-in capital	185,306	31,830
Accumulated other comprehensive (loss) income	(16)	346
Accumulated deficit	(91,226)	(24,838)
Total stockholders' equity	<u>94,069</u>	<u>7,339</u>
Total liabilities and stockholders' equity	<u>\$109,387</u>	<u>\$ 13,828</u>

(1) Retroactively restated for the reverse recapitalization as described in Note 1.

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

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

	Years Ended March 31,	
	2020	2019
Operating expenses:		
Research and development (includes \$3,130 and \$1,193 of stock-based compensation expense for the years ended March 31, 2020 and 2019, respectively)(1)	\$ 47,927	\$ 25,733
General and administrative (includes \$3,833 and \$115 of stock-based compensation expense for the years ended March 31, 2020 and 2019, respectively)(2)	18,151	2,692
Total operating expenses	66,078	28,425
Interest expense	625	—
Other (income) expense, net	(412)	155
Loss before provision for income taxes	(66,291)	(28,580)
Provision for income taxes	97	19
Net loss	\$ (66,388)	\$ (28,599)
Net loss per common share — basic and diluted(3)	\$ (1.54)	\$ (1.29)
Weighted average shares outstanding — basic and diluted(3)	43,199,191	22,170,862

(1) Includes \$159 and \$3,582 of costs allocated from Roivant Sciences Ltd. for the years ended March 31, 2020 and 2019, respectively.

(2) Includes \$1,381 and \$1,180 of costs allocated from Roivant Sciences Ltd. for the years ended March 31, 2020 and 2019, respectively.

(3) Retroactively restated for the reverse recapitalization as described in Note 1.

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

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

	Years Ended March 31,	
	2020	2019
Net loss	\$(66,388)	\$(28,599)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	(362)	185
Total other comprehensive (loss) income	(362)	185
Comprehensive loss	<u>\$(66,750)</u>	<u>\$(28,414)</u>

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

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IMMUNOVANT, INC.
Combined and Consolidated Statements of Stockholders' Equity⁽¹⁾
(In thousands, except share data)

	Series A preferred stock		Common stock		Common stock subscribed	Additional paid-in capital	Net parent investment ⁽²⁾	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
	Shares	\$ —	Shares	\$ —	\$ —	\$ —	\$ (1,658)	\$ 161	\$ —	\$ (1,497)
Balance at March 31, 2018										
Net transfers from parent ⁽²⁾	—	—	—	—	—	—	5,419	—	—	5,419
Foreign currency translation adjustments	—	—	—	—	—	—	—	35	—	35
Net loss	—	—	—	—	—	—	(4,368)	—	—	(4,368)
Common stock subscription	—	—	4,890,662	—	—	—	—	—	—	—
Balance at July 6, 2018 (date of formation)										
Common stock subscription	—	—	31,789,305	\$ 3	\$ (3)	—	\$ (607)	\$ 196	\$ —	\$ (411)
Issuance of common stock, net	—	—	1,910,414	1	—	14,746	—	—	—	14,747
Transfer to accumulated deficit	—	—	—	—	—	—	607	—	(607)	—
Cash contribution	—	—	—	—	—	13,901	—	—	—	13,901
Capital contribution – stock- based compensation	—	—	—	—	—	922	—	—	—	922
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	2,230	—	—	—	2,230
Stock-based compensation	—	—	—	—	—	31	—	—	—	31
Foreign currency translation adjustments	—	—	—	—	—	—	—	150	—	150
Net loss	—	—	—	—	—	—	—	—	(24,231)	(24,231)
Balance at March 31, 2019										
Settlement of common stock subscription	—	—	38,590,381	\$ 4	\$ (3)	\$ 31,830	\$ —	\$ 346	\$ (24,838)	\$ 7,339
Issuance of preferred and common stock, net of deferred offering costs upon Business Combination and Recapitalization (See Note 3)	10,000	—	12,565,000	1	—	109,771	—	—	—	109,772
Conversion of convertible promissory notes	—	—	3,499,995	—	—	35,587	—	—	—	35,587
Capital contribution – stock- based compensation	—	—	—	—	—	175	—	—	—	175
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	1,157	—	—	—	1,157
Stock-based compensation	—	—	—	—	—	6,788	—	—	—	6,788
Foreign currency translation adjustments	—	—	—	—	—	—	—	(362)	—	(362)
Net loss	—	—	—	—	—	—	—	—	(66,388)	(66,388)
Balance at March 31, 2020	10,000	\$ —	54,655,376	\$ 5	\$ —	\$ 185,306	\$ —	\$ (16)	\$ (91,226)	\$ 94,069

(1) Retroactively restated for reverse recapitalization as described in Note 1.

(2) Prior to formation of the Company, Roivant Sciences Ltd. was the Company's parent with 100% ownership interest (See Note 2[A]).

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

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

	Years Ended March 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (66,388)	\$ (28,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	6,963	1,308
Depreciation on property and equipment	21	10
Foreign currency translation adjustments	(362)	185
Loss on disposal of property and equipment	13	—
Gain on extinguishment of convertible notes	(38)	—
Write-off of deferred offering costs	1,628	—
Changes in operating assets and liabilities:		
Prepaid expenses	(2,824)	(2,519)
Income tax receivable	13	(49)
Value-added tax receivable	(96)	(2,913)
Accounts payable	967	(928)
Accrued expenses	6,502	4,912
Due to Roivant Sciences Ltd.	244	46
Net cash used in operating activities	<u>(53,357)</u>	<u>(28,547)</u>
Cash flows from investing activities		
Purchases of property and equipment	(31)	(52)
Net cash used in investing activities	<u>(31)</u>	<u>(52)</u>
Cash flows from financing activities		
Capital contributions	1,157	16,131
Net parent investment	—	5,064
Proceeds from issuance of common stock	—	14,910
Payment of offering costs	(3,107)	(521)
Proceeds from notes payable to Roivant Sciences Ltd.	7,907	—
Repayment of convertible promissory note payable to Roivant Sciences Ltd.	(2,500)	—
Proceeds from convertible promissory notes	35,000	—
Repayment of convertible promissory notes	(2,500)	—
Settlement of common stock subscribed	1	—
Recapitalization transaction (See Note 3)	111,016	—
Net cash provided by financing activities	<u>146,974</u>	<u>35,584</u>
Net change in cash	93,586	6,985
Cash – beginning of period	6,985	—
Cash – end of period	<u>\$100,571</u>	<u>\$ 6,985</u>
Non-cash investing activities		
Payable for purchase of property and equipment	\$ 9	\$ 13
Non-cash financing activities		
Reclassification of net parent investment to accumulated deficit	\$ —	\$ 607
Conversion of convertible promissory notes to common stock	\$ 35,000	\$ —
Common stock issuance costs in accrued expenses	\$ —	\$ 165
Deferred offering costs in accrued expenses	\$ 246	\$ 674
Cancelation of interest on convertible promissory notes recorded in equity	\$ 587	\$ —
Supplemental disclosure of cash paid:		
Income taxes	\$ 61	\$ 68

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

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IMMUNOVANT, INC. Notes to Combined and 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”) (formerly known as Health Sciences Acquisitions Corporation) is a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. The Company is developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits the neonatal fragment crystallizable receptor (FcRn). The Company intends to develop IMVT-1401 for indications in which there is robust evidence that pathogenic immunoglobulin G antibodies drive disease manifestation and for which reduction of these antibodies should lead to clinical benefit for patients with autoimmune diseases.

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

Reverse Recapitalization

On December 18, 2019, Health Sciences Acquisitions Corporation (“HSAC”) completed the acquisition of Immunovant Sciences Ltd. (“ISL”) pursuant to the share exchange agreement dated as of September 29, 2019 (the “Share Exchange Agreement”), by and among HSAC, ISL, the stockholders of ISL (the “Sellers”), and Roivant Sciences Ltd. (“RSL”), as representative of the Sellers (the “Business Combination”). As of immediately prior to the closing of the Business Combination, the Sellers owned 100% of the issued and outstanding common shares of ISL (“ISL Shares”). At the closing of the Business Combination, HSAC acquired 100% of the issued and outstanding ISL Shares, in exchange for 42,080,376 shares of HSAC’s common stock issued to the Sellers and 10,000 shares of HSAC Series A preferred stock issued to RSL (the “Business Combination”). Upon the closing of the Business Combination, ISL became a wholly owned subsidiary of HSAC and HSAC was renamed “Immunovant, Inc.”

The Business Combination was accounted for as a reverse recapitalization and HSAC was treated as the “acquired” company for accounting purposes. The Business Combination was accounted as the equivalent of ISL issuing stock for the net assets of HSAC, accompanied by a recapitalization. Accordingly, all historical financial information presented in these combined and consolidated financial statements represents the accounts of ISL and its wholly owned subsidiaries “as if” ISL is the predecessor to the Company. The shares and net loss per common share, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (0.48906624 Immunovant, Inc. shares for 1 ISL Share).

ISL was founded on July 6, 2018 as a Bermuda exempted limited company and a wholly owned subsidiary of RSL. In July and August 2018, ISL incorporated 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 (formerly, Immunovant, Inc.), a Delaware corporation based in the United States of America, 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. HSAC was incorporated in Delaware on December 6, 2018 and was formed as a blank check company for the purpose of effecting a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses. References herein to “date of formation” or “date of inception” refer to the founding of ISL.

Prior to the closing of the Business Combination, HSAC common stock, units and warrants were traded on The Nasdaq Capital Market (“Nasdaq”) under the ticker symbols “HSAC,” “HSACU” and “HSACW,” respectively. On December 19, 2019, the Company’s common stock, units and warrants began trading on Nasdaq under the ticker symbols “IMVT”, “IMVTU” and “IMVTW,” respectively. One of the primary purposes of the Business Combination was to provide a platform for ISL to gain access to the U.S. capital markets. See Note 3 – Business Combination and Recapitalization for additional details on the Business Combination.

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[B] Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of March 31, 2020, the Company's cash totaled \$100.6 million and its accumulated deficit was \$91.2 million.

Prior to the Business Combination, ISL's operations were financed through capital contributions from RSL or RSL's wholly owned subsidiaries, Roivant Sciences Inc. ("RSI") and Roivant Sciences GmbH ("RSG"), the issuance of equity instruments, and the issuance of promissory notes. 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 IMVT-1401 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. Based on anticipated spend and timing of expenditure assumptions, the Company currently expects that its existing cash as of March 31, 2020 together with funds raised in April 2020 and proceeds from warrants redemption as detailed in Note 12 – Subsequent Events, will be sufficient to fund its operating expenses and capital expenditure requirements into the first half of 2022 from the date the combined and 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 combined and consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("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").

Prior to July 6, 2018 (date of formation), the Company's financial statements were derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with product candidate IMVT-1401, that have been contributed to the Company by RSL, from RSL's financial statements. Because the transfer of assets and liabilities in the formation of the Company were between entities under the common control of RSL and/or its wholly owned subsidiaries, the financial statements of the Company have been presented as if the Company had been a separate business since the acquisition of IMVT-1401 by RSG on December 19, 2017. Prior to July 6, 2018 (date of formation), the Company's financial statements include reasonable allocations for assets and liabilities and expenses attributable to the Company's operations. Beginning on July 6, 2018 (date of formation), the combined and 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.

The Company believes that the assumptions underlying the allocations of expenses as well as assets and liabilities in financial information are reasonable, however, the financial position, results of operations and cash flows may have been materially different if the Company had operated as a stand-alone entity prior to July 6, 2018 (date of formation).

The Company has calculated its income tax amounts using a separate return methodology and it has presented these amounts as if it were a separate taxpayer from RSL.

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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All share and per-share data reported in the combined and consolidated financial statements herein have been retrospectively restated to reflect the effect of the Business Combination (as discussed in Note 3).

[B] Use of Estimates

The preparation of combined and consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the combined and consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based compensation, 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 of COVID-19 pandemic has had on its operations and financial results as of March 31, 2020 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 COVID-19 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 commercialization of products, regulatory approvals, dependence on key products, third-party service providers such as contract research organizations, 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. At March 31, 2020, the cash balance is kept in one banking institution that the Company believes is of high credit quality and is in excess of federally insured levels. The Company maintains its cash with an accredited financial institution 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, 2020, cash consisted of cash held at a financial institution. There were no cash equivalents as of March 31, 2020 and 2019.

[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 combined and consolidated statements of operations.

[G] Impairment of Long-lived Assets

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

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[H] Contingencies

The Company, from time to time, 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.

[I] Research and Development Expense

Research and development costs with no alternative future use are expensed as incurred. 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 research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of product sales over the remaining useful life of the asset. Research and development expenses primarily consist of employee-related costs and expenses from third parties who conduct research and development activities on behalf of the Company. The estimated costs of research and development activities conducted by third-party service providers, which primarily include the conduct of clinical trials and contract manufacturing activities, are accrued over the service periods specified in the contracts and 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, however the Company's understanding of the status and timing of services performed, the number of subjects enrolled, and the rate of subject enrollment may vary from estimates and could result in reporting amounts that are higher or lower than incurred in any particular period. The estimate of accrued research and development expense is dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers.

[J] Leases

In accordance with ASC 842, *Leases*, as adopted by the Company on April 1, 2019, the Company determines if an arrangement is a lease at inception. 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 minimum lease payments over the 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 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 combined and consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

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

The Company's leases are short-term in nature and cancelable at any time. Subsequent to March 31, 2020, the Company entered into two sublease agreements with RSI for office space expiring in 2024. For more information on such subleases, see Note 12 — Subsequent Events.

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[K] 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 combined and 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 expense (benefit) in the accompanying combined and 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.

[L] 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 or performance-based awards without market conditions using the Black-Scholes option pricing model. For performance-based awards with market conditions, the Company determines the fair value of awards as of the grant date using a Monte Carlo simulation model.

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 no 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 industry 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.

As part of the valuation of stock-based compensation under the Black-Scholes option pricing model, it is necessary for the Company to estimate the fair value of its common stock. Prior to the closing of the Business Combination, the fair value of the Company's common stock was estimated on each grant date by the Company's board of directors. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its common stock. The estimation of the fair value of the common stock considered factors including the following: the estimated present value of the Company's future cash flows; the Company's business, financial condition and results of operations; the Company's forecasted operating performance; the illiquid nature of the Company's common stock; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions.

After the closing of the Business Combination, the Company's board of directors determined the fair value of each share of common stock underlying stock-based awards based on the closing price of the Company's common stock as reported by Nasdaq on the date of grant.

Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation expense is recognized, and any previously recognized compensation cost is reversed.

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[M] 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, accounts payable, accrued expenses and amounts due to Roivant Sciences Ltd. These financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

[N] Foreign Currency

The Company has operations in the United States, 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 combined and consolidated balance sheet date and equity is translated using historical rates. Adjustments resulting from the translation of the combined and 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 (loss) income. Foreign exchange transaction gains and losses are included in other income (expense), net in the combined and consolidated statements of operations.

[O] 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 stocks have 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.

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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,	
	2020	2019
Preferred stock as converted	10,000	—
Restricted stock (unvested) (See Note 3)	1,800,000	—
Options	3,873,888	189,269
Warrants (See Note 9)	5,750,000	—
Earnout shares (See Note 3)	20,000,000	—
Total	31,433,888	189,269

The Company was formed on July 6, 2018 and basic and diluted net loss per common share was calculated assuming the shares issued at formation were outstanding for the period prior to incorporation adjusted for subsequent share issuances during the period.

[P] Deferred Offering Costs

Legal, accounting and other costs directly attributable to the issuance of the Company's equity are capitalized within deferred offering costs on the combined and consolidated balance sheets and reclassified to equity upon issuance of the shares. Offering costs comprised of legal, and accounting fees and other costs incurred through June 30, 2019 were directly related to ISL's proposed initial public offering ("IPO"). In August 2019, ISL's board of directors determined to suspend ISL's IPO registration process. Accordingly, the Company has written off deferred offering costs previously capitalized to general and administrative expense within the accompanying combined and consolidated statements of operations for the year ended March 31, 2020.

[Q] Common Stock Warrants

The Company accounts for the issuance of common stock warrants based on the terms of the contract and whether there are any requirements for the Company to net cash settle the contract under any terms or conditions. Warrants for the purchase of 5,750,000 shares of common stock were issued by HSAC as part of the units sold in its IPO in May 2019. Each unit was comprised of one share of common stock and a warrant to purchase one half of one share of common stock upon the consummation of a business combination by HSAC. None of the terms of the warrants were modified as a result of the Business Combination.

[R] Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU No. 2016-02"), a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 requires lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. The Company has adopted this ASU as of April 1, 2019. The Company elected the optional transition method to apply the standard as of the effective date and therefore will not apply the standard to the comparative periods presented in the combined and consolidated financial statements. The Company elected the transition package of three practical expedients permitted within the standard, which eliminates the requirements to reassess prior conclusions about lease identification, lease classification, and initial direct costs. The Company did not elect the hindsight practical expedient, which permits the use of hindsight when determining lease term and impairment of right-of-use assets. Further, the Company elected a short-term lease exception policy to not apply the recognition requirements of this standard to short-term leases with terms of 12 months or less and an accounting policy to account for lease and non-lease components as a single component for certain classes of assets. As all of the Company's leases are short-term in nature and the Company has elected to not apply the recognition requirements of the standard to such leases, there was no impact on the Company's combined and consolidated financial statements and related disclosures from the adoption of the standard.

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In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU No. 2018-07”). ASU No. 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company has adopted this ASU as of April 1, 2019, with no impact on the Company’s condensed combined and consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes* (“ASU No. 2019-12”). The new guidance eliminates certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. It also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for taxable goodwill and allocating taxes to members of a consolidated group. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company early adopted ASU 2019-12 as of January 1, 2020. The adoption did not have an impact on the Company’s combined and consolidated financial position, results of operations, or cash flows.

[S] Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU No. 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU No. 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU No. 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. The Company is currently evaluating the new standard and expects it to have no material impact on the Company’s combined and consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU No. 2018-13”). ASU No. 2018-13 removes, modifies, and adds certain recurring and nonrecurring fair value measurement disclosures, including removing disclosures around the amount(s) of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation process for Level 3 fair value measurements, among other things. ASU No. 2018-13 adds disclosure requirements around changes in unrealized gains and losses included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and a narrative description of measurement uncertainty. The amendments in ASU No. 2018-13 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the combined and consolidated financial statements.

Other recent authoritative guidance issued by the FASB (including technical corrections to the Accounting Standards Codification), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (“SEC”) did not, or are not expected to, have a material impact on the Company’s combined and consolidated financial statements and related disclosures.

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Note 3 — Business Combination and Recapitalization

As discussed in Note 1, on December 18, 2019, HSAC completed the acquisition of ISL and acquired 100% of the ISL Shares in exchange for 42,080,376 shares of HSAC common stock issued to the Sellers and 10,000 shares of HSAC Series A preferred stock issued to RSL. The Business Combination was accounted for as a reverse recapitalization whereby HSAC was treated as the “acquired” company for accounting purposes. This determination was primarily based on the fact that subsequent to the Business Combination, the Sellers have a majority of the voting power of the combined company, ISL will comprise all of the ongoing operations of the combined entity, a majority of the governing body of the combined company, and ISL’s senior management will comprise all of the senior management of the combined company. The Business Combination was accounted as the equivalent of ISL issuing stock for the net assets of HSAC, accompanied by a recapitalization. The net assets of HSAC were stated at historical cost with no goodwill or other intangible assets recorded. Reported amounts from operations included herein prior to the Business Combination are those of ISL. The shares, options and net loss per share available to holders of the Company’s common stock, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (0.48906624 Immunovant, Inc. shares for 1 ISL Share).

The aggregate value of the consideration paid by HSAC in the Business Combination was \$420.9 million, consisting of 42,080,376 shares of HSAC’s common stock and 10,000 shares of HSAC’s Series A preferred stock, in each case, valued at \$10.00 per share (the deemed value of the shares issued pursuant to the Share Exchange Agreement). The closing price per share on the date of the closing of the Business Combination on December 18, 2019 was \$13.88. As the Business Combination was accounted for as a reverse recapitalization, the \$10.00 per share value is disclosed for informational purposes only in order to indicate the fair value of shares transferred. In addition, pursuant to the Share Exchange Agreement, all vested or unvested outstanding options to purchase common shares of ISL under its 2018 Equity Incentive Plan were automatically assumed by the Company and converted into options to purchase 4,408,287 shares of the Company’s common stock with no changes to the terms of the awards.

In connection with the Business Combination and Recapitalization, the Company incurred direct and incremental costs of \$2.8 million, consisting of legal, accounting, financial advisory and other professional fees, which are included in additional paid-in capital in the combined and consolidated balance sheets as of March 31, 2020. The Company incurred additional financial advisory fees related to the Business Combination of \$2.3 million that have been included in general and administrative expense within the accompanying combined and consolidated statements of operations for the year ended March 31, 2020.

Immediately after giving effect to the Business Combination, there were 56,455,376 shares of common stock issued, 54,655,376 shares of common stock outstanding, 10,000 shares of Series A preferred stock and 11,500,000 warrants to purchase 5,750,000 shares of common stock issued and outstanding.

Earnout Shares

The Sellers are entitled to receive up to an additional 20,000,000 shares of the Company’s common stock (the “Earnout Shares”) if the volume-weighted average price of the Company’s shares equals or exceeds the following prices for any 20 trading days within any 30 trading-day period (the “Trading Period”) following December 18, 2019, the date of the closing of the Business Combination:

- (i) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least \$17.50 per share; and
- (ii) during any Trading Period prior to March 31, 2025, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least \$31.50 per share (each of (i) and (ii) are a “Milestone”).

If prior to March 31, 2025, (i) there is a change of control of the Company, (ii) any liquidation, dissolution or winding up of the Company is initiated, (iii) any bankruptcy, dissolution or liquidation proceeding is instituted by or against the Company, or (iv) the Company makes an assignment for the benefit of creditors or consents to the appointment of a custodian, receiver or trustee for all or substantial part of its assets or properties (each, an “Acceleration Event”), then any Earnout Shares that have not been previously issued by the Company (whether or not previously earned) shall be deemed earned and due by the Company to the Sellers, unless in a change of control, the value of the consideration to be received in exchange for a share of the Company’s common stock is lower than the share price thresholds described above.

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The Earnout Shares are indexed to the company's equity and meet the criteria for equity classification. On May 12, 2020, the Company issued 10,000,000 shares of common stock to former stockholders of ISL, (including 8,773,969 shares of common stock issued to RSL) on achievement of first milestone earnout. See Note 12 – Subsequent Events for details related to first earnout milestone.

Sponsor Restricted Stock Agreement

In accordance with that certain restricted stock agreement, dated September 29, 2019, by and between HSAC and Health Sciences Holdings, LLC (the "Sponsor"), the Sponsor subjected 1,800,000 shares of its common stock based on the vesting of 900,000 shares for each milestone ("Sponsor Restricted Shares") to potential forfeiture in the event that the Milestones (as defined above) are not achieved. In the event of an Acceleration Event (as defined above), all of such shares will vest and no longer be subject to forfeiture, unless in a change of control, the value of the consideration to be received in exchange for one share of common stock is lower than the applicable Milestone share price thresholds. Any shares that have not vested on or prior to March 31, 2025 will be forfeited by the Sponsor after such date.

For accounting purposes, the Sponsor Restricted Shares are considered issued but not outstanding as of March 31, 2020. On May 12, 2020, 900,000 shares of the Sponsor Restricted Shares vested and are no longer subject to forfeiture. See Note 12 – Subsequent Events for details related to Sponsor Restricted Stock Agreement.

Registration Rights

In May 2019, HSAC entered into a registration rights agreement with the Sponsor, pursuant to which the Sponsor was granted certain rights relating to the registration of securities of HSAC held by the Sponsor.

In September 2019, concurrent with the execution of the Share Exchange Agreement, HSAC, the Sponsor and the Sellers entered into an amended and restated registration rights agreement (the "Registration Rights Agreement"), which became effective as of the closing of the Business Combination. Under the Registration Rights Agreement, the Sponsor and the Sellers hold registration rights that obligate the Company to register for resale under the Securities Act of 1933, as amended (the "Securities Act") all or any portion of the Registrable Securities (as defined in the Registration Rights Agreement) held by the Sponsor and the Sellers. Each of the Sponsor, RSL and stockholders holding a majority-in-interest of all such Registrable Securities will be entitled to make a written demand for registration under the Securities Act of all or part of their Registrable Securities, so long as such shares are not then restricted under certain lock-up agreements. Subject to certain exceptions, if the Company proposes to file a registration statement under the Securities Act with respect to the Company's securities, under the Registration Rights Agreement, the Company will give notice to the Sponsor and the Sellers as to the proposed filing and offer such stockholders an opportunity to register the resale of such number of their Registrable Securities as they request in writing, subject to certain exceptions. In addition, subject to certain exceptions, such stockholders will be entitled under the Registration Rights Agreement to request in writing that the Company register the resale of any or all of their Registrable Securities on Form S-3 or any other registration statement that may be available at such time.

The Registration Rights do not meet the definition of a registration payment arrangement as there are no terms that require the Company to transfer consideration to the various securityholders if a registration statement is not declared effective or effectiveness is not maintained.

See Note 9 – Stockholders' Equity for details of the Company's capital stock prior to and subsequent to the Business Combination and Recapitalization transaction.

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Note 4 — Material Agreements

On December 19, 2017, RSG, a wholly owned subsidiary of RSL, entered into a license agreement (the “HanAll Agreement”) with 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 IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, in the United States, 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 \$452.5 million upon the achievement of certain development, regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens on net product sales subject to 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.

Since the acquisition of IMVT-1401, RSL and the Company have performed all the development associated with IMVT-1401 and no amounts were incurred by HanAll to research or develop the technology for the years ended March 31, 2020 and 2019.

On August 18, 2018, RSG entered into a sublicense agreement (the “Sublicense Agreement”) with ISG to sublicense this technology, as well as RSG’s knowhow and patents necessary for the development, manufacture or commercialization of any compound or product that pertain to immunology. On December 7, 2018, RSG issued a notice to terminate the Sublicense Agreement with ISG and entered into the 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 IMVT-1401 from RSG in the Licensed Territory, for an aggregate purchase price of \$37.8 million. As a result of the assignment of IMVT-1401 by RSG to ISG, the Company recorded a Swiss value-added tax receivable of \$3.0 million and \$2.9 million as of March 31, 2020 and 2019, respectively and is reflected as a capital contribution from RSL as of March 31, 2020.

In May 2019, the Company achieved its first development and regulatory milestone under the HanAll Agreement which resulted in a \$10.0 million milestone payment that the Company subsequently paid in August 2019. The milestone payment was recorded as research and development expense in the accompanying combined and consolidated statements of operations for the year ended March 31, 2020.

Note 5 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31,	
	2020	2019
Research and development expenses	\$ 8,332	\$4,815
Legal and other professional fees	1,231	1,106
Accrued bonuses	859	288
Other expenses	516	16
Total accrued expenses	\$10,938	\$6,225

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Note 6 — Related Party Transactions

In addition to the agreements discussed in Note 4, in August 2018, the Company entered into services agreement (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 during its formative period. 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. RSI and RSG also provided such services prior to the formalization of the Services Agreements, and such costs have been recognized by the Company in the period in which the services were rendered. 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. The combined and consolidated financial statements also include third-party expenses that have been paid by RSI, RSG and RSL since the inception of the Company. Total expense, inclusive of salary, fringe benefits and stock-based compensation, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company’s matters. For the year ended March 31, 2020, the Company was charged \$1.4 million by RSI, RSG and RSL of which \$1.2 million and \$0.2 million were treated as capital contributions and amounts due to Roivant Sciences Ltd., respectively, in the accompanying combined and consolidated financial statements. For the year ended March 31, 2019, the Company was charged \$2.3 million by RSI, RSG and RSL of which \$2.2 million and \$0.1 million were treated as capital contributions and amounts due to Roivant Sciences Ltd., respectively, in the accompanying combined and consolidated financial statements.

On June 11, 2019, the Company entered into an interest-free promissory note payable with RSL in the amount of \$5.0 million (the “June Promissory Note”). The June Promissory Note was due and payable at the earlier of December 12, 2019 or upon demand by RSL. Subsequently, on August 7, 2019, the Company replaced the June Promissory Note and entered into a convertible promissory note with RSL in the amount of \$5.0 million (the “RSL Convertible Promissory Note”) under the same terms as other convertible promissory notes entered into with RTW Master Fund, Ltd. and RTW Innovation Master Fund, Ltd. (the “RTW Entities”) (see Note 8). On September 26, 2019, \$2.5 million principal amount of the RSL Convertible Promissory Note was prepaid and the accrued interest on such principal amount was forgiven, bringing the principal balance of the RSL Convertible Promissory Note to \$2.5 million. Immediately prior to the closing of the Business Combination, the remaining \$2.5 million principal balance of the RSL Convertible Promissory note was automatically converted into an aggregate of 511,178 ISL Shares, which were then exchanged for an aggregate of 250,000 shares of the Company’s common stock upon the closing of the Business Combination. In accordance with the terms of the RSL Convertible Promissory Note, all interest on the RSL Convertible Promissory Note was waived and canceled immediately prior to the closing of the Business Combination and recorded in additional paid-in capital upon conversion of the underlying note.

On July 17, 2019, the Company entered into an interest-free promissory note payable with RSL in the amount of \$2.9 million (the “July Promissory Note”). The July Promissory Note has a 180-day term and is payable on demand upon the expiration of the term. The July Promissory Note along with \$0.3 million other payables due to RSL are included in amounts due to Roivant Sciences Ltd. in the accompanying combined and consolidated balance sheets as of March 31, 2020. In May 2020, the Company paid and settled the July Promissory Note with RSL. See Note 12 – Subsequent Events for details related to the repayment of the July Promissory Note.

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; however, the Company believes this agreement is material to its business and operations.

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.

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Note 7 — Income Taxes

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

	<u>Years Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
(Loss) income before income taxes		
United States	\$ (9,245)	\$ (1,035)
Switzerland	(53,413)	(27,247)
Bermuda	(3,661)	(405)
United Kingdom	10	(20)
Other	18	127
Total loss before income taxes	<u>\$ (66,291)</u>	<u>\$(28,580)</u>
Current taxes		
United States – Federal	\$ 61	\$ 7
United States – State	34	12
Other	2	—
Total current tax expense	<u>97</u>	<u>19</u>
Deferred tax expense	—	—
Total provision for income taxes	<u>\$ 97</u>	<u>\$ 19</u>

A reconciliation of the provision for income taxes computed at the U.S. statutory rate (21%) for the year ended March 31, 2020 and at the Bermuda statutory rate (0%) for the year ended March 31, 2019 to the provision for income taxes reflected in the combined and consolidated statements of operations is as follows (in thousands):

	<u>Years Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Income tax at statutory rate	<u>\$(13,921)</u>	<u>\$ —</u>
Foreign rate differential	4,255	(3,877)
Tax rate changes	—	(674)
Research and development credits	(1,093)	(605)
Valuation allowance	9,988	5,122
Non-deductible expense	951	57
Other	(83)	(4)
Total provision for income taxes	<u>\$ 97</u>	<u>\$ 19</u>

The Company's effective tax rate was (0.15)% and (0.07)% for the years ended March 31, 2020 and March 31, 2019, 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. Additionally, the Company's effective tax rate for the year ended March 31, 2019 was favorably impacted by an income tax rate change in Switzerland. However, this impact was entirely offset by a change in the valuation allowance.

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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, 2020 and 2019 are as follows (in thousands):

	March 31,	
	2020	2019
Deferred tax assets		
Intangible assets	\$ 6,445	\$ 5,000
Net operating losses	9,443	3,023
Stock-based compensation	1,610	290
Research and development credits	1,487	560
Accrued bonuses	187	65
Total deferred tax assets	19,172	8,938
Valuation allowance	(19,129)	(8,910)
Deferred tax assets, net of valuation allowance	\$ 43	\$ 28
Deferred tax liabilities		
Depreciation	\$ (13)	\$ (11)
Others	(30)	(17)
Total deferred tax liabilities	(43)	(28)
Total net deferred taxes	\$ —	\$ —

As of March 31, 2020, the Company has net operating loss carryforwards in the following jurisdictions: Switzerland of approximately \$67.7 million, which will expire as of March 31, 2027, the United Kingdom of approximately \$1.2 million, which can be carried forward indefinitely with an annual usage limitation, and the United States of approximately \$1.9 million, which can be carried forward indefinitely with an annual usage limitation. The Company has research and development credit carryforwards in the United States in the amount of \$1.5 million which will begin to expire in the fiscal year ending March 31, 2039.

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 \$19.1 million for the year ended March 31, 2020, and \$8.9 million for the year ended March 31, 2019, representing the portion of the net deferred tax assets that is not more likely than not 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.

The Company intends that undistributed earnings of its foreign subsidiaries of approximately \$2.0 million are to be indefinitely reinvested. Should these earnings be distributed in the future in the form of dividends or otherwise, the Company may be subject to withholding taxes and income taxes. As of March 31, 2020, any unrecognized deferred tax liabilities, including any withholding taxes, on these undistributed earnings are expected to be immaterial and have not been recorded. 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 United States federal, state, and local jurisdictions. The Company's March 31, 2020 and 2019 tax returns remain open for tax examinations in all 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 combined and consolidated results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. There are no uncertain tax benefits recorded as of March 31, 2020 and 2019.

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Note 8 — Convertible Notes Payable

On August 1, 2019, the Company issued two convertible promissory notes for an aggregate principal amount of \$25.0 million (the “RTW Convertible Promissory Notes”) payable to the RTW Entities, investors of the Company. The RTW Convertible Promissory Notes accrued interest at 5% per annum and had a maturity date of March 31, 2020, the date upon which all unpaid interest and principal would have been due and payable. Prepayment of the RTW Convertible Promissory Notes prior to the maturity date was not permitted without the consent of the note holders of at least a majority of the outstanding principal amount of the convertible promissory notes issued by the Company. On September 26, 2019, such consent was obtained and \$2.5 million aggregate principal amount of the RTW Convertible Promissory Notes was prepaid and the accrued interest on such principal amount was forgiven, bringing the aggregate principal balance of the RTW Convertible Promissory Notes to \$22.5 million.

On September 26, 2019, the Company issued four convertible promissory notes for an aggregate principal amount of \$10.0 million (the “BVF Convertible Promissory Notes”) payable to entities affiliated with Biotechnology Value Fund, L.P. (“BVF”) under the same terms as the RTW Convertible Promissory Notes.

The RSL Convertible Promissory Note (see Note 5), RTW Convertible Promissory Notes and BVF Convertible Promissory Notes (together, the “Convertible Promissory Notes”) included various conversion and redemption rights upon merger, certain financing events, change in control or maturity.

Immediately prior to the closing of the Business Combination, the Convertible Promissory Notes were automatically converted into an aggregate of 7,156,495 ISL Shares, which were then exchanged for an aggregate of 3,499,995 shares of the Company’s common stock upon the closing of the Business Combination. Accrued interest of \$0.6 million on the Convertible Promissory Notes was waived and canceled immediately prior to the closing of the Business Combination in accordance with the terms of the Convertible Promissory Notes and was recorded within additional paid-in capital on the accompanying combined and consolidated statements of stockholders’ equity upon conversion of the underlying notes.

Note 9 — Stockholders’ Equity

Series A Preferred Stock

In connection with the closing of the Business Combination, the Company designated and issued 10,000 shares of Series A preferred stock, par value \$0.0001 per share, to RSL, all of which shares are outstanding as of March 31, 2020.

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.

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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 the holders of the Series A preferred stock and the common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of the Company's debts and other liabilities, subject to the rights of any blank check preferred stock then outstanding.

Preferred Stock

In connection with the closing of the Business Combination, the Company 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 designated Series A preferred stock, there were no issued and outstanding shares of preferred stock as of March 31, 2020.

Common Stock

In connection with the closing of the Business Combination, 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.

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

	March 31,	
	2020	2019
Conversion of Series A preferred stock	10,000	—
Options outstanding	3,873,888	189,269
Options available for future option grants	5,283,520	3,478,728
Common stock warrants	5,750,000	—
Earnout shares	20,000,000	—
Total	34,917,408	3,667,997

Common Stock Warrants

In May 2019, the Sponsor purchased from HSAC an aggregate of 10,000,000 warrants (the "private warrants") at \$0.50 per private warrant (for a total purchase price of \$5.0 million), with each warrant exercisable for one-half share of common stock at an exercise price of \$11.50 per share simultaneously with the closing of HSAC's IPO in May 2019. Pursuant to the Share Exchange Agreement, all of the private warrants were canceled upon the closing of the Business Combination. The Company did not recognize any expense on the cancellation of the private warrants.

As of March 31, 2020, 11,500,000 warrants were outstanding for the purchase one-half of one share of common stock (an aggregate of 5,750,000 shares) at a price of \$11.50 per whole share, subject to adjustment. The warrants were issued by HSAC as part of the units sold in its IPO in May 2019 and are classified in equity. The warrants are exercisable commencing on May 14, 2020 and expire in December 2024 or earlier upon redemption or liquidation. The warrants are redeemable, at the Company's option, in whole and not in part, at a price of \$0.01 per warrant, upon a minimum of 30 days' prior written notice of redemption, and if, and only if, the last sale price of the Company's common stock equals or exceeds \$16.50 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which the Company sends a notice of redemption to the warrant holders. The warrant holders have 30 days to exercise the warrants upon receipt of notice of redemption. See Note 3 – Business Combination and Recapitalization for a description of the Company's Earnout Shares and Sponsor Restricted Shares, and related impact on Stockholders' Equity.

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From May 14, 2020 through June 15, 2020, 11,438,290 warrants were exercised for an aggregate of 5,719,145 shares of the Company's common stock at a price of \$11.50 per share, for net proceeds of approximately \$65.8 million. See Note 12 – Subsequent Events for details related to redemption of warrants.

Note 10 — Stock-Based Compensation

2019 Equity Incentive Plan

In December 2019, in connection with the Business Combination, 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 2019 Plan became effective immediately upon the closing of the Business Combination. 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 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. Options that are forfeited, canceled or have expired are available for future grants. As of March 31, 2020, options to purchase 216,480 shares of common stock had been granted under the 2019 Plan and 5,283,520 shares remained available for future grant.

2018 Equity Incentive Plan

In September 2018, ISL adopted its 2018 Equity Incentive Plan (the "2018 Plan"), under which 3,667,997 shares of common stock were reserved for grant. In July 2019, the 2018 Plan was amended and restated to increase the number of shares of common stock reserved for grant to 4,768,396. As discussed in Note 3, upon the closing of the Business Combination, the Company assumed all outstanding options, whether or not vested, under the 2018 Plan, with such options henceforth representing the right to purchase a number of shares of the Company's common stock equal to approximately 0.48906624 multiplied by the number of shares of ISL common stock previously represented by such options. For accounting purposes, however, the Company is deemed to have assumed the 2018 Plan. The exchange of the stock options did not result in any incremental compensation expense, since there were no changes to the vesting terms of the awards. As of the effective date of the 2019 Plan, no further stock awards have been or will be made under 2018 Plan. As of March 31, 2020, 3,657,408 stock options were outstanding under the 2018 Plan.

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Stock Option Activity

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

	<u>Number of options</u>	<u>Weighted-average exercise price</u>	<u>Weighted average remaining contractual term (years)</u>	<u>Aggregate intrinsic value (in thousands)</u>
Balance – March 31, 2019	189,269	\$ 4.12	9.64	\$ 707
Granted	4,785,939	8.30		
Forfeited	(719,051)	7.23		
Canceled	(382,269)	7.86		
Balance – March 31, 2020	3,873,888	8.33	9.37	28,029
Exercisable – March 31, 2020	306,735	\$ 7.31	9.17	\$ 2,532

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, 2020. There were no options exercised during the year ended March 31, 2020. The options granted during the year ended March 31, 2020 and 2019 had a weighted-average fair value of \$5.54 and \$2.76 per share, respectively at the grant date.

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:

	<u>Years Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Risk-free interest rate	0.51% – 2.25%	2.38% – 2.97%
Expected term, in years	5.75 – 6.11	6.04 – 6.07
Expected volatility	74.69% – 77.93%	74.79% – 75.11%
Expected dividend yield	— %	— %

For the years ended March 31, 2020 and 2019, stock-based compensation expense under the Company's equity incentive plans was as follows (in thousands):

	<u>Years Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Research and development expenses	\$ 3,125	\$ 29
General and administrative expenses	3,663	2
Total stock-based compensation	\$ 6,788	\$ 31

At March 31, 2020, total unrecognized compensation expense related to non-vested stock option awards was \$17.3 million and is expected to be recognized over the remaining weighted-average service period of 3.1 years.

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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 RSL, RSI, RSG and the Company, stock-based compensation expense of \$0.2 million and \$1.3 million was recorded for years ended March 31, 2020 and 2019, respectively, in the accompanying combined and consolidated statements of operations.

The RSL common share awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. Significant judgment and estimates were used to estimate the fair value of these awards, as they are not publicly traded. RSL common share awards are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value of each RSL common share award is based on various corporate event-based considerations, including targets for RSL's post-IPO market capitalization and future financing events. The fair value of each RSL option on the date of grant is estimated using the Black-Scholes option-pricing model.

Stock-based compensation expense is allocated to the Company over the required service period over which these RSL common share awards and RSL options would vest and is based upon the relative percentage of time utilized by RSL, RSI, and RSG employees on Company matters.

Note 11 — Commitments and Contingencies

In March 2020, COVID-19 disease was declared a pandemic by the World Health Organization. The COVID-19 pandemic is disrupting supply chains and affecting production and sales across a range of industries. Currently, the Company has not suffered significant adverse consequences as a result of the COVID-19 pandemic, but the extent of the impact of COVID-19 on the Company's future operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on employees and vendors all of which are uncertain and cannot be predicted. At this point, the extent to which COVID-19 may impact the Company's future financial condition or results of operations is uncertain.

As of March 31, 2020, the Company did not have any ongoing material financial commitments. The Company expects to enter into other commitments as the business further develops. In the normal course of business, the Company enters into agreements with contract service providers to assist in the performance of its research and development activities. Subject to required notice periods and the Company's obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

Note 12 — Subsequent Events

The Company has evaluated subsequent events through June 29, 2020, the date these combined and consolidated financial statements were available to be issued.

In April 2020, the Company completed an underwritten public offering of 9,613,365 shares of its common stock (including 1,034,483 shares of common stock purchased by RSL and the full exercise of the underwriters' option to purchase 1,253,917 additional shares of common stock) at a price to the public of \$14.50 per share, for net proceeds to the Company of approximately \$131.0 million, after deducting underwriting discounts and commissions and estimated offering expenses.

In April 2020, the Company received \$2.9 million of the Swiss value-added tax receivable that is included in the combined and consolidated balance sheet as of March 31, 2020. In May 2020, the proceeds were used to repay the July Promissory Note which is payable to RSL in the amount of \$2.9 million.

On May 12, 2020, the Company achieved the first milestone earnout under the Share Exchange Agreement and, as a result, 10,000,000 shares of the Company's common stock were issued to former stockholders of ISL, (including 8,773,969 shares of common stock issued to RSL) pursuant to thereto. In addition, upon the satisfaction of this condition and pursuant to the Sponsor Restricted Stock Agreement, 900,000 shares of the Sponsor Restricted Shares vested and are no longer subject to forfeiture.

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On May 14, 2020, the Company's 11,500,000 outstanding warrants became exercisable for an aggregate of 5,750,000 shares of the Company's common stock at a price of \$11.50 per share. From May 14, 2020 through June 15, 2020, an aggregate of 11,438,290 outstanding warrants were exercised for an aggregate of 5,719,145 shares of the Company's common stock at a price of \$11.50 per share, for net proceeds of approximately \$65.8 million.

In June 2020, the Company entered into two sublease agreements with RSI, for the 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. The future operating lease payments under both sublease agreements is \$4.3 million over a lease period of approximately four years.

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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, or 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, 2020, 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, 2020 at the reasonable assurance level.

Management’s Report on Internal Controls over Financial Reporting.

This Annual Report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

Attestation Report of the Registered Public Accounting Firm.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for “emerging growth companies.”

Item 9B. Other Information

None.

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PART III

We intend to file a definitive proxy statement for our 2020 Annual General Meeting of Stockholders (“2020 Proxy Statement”) with the SEC, pursuant to Regulation 14A, not later than 120 days after March 31, 2020. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2020 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 2020 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.

Item 11. Executive Compensation

The information required by this item will be contained in our 2020 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 2020 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plans at March 31, 2020” 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 2020 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 2020 Proxy Statement under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” and is incorporated herein by reference.

Table of Contents**PART IV****Item 15. Exhibits, 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.				
10.1	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
10.2	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
10.3†	2019 Equity Incentive Plan of Immunovant, Inc.				
10.3.1†	Forms of Option Grant Notices and Option Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.				

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Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
10.3.2†	Forms of Restricted Stock Unit Grant Notices and Award Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.				
10.4†	2018 Equity Incentive Plan of Immunovant Sciences Ltd., and forms of award agreements thereunder.	8-K	001-38906	10.4	December 20, 2019
10.5†	Form of Indemnification Agreement.	8-K	001-38906	10.5	December 20, 2019
10.6^	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
10.7	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
10.8	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
10.9	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
10.10	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
10.11†	Employment Agreement with Peter Salzmann, dated as of May 30, 2019.	8-K	001-38906	10.11	December 20, 2019
10.12†	Employment Agreement with Pamela Connealy, dated as of October 22, 2019, as amended November 20, 2019.	8-K	001-38906	10.12	December 20, 2019
10.13†	Employment Agreement with Julia G. Butchko, dated as of October 9, 2019.	8-K	001-38906	10.13	December 20, 2019
10.14†	Employment Agreement with W. Bradford Middlekauff, dated as of April 15, 2019.	8-K	001-38906	10.14	December 20, 2019
10.15†	Employment Agreement with Robert K. Zeldin, dated as of July 8, 2019, as amended July 21, 2019.	8-K	001-38906	10.15	December 20, 2019
10.16†	Separation Agreement and General Release, dated April 7, 2020, by and between Robert K. Zeldin and Immunovant, Inc.	S-1/A	333-235975	10.16	April 8, 2020
16.1	Letter from WithumSmith+Brown, PC.	8-K	001-38906	16.1	December 20, 2019

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Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
21.1	List of Subsidiaries.	8-K	001-38906	21.1	December 20, 2019
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 on Form 10-K)				
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1#	Certification of Principal Executive Officer 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 Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

+ The annexes, schedules, and certain exhibits to the Share Exchange Agreement have been omitted pursuant to Item 601 of Regulation S-K. Immunovant, Inc. hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the Commission upon request.

† Indicates a management contract or compensatory plan, contract or arrangement.

^ Portions of this exhibit have been omitted as we have determined that the omitted information (i) is not material and (ii) would likely cause competitive harm to us if publicly disclosed.

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 on Form 10-K 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.

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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: June 29, 2020

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 Pamela Yanchik Connealy, 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.

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SIGNATURE	TITLE	DATE
/s/ Peter Salzmann Peter Salzmann, M.D.	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	June 29, 2020
/s/ Pamela Yanchik Connealy Pamela Yanchik Connealy	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	June 29, 2020
/s/ Frank M. Torti Frank M. Torti, M.D.	Chairperson of the Board of Directors	June 29, 2020
/s/ Andrew Fromkin Andrew Fromkin	Director	June 29, 2020
/s/ Douglas Hughes Douglas Hughes	Director	June 29, 2020
/s/ George Migausky George Migausky	Director	June 29, 2020
/s/ Atul Pande Atul Pande, M.D.	Director	June 29, 2020
/s/ Eric Venker Eric Venker, M.D., Pharm.D.	Director	June 29, 2020