Table of Contents

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, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38906

IMMUNOVANT, INC.
(Exact name of registrant as specified in its charter)

Delaware	**83-2771572**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1000 Park Forty Plaza Durham, NC **(Address of principal executive offices)**	**27713** **(Zip Code)**

Registrant's telephone number, including area code: (917) 410-3120

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**IMVT**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based on the closing price of the registrant's common stock on The Nasdaq Global Select Market as of September 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1,252.1 million, based on the closing price of the registrant's common stock on The Nasdaq Global Select Market of $16.12 per share.

As of May 14, 2026, the registrant had 205,308,917 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2026 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, 2026.

IMMUNOVANT, INC.
ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS 7
ITEM 1A. RISK FACTORS 49
ITEM 1B. UNRESOLVED STAFF COMMENTS 101
ITEM 1C. CYBERSECURITY 101
ITEM 2. PROPERTIES 102
ITEM 3. LEGAL PROCEEDINGS 102
ITEM 4. MINE SAFETY DISCLOSURES 102

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES 103
ITEM 6. [RESERVED] 104
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 105
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 116
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA 117
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 142
ITEM 9A. CONTROLS AND PROCEDURES 142
ITEM 9B. OTHER INFORMATION 144
ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS 144

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE 145
ITEM 11. EXECUTIVE COMPENSATION 145
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS 145
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE 145
ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES 145

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES 146
ITEM 16. FORM 10-K SUMMARY 148
SIGNATURES 149

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended March 31, 2026 (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "can," "continue," "could," "design," "estimate," "expect," "forecast," "goal," "hope," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will" and "would," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the timing, progress, costs and results of our clinical trials for our product candidates, including IMVT-1402 (also referred to as imeroprubart) and the costs related to the discontinuation of batoclimab, (formerly referred to as IMVT-1401);
- the potential return of certain rights for batoclimab to, and the outcome of negotiations with, HanAll Biopharma Co., Ltd. ("HanAll");
- potential therapeutic benefits and risks in current and future indications and the ability to achieve regulatory approval in licensed jurisdictions;
- future operating or financial results and cash position;
- future acquisitions, business strategy and expected capital spending;
- the timing of meetings with and feedback from regulatory authorities, including feedback on the registrational nature of our clinical studies, as well as any submission of filings for regulatory approval of our product candidates;
- the potential advantages and differentiated profile of our product candidates compared to existing therapies for the applicable indications, including potential benefits of IMVT-1402's product attributes and potential best-in-class profile;
- our ability to successfully manufacture, or have manufactured, drug product for clinical trials and commercialization;
- our ability to successfully commercialize our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- the effects of global factors, geopolitical tensions and adverse macroeconomic conditions, on our business, operations and supply chain, including the potential impact on our clinical trial plans and timelines, such as the enrollment, activation and initiation of additional clinical trial sites, and the results of our clinical trials;
- our expectations regarding the size of the patient populations, opportunity and clinical utility of our product candidates, 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 our product candidates;
- 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 our product candidates;
- our ability to identify, acquire or in-license and develop new product candidates;
- our ability to identify, recruit and retain key personnel;

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

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

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

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

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

We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. In addition, 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), filings we make with the Securities and Exchange Commission, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our stockholders and the public about our company, our product candidates, and other matters. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

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

Industry and Market Data

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

SUMMARY RISK FACTORS

You should consider carefully the risks described under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects includes the following:

- Our business is dependent on the successful and timely development, regulatory approval and commercialization of our product candidates.
- Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control and we may not be able to enroll patients in our trials on our anticipated timelines.
- The results of our preclinical studies and clinical trials may not support our proposed claims for our product candidates, or regulatory approval on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.
- Interim, "top-line" or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our product candidates may be associated with adverse events or cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, cause us to abandon further development or limit the commercial viability of any approved label or market acceptance.
- Roivant Sciences Ltd. ("RSL") owns a significant percentage of shares of our common stock and may exert significant control over matters subject to stockholder approval.
- Our business could be adversely affected by economic downturns, changes in inflation and interest rates, changes in international trade policies and tariffs, natural disasters, political crises, geopolitical events, such as the crises and conflicts in Ukraine and the Middle East, or other macroeconomic conditions, which may negatively impact our business and financial performance in the future.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We rely on third parties to conduct, supervise and monitor our clinical trials and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements or our quality management program fails to detect such events in a timely manner, it may harm our business.
- We do not have our own manufacturing capabilities and rely on third parties to produce clinical supplies and commercial supplies of our product candidates. The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production or our quality management program may fail to detect quality issues at our third-party manufacturers, which may delay or prevent our ability to obtain marketing approval or commercialize our product candidates if approved.
- We have a limited operating history and have never generated any product revenue.
- We will require additional capital to fund our operations. If we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.
- Raising additional funds by issuing equity securities will cause dilution to existing stockholders. Raising additional funds through debt financings may involve restrictive covenants and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.
- Our intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

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

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

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

- We and the third parties with whom we work are subject to stringent and changing privacy, data protection and information security laws, contractual obligations, self-regulatory schemes, government regulation, industry standards and other obligations related to data privacy and security. The actual or perceived failure by us or the third parties with whom we work to comply with such obligations could result in harm to our reputation, regulatory investigations or actions, significant fines and liability, disruption of our clinical trials or other material adverse effects on our business.

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

PART I

Item 1. Business

Overview

Immunovant, Inc. ("Immunovant," "we" or the "Company") is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. Our focus is on developing IMVT-1402 (imeroprubart), a potentially best-in-class inhibitor of the neonatal fragment crystallizable receptor ("FcRn"), to address autoimmune diseases driven by high levels of pathogenic immunoglobulin G ("IgG") antibodies. FcRn is involved in preventing the degradation of IgG antibodies, and inhibition of FcRn has been shown to reduce levels of total IgG and pathogenic IgG antibodies.

We believe that FcRn inhibition has broad therapeutic and commercial potential to address pathogenic IgG-mediated autoimmune diseases in several therapeutic areas, including but not limited to, endocrinology, neurology, rheumatology and dermatology. Third-party estimates suggest over four million patients in the United States and Europe could benefit from anti-FcRn treatments across more than 20 indications that have been publicly announced for research and development by multiple companies, with two indications that are already approved and launched quickly reaching multi-billions of dollars in global annual sales.

Consistent evidence observed across the class in eight indications in Phase 2 and 3 trials with FcRn inhibitors has indicated that deeper IgG reductions correlate with meaningful improvements in clinical outcomes. This has also been validated with Immunovant's own Phase 2 and 3 studies evaluating its first-generation anti-FcRn antibody, batoclimab, in Graves' disease ("GD"), myasthenia gravis ("MG") and chronic inflammatory demyelinating polyneuropathy ("CIDP") which showed that IgG reductions of greater than or equal to 70% led to meaningfully better outcomes compared to reductions below 70% across a range of clinical measures.

In a Phase 1 clinical trial, healthy adults dosed with IMVT-1402 showed deep, dose-dependent IgG reductions. We expect to be able to reach approximately 80% IgG reductions with continued weekly dosing of 600 mg of IMVT-1402, offering deeper IgG reductions than observed with other competitor anti-FcRn programs, therefore representing a potential best-in-class opportunity. In the Phase 1 clinical trial, across all evaluated doses, IMVT-1402 demonstrated no or minimal reductions in albumin and no or minimal increases in LDL cholesterol levels, which are off-target effects observed in some anti-FcRn antibodies, including batoclimab. We believe IMVT-1402's profile has the potential to offer best-in-class efficacy, in addition to its potentially favorable safety profile and convenient administration with a simple self-administered auto-injector expected at launch.

We are currently progressing a broad set of programs for IMVT-1402 and have ongoing studies in six indications, including potentially registrational trials in GD, difficult-to-treat rheumatoid arthritis ("D2T RA"), MG, CIDP and Sjögren's disease ("SjD"), and a proof-of-concept trial in cutaneous lupus erythematosus ("CLE"). Our primary focus is to execute these six indications first, with plans to assess new indications for IMVT-1402 in the future. All studies evaluating IMVT-1402 are being conducted using the intended commercial drug formulation and delivery device, the YpsoMate® autoinjector developed by Ypsomed AG, which is utilized for multiple approved products.

IMVT-1402 and batoclimab are fully human monoclonal antibodies that target FcRn. These antibodies are the result of a multi-step, multi-year research program conducted in collaboration with HanAll to design highly potent anti-FcRn antibodies that may be optimized as a simple, subcutaneous injection with dosing that has been shown to deliver better efficacy at the high dose and similar efficacy at the low dose compared to standard FcRn inhibition by competitors.

In April 2026, we announced top-line results from two Phase 3 clinical studies evaluating batoclimab as an investigational treatment for adults with active, moderate-to-severe thyroid eye disease ("TED"), neither of which met the primary endpoint. The safety profile observed in these studies was consistent with prior batoclimab studies, with no new safety signals identified. Following these results, we made a decision to discontinue further development of batoclimab across all indications to focus fully on IMVT-1402. Learnings from the batoclimab program, including clinical data, operational trial experience, and relationships with investigators, have been and continue to be leveraged to inform the development of IMVT-1402.

Business Strategy

We are pursuing a broad anti-FcRn strategy based on the potential best-in-class profile of IMVT-1402 for the treatment of IgG-mediated autoimmune diseases. To execute our strategy, we plan to:

- *Prioritize areas of significant unmet medical need where IMVT-1402 could potentially be first- and best-in-class.* We plan to expand the use of FcRn inhibitors in indications that benefit a greater number of patients with several potential first- and best-in-class indications such as GD, D2T RA and CLE with significant unmet medical need. We believe the probability of technical success for IMVT-1402 is strong, given its potential to achieve best-in-class IgG reductions, along with the batoclimab proof-of-concept data we have generated in GD, the IMVT-1402 case study data presented in CLE, and a competitor's data in RA.

- *Maximize the commercial potential of IMVT-1402 with a clear, differentiated and potentially best-in-class profile in established markets.* We plan to leverage the potential best-in-class profile of IMVT-1402 in indications where the anti-FcRn mechanism already has established a commercial presence, such as MG and CIDP. Data generated by batoclimab in these indications support our hypothesis that IMVT-1402 could potentially offer best-in-class efficacy at the high dose with the convenience of a well-established self-administered autoinjector and a potentially favorable safety profile.

- *Focus on rapid clinical execution as a key priority.* We plan to focus on clinical execution to maintain our head start in the indications identified above and to be nearly-first and potentially best-in-class for indications such as SjD where we can launch in close proximity to in-class competition and expect a differentiated clinical profile. Data generated by a competitor in SjD supports our belief that IMVT-1402 could potentially offer best-in-class efficacy at the high dose due to best-in-class IgG reductions with the convenience of a well-established self-administered autoinjector and potentially favorable safety profile.

- *Evaluate potential additional indications.* We intend to thoroughly evaluate potential additional indications based on the degree of unmet medical need, the potential benefit offered by anti-FcRn treatment, the target patient population size and the commercial potential.

Our Pipeline and Anticipated Milestones

Our research and development programs are organized and managed by therapeutic area and our clinical trials address specific target indications within these areas. The following is our current development pipeline and anticipated milestones for IMVT-1402:

Indication	Study	Data Catalyst	2H 2026	2027	2028
ACPA+ D2T RA	Potentially Registrational	Further Updates	■		
CLE	POC	Top Line Results	■		
GD	Potentially Registrational	Top Line Results		■	
MG	Potentially Registrational	Top Line Results		▢	
SjD	Potentially Registrational	Top Line Results			■
CIDP	Potentially Registrational	Top Line Results			▢

■ Rheumatology ■ Dermatology ■ Endocrinology ▢ Neurology

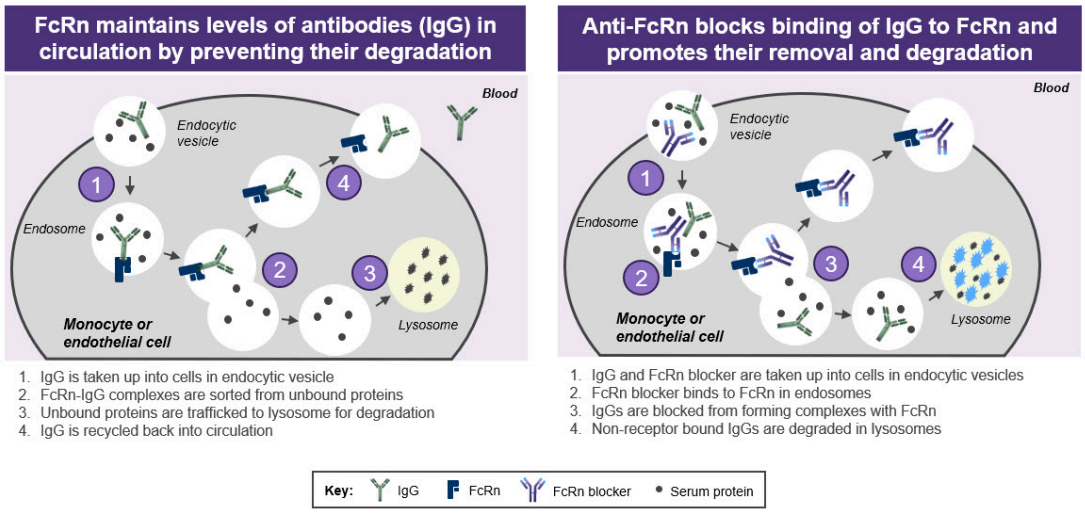
The regulatory path for IMVT-1402, including whether any ongoing or future clinical trials may be considered registrational or registration-enabling, depends on future alignment with FDA on clinical trial design, selection of endpoints, statistical analysis plans, and overall development strategy
Note: GD: Graves' disease; ACPA+: Anti-citrullinated peptide antibody positive; D2T RA: difficult-to-treat rheumatoid arthritis; CLE: Cutaneous lupus erythematosus; MG: Myasthenia gravis; SjD: Sjogren's disease; CIDP: Chronic inflammatory demyelinating polyneuropathy
All references are to calendar years and are approximate and subject to change

The Role of FcRn in Autoimmune Disease

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

IgG antibodies are continuously being removed from circulation and internalized in cellular organelles called endosomes. FcRn is the primary protein responsible for preventing the degradation of IgG antibodies. 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.

Inhibition of FcRn, such as through the use of an anti-FcRn antibody, has been shown to reduce levels of pathogenic IgG antibodies. Anti-FcRn antibodies, including our product candidates, bind to FcRn thereby blocking IgG antibodies from forming complexes with FcRn under the more acidic conditions of the endosome. As a result, unbound IgG antibodies are degraded in the lysosome rather than being transported by FcRn for release back into circulation. This anti-FcRn mechanism of action is depicted in the graphic below.



Limitations of Current Treatment Options in Autoimmune Disease

Treatment for IgG-driven autoimmune diseases varies widely, however many patients are commonly treated using intravenous or subcutaneous immunoglobulins ("IVIg," "SCIg"), corticosteroids, plasma exchange ("PLEX") and immunomodulatory therapies. Despite the availability of the therapies, there remains significant unmet medical need. For example, although immunoglobulin therapy (IVIg, SCIg) is effective, it may be associated with significant side effects and complications such as severe headache, thromboembolism and hemolysis. Additionally, IVIg therapy imposes a burden on patients' time and at-home administration options remain limited. IVIg supply constraints have occurred, and IVIg is also not available in all markets. SCIg therapy often requires frequent administration at multiple infusion sites using an external pump to deliver the requisite volume of therapy, which presents challenges to patients requiring therapy on a continuous basis.

Corticosteroid therapy, though effective, has well-known serious adverse effects (e.g., weight gain, hypertension, diabetes and osteoporosis), especially with chronic use. PLEX requires central venous access and is not universally available. Immunomodulatory therapies are all associated with significant potential risks, including the possibility of malignancy and infection. For example, these include azathioprine – cytopenia; cyclosporine – hypertension, nephrotoxicity; mycophenolate – blood dyscrasias including neutropenia and red blood cell ("RBC") aplasia; rituximab – renal toxicity; and cyclophosphamide – cardiac, pulmonary and renal toxicity as well as bone marrow suppression and infertility. The currently available treatments are associated with significant potential risk of adverse effects, generally impose a high burden on patient's time and effort and may be subject to restricted availability. There remains a high unmet need for safe and effective targeted therapies for patients suffering from autoantibody-driven disease.

Product Candidate - IMVT-1402

IMVT-1402 is a fully human monoclonal antibody that inhibits FcRn with a potentially best-in-class profile, offering potentially best-in-class efficacy, a favorable route of administration and a potentially favorable safety profile.

IMVT-1402 has been assigned the nonproprietary name imeroprubart on the World Health Organization's Recommended International Nonproprietary Names List 93, which has also been approved by the U.S. Adopted Names Council.

In September and November of 2023, we announced results from a Phase 1 clinical trial in healthy adults in New Zealand. In the study's 300 mg multiple-ascending dose ("MAD") cohort, a statistically significant reduction of 63% from baseline in mean total IgG levels was observed after four weekly 300 mg subcutaneous doses of IMVT-1402. In the 600 mg MAD cohort, we observed a statistically significant reduction of 74% from baseline in mean total IgG levels after four weekly 600 mg subcutaneous doses of IMVT-1402. No or minimal reductions in albumin and no or minimal increases in LDL cholesterol levels were observed in healthy adults administered IMVT-1402 in either dose cohort; the changes in albumin and LDL cholesterol were similar to those observed with placebo administration. Across all doses evaluated, treatment with IMVT-1402 was generally well tolerated, with only mild or moderate treatment-emergent adverse events observed.

Based on trial results announced to date across the anti-FcRn class and the strength of its potential best-in-class profile, we are pursuing development of IMVT-1402 in endocrinology, neurology, rheumatology, dermatology and possibly other therapeutic areas, with a focus on indications representing first-in-class opportunities, or opportunities where we can leverage our own batoclimab or existing in-class clinical data to build confidence in a best-in-class profile. We are currently progressing a broad set of programs for IMVT-1402 and have ongoing studies in six indications, including potentially registrational trials in GD, D2T RA, MG, CIDP and SjD, and a proof-of-concept trial in CLE.

Our Therapeutic Areas

Endocrine Diseases

Graves' Disease

GD Overview

GD is an autoimmune disease that affects the thyroid gland. Patients with GD develop IgG autoantibodies that bind to the thyroid-stimulating hormone receptor ("TSHR") present on the thyroid gland, which induces increased and uncontrolled secretion of thyroid hormones, resulting in hyperthyroidism. GD is the most common cause of hyperthyroidism and occurs at all ages but especially in adults aged between 20 and 50 years and can impact women of reproductive age. Because thyroid hormones play an important role in controlling functions of many organs such as heart, central and peripheral nervous system, muscle, bone, and skin, the presence of excessive thyroid hormones is associated with a variety of signs and symptoms including enlarged thyroid gland (goiter), palpitations, arrhythmia, anxiety, weight loss, insomnia, osteoporosis, and pretibial myxedema.

The treatment of GD has seen minimal innovation in therapeutic options over the past 70-plus years. Antithyroid drugs ("ATDs"), as the only existing pharmacological therapy, do not address the underlying disease pathology characterized by high levels of stimulating TSHR antibodies ("TRAb"). A conservative analysis of Inovalon claims data estimates that the prevalence of Graves' patients is approximately 880,000 in the U.S., and further analysis suggests that there are approximately 330,000 patients who have relapsed on ATDs and who have opted not to pursue ablation. Other market-sizing analyses by various methods suggest that 25-30% of Graves' patients are relapsed, uncontrolled on or intolerant to ATDs, representing a potentially significant unmet medical need.

Current Treatment Paradigm

The main treatment goal of GD is to reduce thyroid hormone levels. There are 3 options currently available: surgery, radioiodine ("RAI"), and ATDs. The most commonly prescribed ATDs in the U.S. are the thionamides, methimazole and propylthiouracil. An internal chart review of over 1,000 patient records from over 140 endocrinologists and a patient survey of 100 patients indicate that approximately 25-30% of GD patients remain uncontrolled on ATDs. A recent study showed that Graves' patients with persistent stimulating TRAb levels had a 6-fold increased risk for relapse after ATD withdrawal. Collectively, these data suggest that a treatment for GD targeting the reduction or elimination of circulating stimulating TRAb would address the underlying autoimmune pathogenesis of the disease and would restore normal thyroid function.

Surgery, which involves partial or entire removal of the thyroid gland (thyroidectomy) is an option, especially for patients with large goiters, women planning pregnancy and, in some cases, patients who have failed to respond to ATDs. Although any such surgical procedure may lead to an immediate resolution of the hyperthyroidism, it is associated with potential complications including parathyroid gland injury, which may lead to hypocalcemia, and damage of the laryngeal nerve. Treatment with RAI destroys the thyroid using ionizing radiation. It is considered an alternative to medical management in several countries, especially if ATDs are contraindicated or among patients who do not respond to this drug class. Since RAI can worsen TED, it is not recommended in patients with TED or in smokers who are at higher risk of developing TED, and in women who are pregnant or lactating. Finally, recent data suggest an association between RAI and increased risk for several types of cancer. In addition, RAI is associated with sustained increases in TRAb titers, risk for de novo TED and worsening of pre-existing TED. Both thyroidectomy and RAI may result in hypothyroidism, requiring lifelong treatment with thyroid hormone replacement. Given these risks, the treatment paradigm for GD continues to shift away from RAI and thyroidectomy, resulting in an increasing number of patients who are not controlled on ATDs but who are choosing not to undergo ablation. Rates of surgery and RAI have declined significantly in the U.S. in recent years, to about 11% of patients in 2021, according to an analysis of claims data, from more than half of patients in 2005.

Proof-of-Concept Trial with Batoclimab

We initially tested the potential of FcRn inhibition for the treatment of GD in a Phase 2 proof-of-concept trial (NCT05907668) evaluating our first-generation FcRn inhibitor, batoclimab.

The study included a 24-week batoclimab treatment period with a dose step-down midway through the treatment period (Weeks 0-12 at 680 mg weekly ("QW") subcutaneously ("SC") and Weeks 13-24 at 340 mg QW SC), followed by a 24-week off-treatment follow-up period. The study enrolled participants with active GD as documented by presence of elevated TRAb and who were hyperthyroid despite current treatment with standard of care ATD therapy. The primary endpoint of the study measured response as the proportion of participants who at Week 24 achieved normalization of free triiodothyronine ("T3") and free thyroxine ("T4"), or have T3/T4 below the lower limit of normal ("LLN"), without an increase in ATD dose from baseline. A total of 25 subjects were enrolled in the treatment period, and 21 subjects entered the 24-week off-treatment follow-up period and could be assessed for maintenance of response. In data previously disclosed in September 2024 that was reanalyzed to include an additional patient who discontinued prior to Week 12 but remained in off-drug follow-up, at the end of the first 12 weeks, a mean IgG reduction of 77% and an 80% response rate (defined as T3 and T4 falling below the upper limit of normal ("ULN") without increasing the ATD dose) were observed. 60% of subjects treated with higher dose batoclimab were observed to have an ATD-Free Response (defined as T3 and T4 falling below the ULN and the patient simultaneously tapering completely off their ATD) at the end of the first 12 weeks. During weeks 13 to 24, patients receiving lower dose batoclimab were observed to have mean IgG reduction of 65% with a correspondingly lower responder rate of 72% and a lower ATD-Free Response rate of 40% at the end of the second 12 weeks. Patients who were observed to have at least a 70% IgG reduction at the end of the evaluation period had nearly a threefold higher ATD-Free Response rate than those who did not (64% vs. 23%).

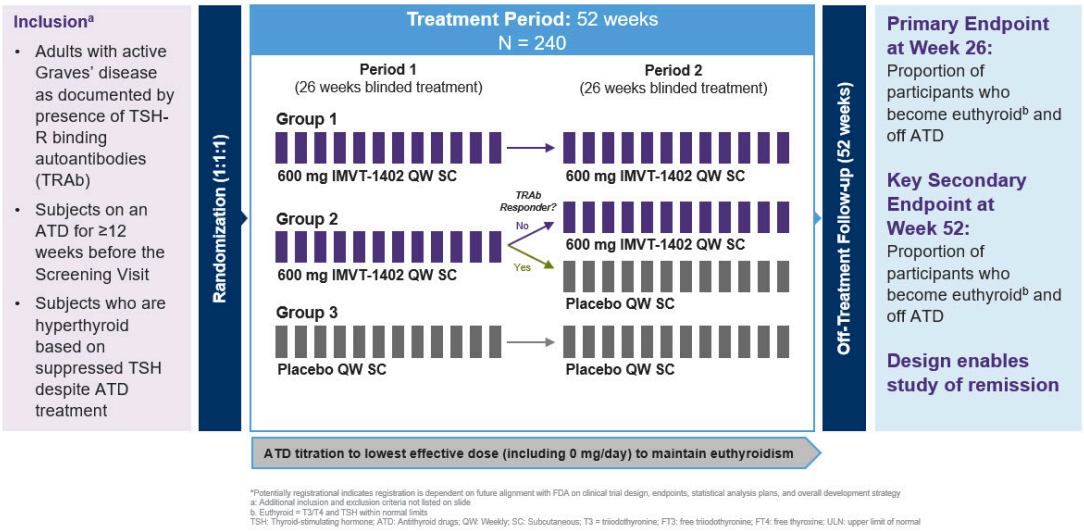
Six-month off-treatment data was presented at the American Thyroid Association Annual Meeting in September 2025. At completion of the follow-up period at Week 48 (i.e., subjects off-treatment for 24 weeks), approximately 80% (17/21) of those subjects maintained T3/T4 values ≤ ULN, suggestive of strong durability of the response observed at Week 24 as evaluated at approximately six months off treatment at Week 48. Of these 17 subjects, approximately 50% (8/17) were ATD-free and an additional approximately 30% (5/17) were on ATD doses of 2.5 mg/day at six months off batoclimab treatment. Total IgG and TRAb levels declined through Week 24, consistent with previous observations, and while total IgG rebounded after treatment ended, pathogenic TRAb levels remained suppressed at Week 48. Safety and tolerability were observed to be consistent with prior batoclimab studies.

This study is now completed, with its data suggesting the potential of FcRn inhibition for the treatment of GD by modifying the underlying disease pathology, which is driven by TRAb. As such, GD is a key strategic priority for our development of IMVT-1402.

IMVT-1402 Development Program in GD

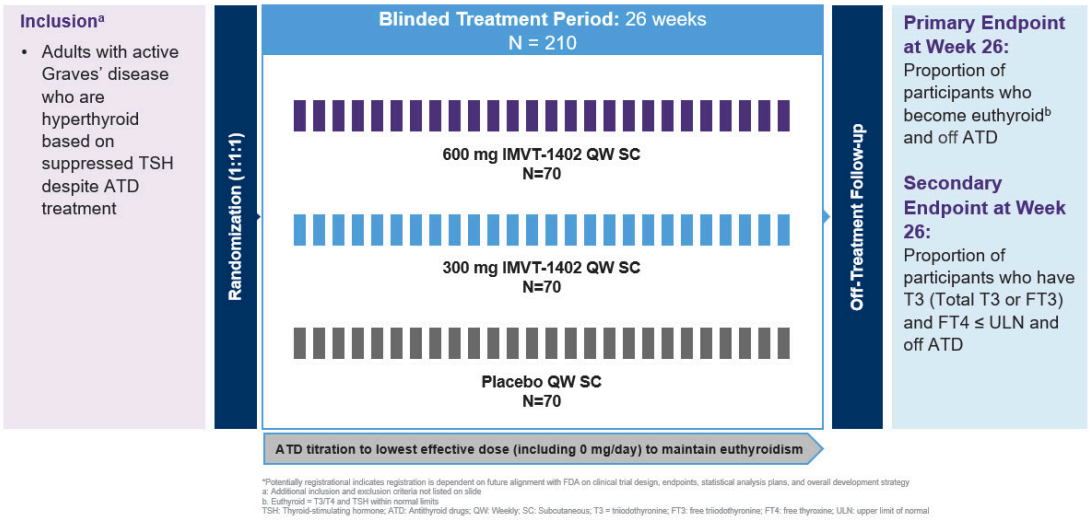
In December 2024, we initiated a potentially registrational trial evaluating IMVT-1402 in adults with GD. This study (NCT06727604) is a randomized, placebo-controlled, 52-week trial in Graves' patients who are hyperthyroid despite treatment with an ATD for 12 or more weeks prior to beginning the study. The study is expected to enroll approximately 240 participants randomized (1:1:1) to one of two blinded treatment groups each receiving IMVT-1402, 600 mg weekly SC, or a matched placebo group. Participants will be evaluated over two consecutive 26-week blinded treatment periods. Over the course of the treatment periods, background ATD treatment will be titrated to the lowest effective dose, including elimination of ATD treatment, to maintain normal thyroid lab values. Following the initial 26-week period, participants in the IMVT-1402 treatment group 2 will be assigned to either continued treatment with IMVT-1402 at the same dose or matching placebo for the second 26-week study period based on the participant's TRAb value and euthyroid status determined at week 26. The study's primary endpoint is the proportion of participants who are euthyroid and off ATD at study week 26. A key secondary endpoint will measure the proportion of participants who become euthyroid and stop ATD treatment at week 52. We expect to report top-line results from this trial in calendar year 2027.

More details on the trial design are described in the figure below:



In June 2025, we initiated a second potentially registrational trial evaluating IMVT-1402 in adults with GD. This study (NCT07018323) is a randomized, placebo-controlled, 26-week trial in Graves' patients who are hyperthyroid despite treatment with an ATD for 12 or more weeks prior to beginning the study. The study is expected to enroll approximately 210 participants randomized (1:1:1) to one of three blinded treatment groups receiving IMVT-1402 600 mg weekly SC, IMVT-1402 300 mg weekly SC, or matched placebo group. Over the course of the treatment periods, background ATD treatment will be titrated to the lowest effective dose, including elimination of ATD treatment, to maintain normal thyroid lab values. The study's primary endpoint is the proportion of participants in the 600 mg weekly SC dose group who are euthyroid and are off ATD versus placebo at study week 26. A key secondary endpoint will measure the proportion of participants in the 600 mg weekly SC dose group who have T3 (Total T3 or FT3) and FT4 ≤ULN and are off ATD versus placebo. We expect to report top-line results from this trial in calendar year 2027.

More details on the trial design are described in the figure below:



Rheumatology Diseases

Rheumatoid Arthritis

RA Overview

RA is a chronic progressive autoimmune disease that causes inflammation in the joints and surrounding tissues. Inadequate control of the joint inflammation associated with RA may result in irreversible joint erosions. The estimated prevalence of patients treated with biologic or targeted synthetic disease modifying anti-rheumatic drugs ("DMARDs") in the U.S. is approximately 820,000, approximately 15% of which had an inadequate response to two or more such prior advanced DMARD mechanisms. The RA described in this subset of patients is sometimes referred to as difficult-to-treat ("D2T"), refractory, or multi-advanced mechanism failure RA. Of those, approximately 70% are autoantibody positive, representing approximately 85,000 patients with significant unmet medical need in the U.S. Several autoantibodies have been identified in RA, including rheumatoid factor ("RF") and anti-citrullinated protein antibodies ("ACPA"). These RA-specific autoantibodies are found in 70-80% of RA patients and exacerbate inflammation via immune complex formation. Positivity for RF and ACPA seems to have an amplifying effect on disease, resulting in an aggressive phenotype with more severe disease manifestations. Seropositive RA is also associated with poor outcomes on currently available therapies.

Current Treatment Paradigm

Therapeutic approaches for RA are intended to help control joint inflammation, damage and other associated disease manifestations. Currently available treatments include a variety of conventional oral, targeted synthetic and biologic DMARD treatments. These therapies primarily function by modulating the immune response and limiting the activity of pro-inflammatory cytokines such as tumor necrosis factor-alpha ("TNF-α"), interleukin-6 ("IL-6"), and others impacting the pathogenesis of RA. While many patients experience symptom relief and disease control with these agents, D2T RA patients continue to experience active disease despite undergoing multiple lines of therapy with different mechanisms of action. For these patients, therapeutic options remain very limited while the risk of irreversible joint damage persists, highlighting a critical unmet medical need. The European Alliance of Associations for Rheumatology (EULAR) has defined this RA subset in the clinical setting as D2T RA and provided points to consider in its management. Nevertheless, innovative strategies and novel therapeutic targets are needed to improve outcomes and quality of life for this patient population.

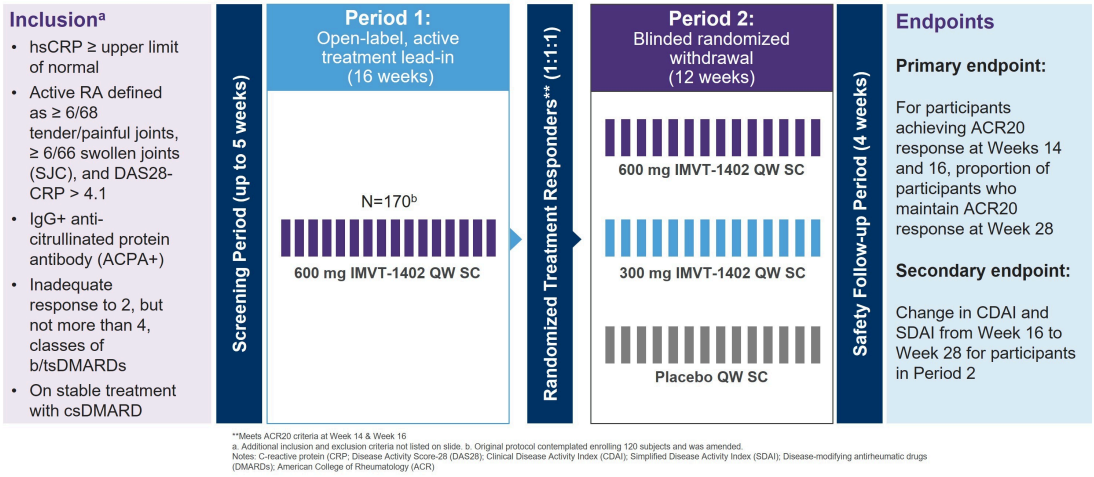
Anti-FcRn as a Potential Treatment for D2T RA

Because of the role of FcRn in preventing the degradation of IgG autoantibodies, such as ACPAs, FcRn inhibition is an attractive mechanism as a potential treatment for ACPA-positive RA. Recent industry experience with anti-FcRn therapies has informed our approach to evaluating RA. Johnson & Johnson's IRIS-RA Phase 2a placebo-controlled, proof-of-concept trial evaluating nipocalimab in patients with RA and inadequate response or intolerance to anti-TNF therapy demonstrated that deeper ACPA IgG reduction correlated with improved rates of clinical response. We are focused on the subset of RA patients with ACPA-positive D2T RA, who have failed two or more prior advanced mechanism therapies, inclusive of biologics (TNFα inhibitors, IL-6R inhibitors, CD80/86 inhibitors, CD20 inhibitors) and targeted synthetic DMARDs (e.g., Janus kinase ("JAK") inhibitors). For patients failing two or more prior advanced mechanisms in addition to conventional DMARDs, IMVT-1402 would be the fourth line or later line of therapy.

IMVT-1402 as a Potential Treatment for D2T RA

In December 2024, we initiated a potentially registrational trial evaluating IMVT-1402 in ACPA-positive D2T RA. This trial (NCT06754462) is fully enrolled, and all participants have completed an initial 16-week open-label, active treatment period (Period 1). To ensure the enrollment of patients with active D2T RA, the trial inclusion criteria require elevated ACPA levels, on stable conventional DMARD treatment, and prior inadequate response to at least two (but not more than four) classes of advanced mechanisms (biologics or targeted synthetic DMARDs). The study will evaluate IMVT-1402 600 mg weekly SC during the open-label induction phase of the trial with the intent of maximizing reduction in ACPA levels. Participants achieving a response at weeks 14 and 16 in Period 1 per the American College of Rheumatology response criteria 20 ("ACR20") will be randomized in a 1:1:1 ratio to receive blinded treatment in Period 2 with either IMVT-1402 600 mg, IMVT-1402 300 mg or placebo, weekly SC for 12 weeks. The primary endpoint will assess the proportion of such participants who maintain the ACR20 response at week 28. Eligible participants who complete week 28 will have the option to receive IMVT-1402 for an additional period of 48 weeks as part of a long-term extension period.

More details on the study design are described in the figure below:



**Meets ACR20 criteria at Week 14 & Week 16
a. Additional inclusion and exclusion criteria not listed on slide. b. Original protocol contemplated enrolling 120 subjects and was amended.
Notes: C-reactive protein (CRP; Disease Activity Score-28 (DAS28); Clinical Disease Activity Index (CDAI); Simplified Disease Activity Index (SDAI); Disease-modifying antirheumatic drugs (DMARDs); American College of Rheumatology (ACR)

The trial is currently ongoing and has enrolled a total of 170 participants in Period 1. At the completion of Period 1, 165 of the 170 enrolled patients were evaluable for ACR20 response to determine eligibility to continue to Period 2 and the primary efficacy analysis for the study. The enrollment inclusion criteria described above resulted in a heavily pretreated population: 86.7% (143/165) had failed two prior mechanisms of advanced therapies (i.e., biologic or targeted synthetic DMARDs), and the mean time from disease diagnosis was 12.8 years. Baseline disease activity was high, with a mean of 24.2 tender joints, 16.7 swollen joints, and DAS28-CRP score of 6.1.

At Week 16, the ACR20, ACR50, and ACR70 response rates observed were 72.7%, 54.5%, and 35.8%, respectively; participants who discontinued prior to Week 16 were imputed as non-responders. Among the subset of participants who had failed at least a JAK inhibitor and an anti-TNF inhibitor (N=107), the ACR20, ACR50, and ACR70 response rates observed at Week 16 were 72.0%, 53.3%, and 37.4%, respectively. ACR20 response is defined as a ≥ 20% improvement from baseline in tender joint count and swollen joint count and a ≥ 20% improvement from baseline in at least 3 of 5 additional clinical parameters. Similarly, ACR50 and ACR70 responses are a calculation of 50% or 70% improvement, respectively, in the number of swollen and tender joints and 3 of 5 assessment parameters.

Period 1 was conducted in an open-label setting, with joint assessments performed by independent assessors blinded to treatment status to control for the potential for assessor bias in the response measures. IMVT-1402 was observed to be safe and well-tolerated in Period 1, and no new drug-related safety signals were identified. Study participants meeting the criteria for an ACR20 response at Week 16 are eligible to advance to Period 2 of the trial, where the primary endpoint will be assessed at Week 28. Further updates on this program are expected in the second half of calendar year 2026.

Sjögren's Disease

SjD Overview

Sjögren's disease, formerly referred to as Sjögren's syndrome, is a chronic autoimmune disease characterized by lymphocytic infiltration of the salivary and lacrimal glands. It is classically associated with severe dryness of the eyes and mouth; the latter frequently associated with difficulty swallowing or speaking, tooth decay, gum disease and impaired quality of life. Up to 50% of affected individuals also develop extra-glandular manifestations that can impact a variety of organ systems such as the joints, skin, lungs, gastrointestinal tract, nervous system, or kidneys.

SjD may occur in isolation (primary SjD) or in association with another systemic autoimmune disease such as rheumatoid arthritis (secondary SjD). It can be challenging to diagnose SjD based on symptoms alone due to the heterogeneity at presentation. However, serological testing including autoantibodies can help inform diagnosis. Autoantibodies including anti-Ro/SSA and anti-La/SSB have been detected in approximately 50-70% of patients with primary SjD and play crucial roles in both the diagnosis and prognosis of the disease.

The estimated prevalence of primary SjD is approximately 290,000 in the U.S. It is estimated that up to 30% of primary SjD patients have moderate-to-severe disease with anti-Ro/SSA antibodies, representing approximately 90,000 SjD patients with significant unmet medical need in the U.S.

Current Treatment Paradigm

No therapies have been approved specifically for the treatment of SjD. Therapeutic approaches for SjD disease include local agents such as pilocarpine hydrochloride and cevimeline hydrochloride for oral and ocular dryness as well as systemic treatments such as hydroxychloroquine, methotrexate, mycophenolate sodium, azathioprine, and cyclosporine to address organ manifestations. This results in frequent visits with healthcare professionals and a high burden of treatment for Sjögren's patients, suggesting a need for the development of novel treatments that target the underlying pathophysiological mechanism of this disease.

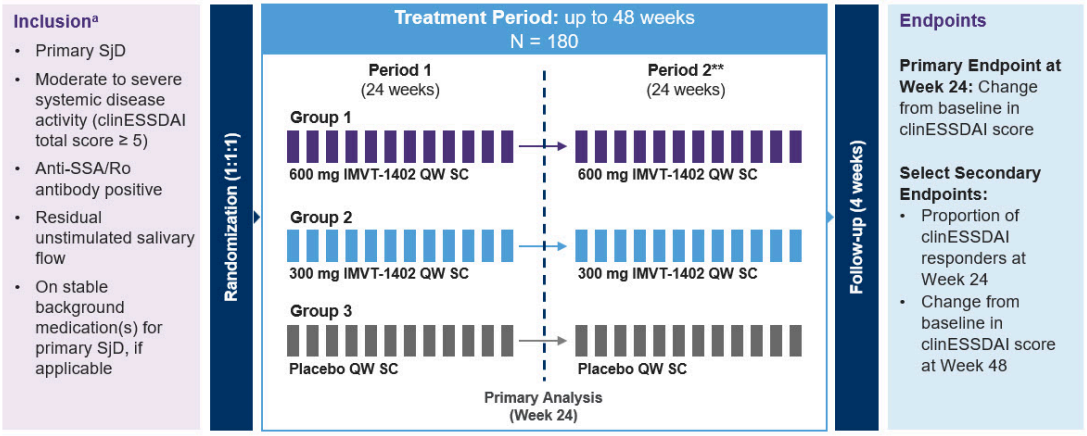
Anti-FcRn as a Potential Treatment for SjD

Recent in-class data from a Phase 2 placebo-controlled, multicenter trial evaluating nipocalimab in patients with SjD provides support for anti-FcRn proof of mechanism. The study met its primary endpoint, with statistically significant improvement in Clinical European League Against Rheumatism Sjögren's Syndrome Disease Activity Index ("ClinESSDAI") score, a key SjD activity index, in the high dose nipocalimab group compared to placebo. A clear dose response in ClinESSDAI observed in the trial supports the potential correlation between degree of IgG suppression and improved clinical outcomes.

IMVT-1402 as a Potential Treatment for SjD

In June 2025, we initiated a potentially registrational trial evaluating IMVT-1402 in SjD. This trial (NCT06979531) is a randomized, double-blind, placebo controlled, parallel-group study to assess the efficacy, safety, and tolerability of IMVT-1402 in adult participants with moderate to severe systemic primary SjD. The trial is anticipated to enroll approximately 180 participants randomized in a 1:1:1 ratio to receive IMVT-1402 600 mg, IMVT-1402 300 mg or placebo weekly SC for two 24-week blinded treatment periods. The primary endpoint will assess the efficacy of IMVT-1402 compared to placebo as assessed by ClinESSDAI score at week 24. Participants assessed as responders at week 24, defined as participants that show an improvement of ≥ 4 points from baseline ClinESSDAI score, will continue on treatment for a second 24-week period. A key secondary endpoint will assess change from baseline in ClinESSDAI score at week 48. We expect to report top-line results from this trial in calendar year 2028.

More details on the trial design are described in the figure below:



*Potentially registrational indicates registration is dependent on future alignment with FDA on clinical trial design, endpoints, statistical analysis plans, and overall development strategy
**Only ClinESSDAI responders (improvement of ≥ 4 points from baseline) continue through period 2
a. Additional inclusion and exclusion criteria not listed on slide
QW: Weekly; SC: Subcutaneous; ClinESSDAI: clinical European League Against Rheumatism Sjögren's Syndrome Disease Activity Index

Dermatology Diseases

Cutaneous Lupus Erythematosus

CLE Overview

CLE is a rare, chronic skin disease characterized by skin-specific disease activity, inflammation and eventually damage. Triggered by sun exposure, CLE manifests as a recognizable rash and painful skin lesions, often with related symptoms such as itching, burning and alopecia. Subacute Cutaneous LE ("SCLE") and Chronic Cutaneous LE ("CCLE") are subtypes of CLE with distinct skin presentation and clinical course and high unmet medical need. The estimated prevalence of SCLE and CCLE is approximately 153,000 in the U.S. Approximately 50% of these SCLE and CCLE patients do not adequately respond to first-line therapies representing approximately 75,000 patients with potential significant unmet medical need in the U.S. IgG autoantibodies and immune complexes are observed to play a critical role in CLE disease pathophysiology.

Current Treatment Paradigm

First-line therapies are photoprotection, topical steroids and broad-spectrum therapies (i.e. DMARDs, antimalarials and corticosteroids) followed by IVIg or off-label biologics. It is estimated that approximately 50% of patients are not optimally managed with or without topical steroids due to insufficient response, relapse, or risk of retinopathy following first-line antimalarials.

IMVT-1402 as a Potential Treatment for CLE

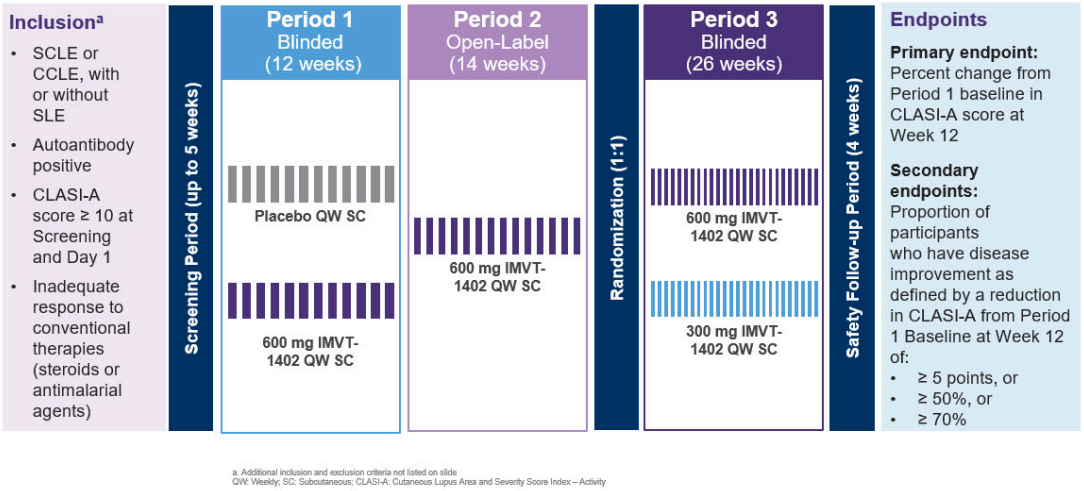
There is growing biologic and translational evidence supporting the role of IgG autoantibodies and immune complexes in the pathogenesis of CLE. Furthermore, published case studies using IVIg offer strong mechanistic evidence for the role of IgG autoantibodies in driving disease. Blocking FcRn may disrupt CLE pathology by providing upstream inhibition of the inflammatory cascade triggered in cells by pathogenic antibodies and immune complexes.

In addition, in April 2025, we presented observations from a proof-of-principle case study evaluating IMVT-1402 in a SCLE patient over a period of 12 weeks. The participant in the case study, a 57-year-old female, had alopecia and skin manifestations in multiple locations with a baseline Cutaneous Lupus Erythematosus Disease area and Severity Index activity ("CLASI-A") score at screening of 36, which falls into the severe range on the clinical scale. The participant received open-label weekly treatment with 600 mg of IMVT-1402 for 12 weeks and saw significant clinical improvement in both skin lesions and alopecia. By week 12, the participant had a greater than 60% reduction in CLASI-A score to 13. A 5-point reduction in CLASI-A is considered clinically meaningful and this participant improved by 23 points by week 12. The participant also achieved approximately 78% total IgG reduction from baseline by week 12. A second patient dosed in this study also showed significant clinical improvement, with a CLASI-A score of 18 at screening reduced to 8 by week 12 of QW dosing, a > 50% improvement. We believe the initial data from this case study may provide important support for the mechanism and for the potential of IMVT-1402 as a first- and best-in-class anti-FcRn therapy in CLE.

IMVT-1402 Proof-of-Concept Trial in CLE

In February 2025, we initiated a proof-of-concept trial of IMVT-1402 in CLE. This Phase 2b trial (NCT06980805) is a randomized, double-blind, placebo-controlled trial to assess the safety, tolerability and efficacy of IMVT-1402 in participants with active SCLE and/or CCLE with or without systemic manifestations. This trial is fully enrolled, with participants randomized 1:1 to IMVT-1402 600 mg QW SC or placebo QW SC for 12 weeks during Period 1. Participants who complete Period 1 will enter Period 2, during which all participants will receive IMVT-1402 600 mg QW SC for 14 weeks. After completion of Period 2, participants will be rerandomized 1:1 to blinded IMVT-1402 300 mg or 600 mg SC QW for 26 weeks in Period 3. The primary endpoint will evaluate the efficacy of IMVT-1402 compared to placebo based on percent change from Period 1 baseline in CLASI-A score at week 12. We expect to report top-line results from this trial in the second half of calendar year 2026.

More details on the trial design are described in the figure below:



a. Additional inclusion and exclusion criteria not listed on slide
QW: Weekly; SC: Subcutaneous; CLASI-A: Cutaneous Lupus Area and Severity Score Index – Activity

Neurological Diseases

Myasthenia Gravis

MG 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 ocular muscles, or which can be more generalized throughout the body including muscles of respiration.

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. Approximately 15% to 20% of MG patients will experience at least one myasthenic crisis during which the impairment of muscles required to breathe can become life-threatening.

The prevalence of MG is estimated to be approximately 59,000 to 116,000 cases in the U.S. with 35% of patients not well-controlled on the current standard of care, representing approximately 20,000 to 35,000 patients with significant unmet medical need in the U.S. The majority of these patients demonstrate elevated serum levels of acetylcholine receptor (“AChR”) antibodies.

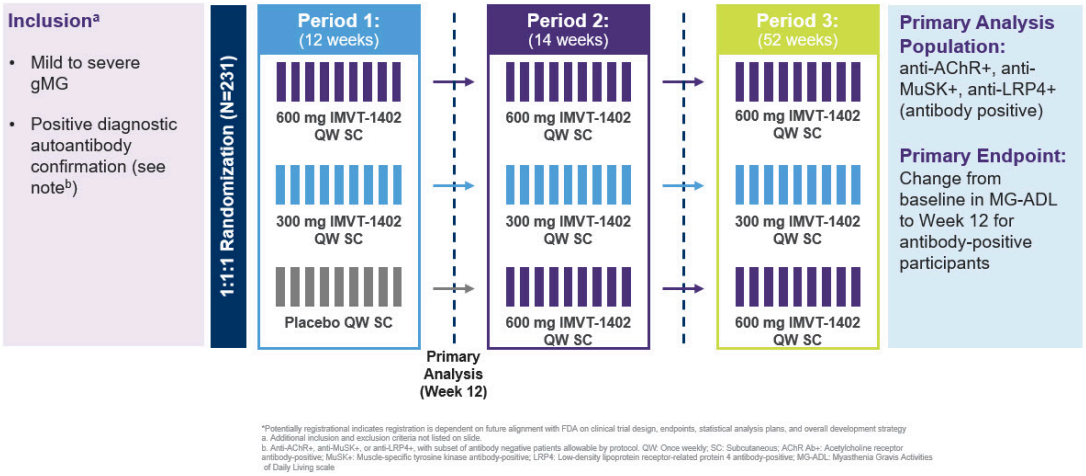
Current Treatment Paradigm

Very early-stage MG is symptomatically treated with acetylcholinesterase inhibitors. 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 certain patients. As MG becomes more advanced, patients can be treated during exacerbations with IVIg, which provides therapeutic benefit through multiple potential mechanisms including the saturation of FcRn. Physicians direct patients with more advanced chronic disease and patients in times of crisis to therapies that reduce levels of circulating IgG antibodies via PLEX or a variant of PLEX, immunoadsorption. More recent novel mechanism of action therapies include FcRn inhibitors, which generally reduced IgG by 60-70% in their Phase 3 trials at approved doses, and complement inhibitors.

IMVT-1402 as a Potential Treatment for MG

In March 2025, we initiated a potentially registrational trial evaluating IMVT-1402 in adults with MG. This Phase 3 trial (NCT07039916) is a randomized, placebo-controlled, 26-week trial. This study is expected to enroll approximately 230 participants randomized (1:1:1) to one of three blinded treatment groups receiving IMVT-1402 600 mg weekly SC, IMVT-1402 300 mg weekly SC, or matched placebo group for the 12-week induction period. Participants on treatment will continue to be on the same treatment for the 14-week maintenance period, while patients on placebo will receive IMVT-1402 600 mg weekly SC. The study also includes a 52-week long-term extension. The study’s primary endpoint is the change in MG-ADL from baseline at week 12. We expect to report top-line results from this trial in calendar year 2027.

More details on the trial design are described in the figure below:



Chronic Inflammatory Demyelinating Polyneuropathy

CIDP Overview

CIDP is believed to be an immune-mediated neuropathy characterized by demyelination of peripheral nerves and nerve roots that is driven by pathologic, autoreactive IgG antibodies. The estimated prevalence of CIDP is approximately 58,000 patients in the U.S., with approximately 30% inadequately controlled on treatment, representing approximately 16,000 patients with significant unmet medical need in the U.S.

CIDP typically presents with progressive or relapsing, symmetric involvement of both proximal and distal extremity muscle weakness over the course of several weeks. While the pathophysiology of CIDP is not completely understood, passive serum transfer animal models and the response of CIDP patients to intravenous immunoglobulin, plasma exchange and FcRn blockade suggests that autoantibodies are involved in its pathogenesis. Autoantibody-induced degeneration and demyelination would be expected to cause characteristic electrophysiologic alterations of the peripheral nerves and is clinically manifested by the sensorimotor deficits of CIDP.

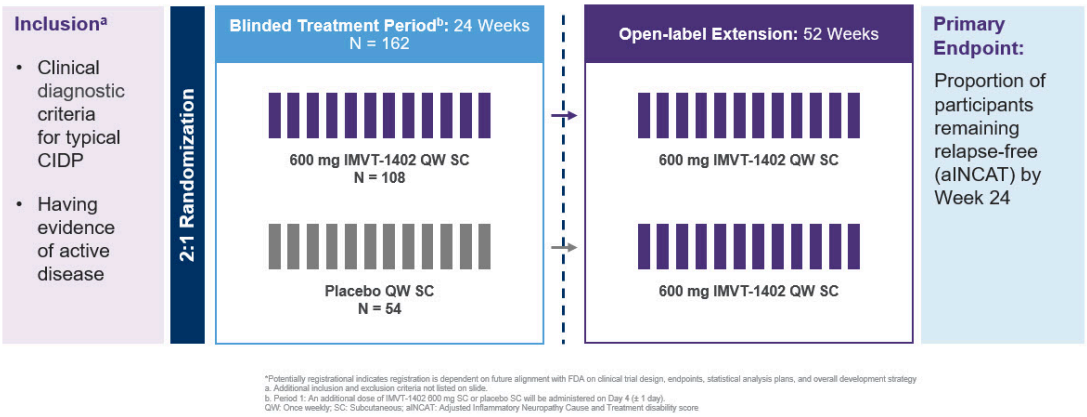
Current Treatment Paradigm

IVIg, corticosteroids and PLEX are first-line therapies in the treatment of CIDP. For patients who fail to achieve objective improvement (i.e., of impairment and disability) after three months of treatment with a first-line agent, another agent may be tried. Alternative options include rituximab, cyclophosphamide or cyclosporine, despite limited evidence supporting their use. Once objective improvement is achieved, the patient may be switched to maintenance treatment, the goal of which is to reduce the dose or frequency of treatment while still controlling disease. For maintenance therapy, patients may be switched from IVIg to SCIg, and immunomodulatory agents such as azathioprine, cyclosporine or mycophenolate may be used for IVIg dose-reducing, corticosteroid-sparing or PLEX frequency-reducing effect. For long term management of clinically stable patients, therapy should be periodically reduced or stopped to assess if treatment is still required. An anti-FcRn inhibitor has also been approved for the treatment of CIDP; however, we believe there is still meaningful room to improve on efficacy.

IMVT-1402 as a Potential Treatment for CIDP

In March 2025, we initiated a potentially registrational trial evaluating IMVT-1402 in adults with CIDP. This trial (NCT07032662) is a randomized, placebo-controlled, 24-week trial in CIDP patients, followed by a 52-week open label extension. The study is expected to enroll approximately 162 participants randomized (2:1) to one either receiving IMVT-1402 600 mg weekly SC, or matched placebo for the 24-week treatment period. The study's primary endpoint will evaluate the proportion of participants remaining relapse free at week 24, where relapse is defined as worsening on the adjusted inflammatory neuropathy cause and treatment (aINCAT) score at any time point relative to baseline. We expect to report top-line results from this trial in calendar year 2028.

More details on the trial design are described in the figure below:



Key Agreements

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, Roivant Sciences GmbH ("RSG"), a wholly owned subsidiary of Roivant Sciences Ltd ("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 (a) develop, import and use (i) the antibody referred to as batoclimab, (ii) certain back-up and next-generation antibodies (including IMVT-1402) and (iii) products containing such antibodies, and (b) to commercialize such products, in the U.S., Canada, Mexico, the EU, the UK, 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 U.S. and EU; (2) an affiliate of RSG in any country in the Licensed Territory; and (3) a third party in the U.S. and EU only after submission of a biologics license application ("BLA") in the U.S. or a Marketing Authorization Application in the EU. Pursuant to the HanAll Agreement, RSG granted to HanAll an exclusive, royalty-free license under certain RSG patents, know-how and other intellectual property controlled by RSG relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the Licensed Territory. HanAll also reserves the right to conduct discovery or research activities with the batoclimab antibody and certain back-up and next-generation antibodies (including IMVT-1402), with or through a contract research organization or service provider in the Licensed Territory.

In December 2018, we obtained and assumed all of the rights, title, interest and future obligations under the HanAll Agreement from RSG, including all rights to IMVT-1402 and batoclimab 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. In January 2026, we completed an internal reorganization and transfer of intellectual property rights related to our product candidates between two wholly-owned subsidiaries of the Company. Ownership and rights to such intellectual property remain with us and our subsidiaries.

Pursuant to the HanAll Agreement, we will be responsible for future contingent payments and royalties, including up to an aggregate of $420.0 million upon the achievement of certain regulatory and sales milestone events. We are also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens percentage of net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of: (A) the date on which the last valid claim of the licensed patents expires; (B) the date on which the data or market exclusivity expires; and (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 to the HanAll Agreement 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 insolvency events. HanAll may terminate the HanAll Agreement if we or our affiliates challenge the validity or enforceability of any of the licensed patents. We have commenced discussions with HanAll regarding the future disposition of batoclimab, including the potential return to HanAll of certain rights for batoclimab. In April 2026, we notified HanAll of our decision to indefinitely delay further development of batoclimab and focus our resources fully on IMVT-1402. Under the HanAll Agreement, we retain final decision-making authority over development and regulatory matters for licensed products in our Licensed Territory, and we believe we have satisfied our obligations under the HanAll Agreement, including with respect to batoclimab. HanAll may disagree with our interpretation of the agreement or our actions thereunder, and we may be unable to reach an agreement with HanAll regarding the future of batoclimab. This could result in a dispute with HanAll involving arbitration or litigation.

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. Consistent with its model, Roivant has provided us with operational assistance, as well as 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 our employees to participate in Roivant's career development program which facilitates employee mobility across members of the Roivant family of companies;
- benefit from shared learnings best practices, and external industry relationships across the Roivant family of companies; and

- derive certain benefits of scale upon becoming a commercial-stage company.

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

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

Sales and Marketing

We do not currently have our own sales or distribution capabilities and our marketing capabilities are limited. In order to commercialize IMVT-1402, or any other product candidate, if approved for commercial sale, we would have to develop additional infrastructure to support global product sales and marketing activities. We intend to build a small, targeted specialty sales organization in the U.S., targeting specialist physicians that treat high numbers of patients with autoimmune conditions. We believe these physicians treat a majority of patients with the autoimmune indications for which we intend to seek regulatory approval 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-1402, or any other product candidates inside and outside the U.S.

Manufacturing

We do not currently own or operate manufacturing facilities for the manufacturing, testing, storage and distribution of clinical or commercial quantities of our product candidates, which include drug-device combination products that we are developing. We currently rely and intend to continue to rely on contract manufacturing organizations ("CMOs") for drug substance, drug product and delivery devices, as well as labeling, packaging and distribution, and we do not have plans to develop our own manufacturing operations in the foreseeable future.

Currently, we contract with well-established third-party manufacturers for the manufacture of our drug substance and our drug product. With respect to IMVT-1402, we have established arrangements with CMOs to supply drug substance and drug product to support our current and planned clinical trial programs, as well as anticipated commercial supply to support the potential launch of IMVT-1402, if approved.

As our clinical needs and commercial plans continue to evolve, we may engage additional third-party manufacturers to support clinical trials for our product candidates as well as commercialization of our product candidates, if approved. In addition, we have personnel with substantial technical and product development experience who actively manage the CMOs producing our product candidates and plan to use such personnel to manage CMOs for any 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 current good manufacturing practice ("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. We are aware of several FcRn inhibitors that are in clinical development. These include efgartigimod (Argenx SE), nipocalimab (Johnson & Johnson) and rozanolixizumab (UCB). In 2023, the FDA approved VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of generalized myasthenia gravis ("gMG") in adults who test positive for the AChR antibody. Previously, the FDA approved VYVGART (efgartigimod alfa-fcab) in the same patient population in 2021. In 2023, the FDA also approved RYSTIGGO® (rozanolixizumab-noli) for the treatment of gMG in adult patients who are AChR or anti-muscle-specific tyrosine kinase antibody positive. In 2024, the FDA expanded the label for VYVGART Hytrulo to include the treatment of CIDP. In 2025, the FDA approved the VYVGART Hytrulo prefilled syringe for the treatment of adult patients with AChR antibody positive gMG and adult patients with CIDP. In 2025, IMAAVY® (nipocalimab-aahu), an anti-FcRn monoclonal antibody, was approved by the FDA for the treatment of MG in adult and pediatric patients aged 12 and older who are anti-AChR and anti-MuSK antibody positive. Viridian Therapeutics is developing a portfolio of engineered FcRn inhibitors, including VRDN-006 and VRDN-008, both of which are currently in Phase 1 development, and have the potential to treat a broad array of autoimmune diseases.

Our product candidates, if approved, may also face competition from agents with different mechanisms of action. 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. SOLIRIS® (eculizumab), marketed by AstraZeneca, is an antibody inhibitor of the C5 protein approved in 2017 for the treatment of MG in patients who are positive for anti-AChR antibodies. Other C5 complement inhibitors approved in gMG include ULTOMIRIS® (ravulizumab-cwvz), which was approved in April 2022, and ZILBRYSQ® (zilucoplan), approved in October 2023. In December 2025, Amgen announced FDA approval of UPLIZNA® (inebilizumab), a CD19-targeted humanized monoclonal antibody, for the treatment of AChR-positive gMG.

For CIDP, our product candidates may also face competition from agents in Phase 3 with different mechanisms of action including C1 inhibitors riliprubart (Sanofi), DNTH103 (Dianthus) and C2 inhibitor empasiprubart (Argenx SE).

For Graves' disease, we are aware of multiple agents with different mechanisms of action that are in early-stage development including TSH antagonists being developed by Crinetics Pharmaceuticals and Lycia Therapeutics (LCA-0321) and currently in IND-enabling studies, Biohaven's IgG degrader (BHV-1300) in a Phase 1 study, Merida Biosciences' FC biotherapeutic targeting TSHR (MER511) in a Phase 1 study, Yarrow Bioscience's anti-TSHR antibody (YB-101) entering a Phase 1b/2b trial, and Sanofi's BTK inhibitor (rilzabrutinib) in a Phase 2 study. In January 2026, Viridian announced pre-clinical development of an anti-TRAb, half-life extended monoclonal antibody candidate with potential use in the treatment of Graves' disease and TED, which is intended to be delivered by subcutaneous administration via autoinjector. In March 2026, Argenx SE announced a registrational clinical trial in Graves' disease is expected to initiate in 2026.

For RA, which is the most common systemic autoimmune disease, treatment options include a variety of conventional oral, targeted synthetic and biologic DMARDs. However, for the subset of patients characterized by inadequate response to two or more biologic or targeted DMARDs, no proven treatment options are available.

For CLE, a dermatology focused therapeutic category with no treatment innovation for more than 50 years, treatment options include prevention of exposure to sunlight with the utilization of both topical and systemic therapies such as antimalarials, immunomodulators and immunosuppressives (methotrexate, mycophenolate). With the significant unmet need and increasing demand for biologic therapies in dermatology and rheumatology, the competitive landscape for SCLE and CCLE is a growing market for novel therapies and diagnostic tools in early and late-stage development. Biogen announced positive data in March 2026 from the Phase 2 portion of its Phase 2/3 study evaluating litifilimab (a humanized IgG1 monoclonal antibody targeting blood dendritic cell antigen 2 (BDCA2)). AstraZeneca is conducting a Phase 3 study of its type I interferon receptor inhibitor, anifrolumab. Merck also has entered Phase 3 evaluations of enpatoran, its oral, selective small-molecule inhibitor of Toll-like receptors 7 and 8.

For SjD, therapeutic approaches include a variety of local agents to address the associated dry eye and mouth and/or immunosuppressive treatments to address the systemic manifestations of disease. Although a variety of drug classes have been trialed to-date, there are no disease-modifying therapies approved for the treatment of SjD. Anti-FcRns nipocalimab and efgartigimod are currently in Phase 3 trials in SjD. IMVT-1402 may also face competition from other drug classes, including inhibitors of TYK2 (deucravacitinib), CD40 (dazodalibep), BAFF (ianalumab) or BLyS/APRIL (telitacicept).

Drug development is highly competitive and subject to rapid and significant technological advancements. For example, Argenx SE is developing its next generation FcRn inhibitors, ARGX-213, which is in a registrational study for an undisclosed indication, as well as ARGX-124, which is in early clinical development. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. In December 2025, VYNE Therapeutics Inc. and Yarrow Bioscience, Inc. entered into a definitive merger agreement, following completion of which, the combined company plans to focus on advancing YB-101, a clinical stage TSHR antibody for the treatment of GD and TED. In March 2026, Biogen agreed to acquire Apellis Pharmaceuticals for $5.6 billion, expanding its immunology and rare disease portfolio. 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.

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

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for IMVT-1402, batoclimab, and any of our future product candidates, their use in the planned indications, 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, and continue 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 a risk that competitors may make an alteration to any products we develop or processes we use which may provide sufficient basis for the competitor to avoid infringing our patent claims. In addition, patents, if granted, will expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates.

Following our assumption of all rights, title, interest and obligations under the HanAll Agreement from RSG in December 2018, by virtue of the license of patent rights under the HanAll Agreement, ISG became the exclusive licensee of certain patents, patent applications and know-how directed to batoclimab, IMVT-1402, and certain back-up and next-generation antibodies, and products containing such antibodies, in the Licensed Territory. In January 2026, the Company completed an internal reorganization and transfer of intellectual property rights related to the Company's product candidates between two wholly-owned subsidiaries of the Company. As of January 14, 2026, IMVT Corporation ("IMVT Corp") assumed control of all IP rights directed to batoclimab, IMVT-1402, and certain back-up and next-generation antibodies, and products containing such antibodies, in the Licensed Territory. As of March 31, 2026, the in-licensed patent portfolio includes a patent family covering batoclimab with pending patent applications and/or issued patent(s) in the U.S., Argentina, Brazil, Canada, European Patent Office, Israel, Mexico and Saudi Arabia. This in-licensed patent family was filed in 2015 and discloses anti-FcRn antibodies, including batoclimab, pharmaceutical compositions thereof, methods of treating autoimmune disease using the same, polynucleotides encoding such antibodies, expression vectors including such polynucleotides, host cells transfected with such recombinant expression vectors, methods of manufacturing such antibodies and methods of detecting FcRn in vivo or in vitro using such antibodies. Notably, in this in-licensed patent family, a U.S. patent was issued on July 2, 2019, with claims directed to batoclimab as defined by its CDRs and epitope or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof. Furthermore, another U.S. patent was issued in this in-licensed patent family on January 28, 2020, with claims directed to batoclimab as defined by its CDRs or antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of producing such antibody or antigen-binding fragment. A further patent was issued in the U.S. on March 28, 2023 with claims to two isolated anti-FcRn antibodies other than batoclimab or an antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of preparing such antibody or antigen-binding fragment. A European patent in this family was issued on May 10, 2023 with claims directed to batoclimab as defined by its heavy and light chain variable sequences. There are also issued patents in this family in Brazil, Canada, Israel, Mexico and Saudi Arabia. In this family, applications are pending in Argentina, Mexico, the U.S. and in Europe. The patents of this patent family may expire in 2035, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

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

Additionally, as of March 31, 2026, independent of the licensed patent portfolio, IMVT Corp owns a patent family directed to methods of treating thyroid eye disease (a.k.a., Graves' ophthalmopathy) using anti-FcRn antibodies that include pending patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Chile, Europe, Israel, and Mexico. Any patent issued from this patent family may expire in 2039, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Further, IMVT Corp owns a patent family directed to and methods of treating warm autoimmune hemolytic anemia using anti-FcRn antibodies that include pending patent applications in the U.S. and in European Patent Office. Any patent issued from this patent family may expire in 2040, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp jointly owns rights with HanAll to a patent family covering IMVT-1402 and its uses to treat autoimmune disease, which includes patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Chile, Colombia, Egypt, European Patent Office, Israel, Mexico, Panama, Peru and Saudi Arabia. Notably, in this patent family, a U.S. patent was issued on March 12, 2024, with claims directed to IMVT-1402 as defined by its CDRs, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, methods of treating an autoimmune disease using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of preparing such antibody or antigen-binding fragment. The patents of this patent family may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns patent families directed to methods of treating Graves' disease (GD) and methods of treating CIDP using anti-FcRn antibodies including IMVT-1402 and batoclimab, which include pending patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Chile, Columbia, Egypt, Europe, Israel, Mexico, and Saudi Arabia. Any patent issued from these patent families may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns a patent family directed to high concentration protein formulations with polysorbate excipients and methods of making the same which include pending patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Europe, and Mexico. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns a Patent Cooperation Treaty ("PCT") application directed to methods of improving anti-FcRn therapies, which describes specific dosing regimens for IMVT-1402. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns PCT application and a corresponding Argentine application directed to formulations for anti-FcRn antibodies. Any patent issued from this patent family may expire in 2045, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns a PCT application and a corresponding Argentine provisional application directed to methods of treating skin diseases using anti-FcRn antibodies including IMVT-1402 and batoclimab. Any patent issued from this patent family may expire in 2046, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

IMVT Corp also owns a U.S. provisional application directed to methods of inducing remission in GD patients using anti-FcRn antibodies including IMVT-1402 and batoclimab. Any patent issued from this patent family may expire in 2046, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date (or the PCT filing date if such U.S. application is a national phase application), 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. Additionally, 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.

IMVT Corp owns a registered trademark for IMMUNOVANT and the combination of its logo Y-shaped antibody and IMMUNOVANT in the United States and many other jurisdictions throughout the world for goods and services. As of March 31, 2026, this trademark portfolio includes pending trademark applications and/or registered trademarks in the U.S. and/or foreign jurisdictions. Under the HanAll Agreement, we have the right to market IMVT-1402 and batoclimab in the Licensed Territory under the trademarks of our choice, subject to regulatory approval. However, upon termination of the HanAll Agreement, we must assign to HanAll all rights, title and interest in and to any and all trademarks we use in the development, manufacture or commercialization of the licensed products.

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

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

Government Regulation

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

FDA Drug Approval Process

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

- completion of preclinical laboratory tests and animal studies performed in accordance with applicable regulations and guidance, including the FDA's current Good Laboratory Practices ("GLP") regulations, International Council for Harmonisation ("ICH") guidance and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated at least annually or when significant changes are made;
- approval by an institutional review board ("IRB") or positive ethics committee opinion for each clinical site before the trial is commenced;
- conduct of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP and other clinical-trial related regulations and guidance to evaluate the safety, purity and potency of the proposed biologic product candidate for each proposed indication;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials that includes manufacturing information and substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;

- potential FDA audit of selected clinical investigation sites, preclinical studies and/or Immunovant as clinical trial sponsor to assess compliance with FDA's GCP standards;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies);
- agreement with FDA on the final labeling for the product and the design and implementation of any required Risk Evaluation and Mitigation Strategy ("REMS"); and
- FDA review and approval, or licensure, of the BLA, including satisfactory completion of an FDA Advisory Committee review, if applicable, to permit commercial marketing or sale of the product for particular indications for use in the U.S.

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

European Union Drug Approval Process

Changes to EU's General Pharmaceutical Law

The EU's pharmaceutical legislation is currently changing. In December 2025, the EU legislators reached an agreement on the proposed new rules. Key changes will include:

- one year reduction in base-line regulatory data exclusivity;
- re-coup option of lost data exclusivity product with strict conditions;
- launch and supply obligations based on "best efforts" with non-compliance resulting in loss of protections at Member State level;
- expansion of the Bolar exemption to health technology assessments, pricing, and reimbursement submissions;
- reduction in the "standard" orphan market exclusivity period;
- transferable data exclusivity voucher for priority antimicrobials;
- shortened EMA review timelines and other procedural reforms.

The new legislation will enter into application 24 months after final publication in the Official Journal of the European Union, which is currently expected in Q4 2026. Other proposed EU acts, such as the Critical Medicines Act and the Biotech Act, may bring additional changes.

Approvals

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

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

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

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

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

The above-described timelines will be reduced with the newly adopted revised EU pharmaceutical legislation, including reduced assessment time (210 to 180 days) and a Commission Implementing Decision must be completed within 46 days, down from the previous 67-day timeframe.

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

The above-described rules will change with the newly adopted revised EU pharmaceutical legislation. In particular, marketing authorizations will now be valid indefinitely, eliminating the requirement for five-year renewals.

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

The above-described regulatory exclusivity rules will change with the newly adopted revised EU pharmaceutical legislation, introducing amongst other a one year base-line reduction of market exclusivity which can be "recouped" under certain circumstances. Specifically, companies can secure additional one-year extensions if their product addresses an unmet medical need, or contains a new active substance meeting certain requirements. The cumulative duration of these market exclusivity periods may not exceed two years. Market protection can also be extended once by a further year if, during the data protection period, the product is granted authorization for one or more new therapeutic indications demonstrating significant clinical benefit compared to existing therapies.

Drug-Device Combinations

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

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

Brexit and the Regulatory Framework in the United Kingdom

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency ("MHRA") is now the UK's standalone regulator for medicinal products and medical devices. The United Kingdom is now a third country to the EU.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation and such changes were laid in parliament on December 12, 2024. On April 10, 2025, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024 came into law. A 12-month implementation period will apply before the amended regulations come fully into force on April 10, 2026. The main changes are to implement a risk-proportionate approach where low-risk trials can receive faster approval through automatic authorization, the establishment of a combined review process to integrate ethics committee and regulatory approvals into a single approval, and the implementation of enhanced transparency requirements to mandate the registration of clinical trials in a public registry and the publication of trial results within 12 months of trial completion.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope authorizations of the EU in relation to centrally authorized medicinal products until January 31, 2025. However, on January 31, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products, as marketing authorizations valid in Great Britain became valid in the United Kingdom. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The MHRA has also introduced changes to national marketing authorization procedures. This includes the introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedure. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP") when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the UK.

The MHRA offers new assessment procedures for marketing authorization applications for medicinal products. The new marketing authorization application assessment procedures include:

- International Recognition Procedure. Since January 1, 2024, the MHRA may rely on the IRP when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. Reference Regulators include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures, is considered to be authorizations for the purposes of the IRP;

- National marketing authorization applications. The MHRA offers a timeline of no more than 150 days (excluding clock-stop periods where further information is requested) for the assessment of national applications for the marketing authorization of a medicinal product in the UK; and

- The "rolling review" route, which allows companies to make an application in stages, throughout the product's development, rather than as a consolidated full dossier submission. This route is available for new active substances in the UK.

Nonclinical and Clinical Development

Before testing any biologic product candidate in humans, the product candidate undergoes preclinical testing. Preclinical tests, also referred to as non-clinical studies, include laboratory evaluations of the product chemistry, pharmacology, toxicity and formulation, as well as animal studies to assess the pharmacokinetics, metabolism, bio-distribution, elimination and toxicity of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements and certain preclinical trials must conform to the FDA's GLP requirements.

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

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

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or independent data monitoring committee, which provides direction for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries. Information about most clinical trials must be submitted within specific timeframes for publication on the *www.clinicaltrials.gov* website maintained by the U.S. National Institutes of Health (the "NIH"). Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the NIH.

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

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

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

A therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients, intermediate-size patient populations, or for widespread treatment use under an expanded access protocol, under certain circumstances. Pursuant to the 21st Century Cures Act, or Cures Act, which was signed into law in December 2016, the manufacturer of one or more investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational product.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

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.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR"). The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

Clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

BLA Submission, Review and Approval

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

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

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

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

Expedited Development and Review Programs and other Marketing Authorization Procedures

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

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

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

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

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

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

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

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

The above-described concepts will largely continue under the newly adopted revised EU pharmaceutical legislation.

Orphan Drug Designation

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

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

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

In the EU, to maintain an ODD, a sponsor must demonstrate that it still satisfies the orphan designation criteria at the time of the marketing authorization. This includes a requirement for the sponsor to demonstrate “significant benefit” compared with any treatments that are authorized at the time of the re-evaluation of the orphan criteria. Comparators may include products that are authorized after the sponsor has submitted its marketing authorization, but before the sponsor’s orphan designation criteria have been re-assessed.

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

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

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

The above-described ODD rules will change with the newly adopted revised EU pharmaceutical legislation, introducing amongst other a one year base-line reduction of market exclusivity to nine years (but 11 years for a new breakthrough orphan category). Other changes also include only an additional one year of market exclusivity for new orphan indication, which can be granted maximum twice.

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

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 Food and Drug Administration Safety and Innovation Act ("FDASIA") amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to require that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs.

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

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

Under the new pharmaceutical legislation, PIPs may in some cases be developed in an "evolutionary" manner, allowing studies to adapt over time as scientific knowledge develops. By contrast, the text also imposes a potentially heavy new burden by restricting the current possibility to waive the obligation to conduct pediatric studies where the disease or condition occurs only in adult populations, or where the product is not expected to represent a significant therapeutic benefit for pediatric patients. Such waivers may not be granted where the product displays a mechanism of action, including where its action is directed at a specific molecular target or biological pathway, that on the basis of existing scientific data is "relevant for a different disease or condition in the same therapeutic area in children" compared to the adult population. In addition, where a pediatric indication is authorized following completion of a PIP, MAHs will be required to place the product on the market within two years of approval of that indication, reinforcing obligations on timely launch and availability.

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 adverse events of unanticipated severity or frequency involving our product candidates or anti-FcRn product candidates developed by others, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

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

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

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

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

The above-described concepts will largely continue under the newly adopted revised EU pharmaceutical legislation. One new change is that under the new rules, it is explicitly prohibited to do any form of advertising that aims to highlight negatively another medicinal product, as well as advertising that suggests that a medicinal product is safer or more effective than another medicinal product, unless demonstrated and supported by the SmPC.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act ("Affordable Care Act") signed into law in 2010 includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

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

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

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

The above-described concepts will largely continue under the newly adopted revised EU pharmaceutical legislation. However, generic, hybrid and biosimilar entry will in several instances be available earlier than under today's rules.

Other U.S. Healthcare Laws and Compliance Requirements

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

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

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the Anti-Kickback Statute can result in significant civil and criminal fines and penalties, imprisonment and exclusion from federal healthcare programs. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act ("FCA") (discussed below).

The federal false claims laws and civil monetary penalty laws, including the FCA, prohibit any person or entity from, among other things, (i) knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, including claims submitted to federal healthcare programs, such as Medicare and Medicaid, (ii) 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, (iii) knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government, or (iv) knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money. A claim includes "any request or demand" for money or property presented to the U.S. government. Private individuals, commonly known as "whistleblowers," can bring FCA *qui tam* actions, on behalf of the government and may share in amounts paid by the entity to the government in recovery or settlement. 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 included additional federal criminal statutory provisions 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.

In addition, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information. 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 clearing houses") or other "business associates", or otherwise act as a covered entity under HIPAA, we would be subject to the data privacy, security and security breach notification provisions of HIPAA, as amended by HITECH. Those regulations authorize the imposition of civil and criminal penalties, damages, injunctions, attorneys' fees and costs. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payment Sunshine Act (the "Sunshine Act") within the Affordable Care Act, and its implementing regulations, requires that certain manufacturers of drugs, devices, biological and medical supplies, among others, report annually to CMS information related to certain payments or other transfers of value made or distributed to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, certified nurse midwives, and U.S. teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to timely, accurately, and completely submit the required information for all payments, transfers of value, and ownership or investment interest may result in civil monetary penalties.

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. Multiple states have adopted laws that require the reporting of certain pricing information, including information pertaining to and justifying price increases, prohibit prescription drug price gouging, or impose payment caps on certain pharmaceutical products deemed by the state to be "high cost." These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts.

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

Additionally, to the extent that we have business operations in foreign countries, sell any of our products in foreign countries and jurisdictions, or engage with physicians from other countries, including Canada or the EU, we may be subject to additional, comparable, regulation.

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

Privacy, Data Protection and Information Security

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

Coverage, Pricing and Reimbursement

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

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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

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

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

In addition, some EEA countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.

Since January 2025, Regulation No 2021/2282 on HTA has been applicable, with phased implementation based on the type of product, i.e., oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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

Healthcare Reform

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

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. The Affordable Care Act, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been amendments to and legal and political challenges to certain aspects of the Affordable Care Act. For example, while Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain mandated fees, and increasing the point-of-sale coverage gap discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In June 2021, the U.S. Supreme Court dismissed a lawsuit challenging the constitutionality of certain aspects of the ACA, without ruling on the merits of the constitutionality arguments. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. These enhanced subsidies expired on December 31, 2025 but remain the subject of Congressional debate. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and implementing a new manufacturer discount program. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. It is unclear how any future challenges and the healthcare reform measures of the current presidential administration will impact the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is also unclear, particularly given the recent change in administration.

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, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2032 unless additional Congressional action is taken.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, presidential executive orders and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. CMS has and continues to take steps to implement the IRA, including negotiating and publishing "maximum fair prices" for drugs selected under the IRA's price negotiation framework and releasing quarterly lists of Medicare Part B products and annual lists of Medicare Part D products that are subject to adjusted coinsurance rates based on the inflationary rebate provisions of the IRA. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services, the Secretary of the U.S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. Additionally, when originally enacted, the IRA explicitly excluded from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. However, the OBBBA signed into law on July 4, 2025, amended the applicable statute to broaden the orphan drug exclusion such that products with more than one orphan designation and more than one approved indication will remain exempt from price negotiation, so long as each approved indication is for a rare disease or condition. The OBBBA also postpones the start of price negotiation requirements for drugs and biologics with orphan designations until the product receives approval for a non-orphan indication.

On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

The current presidential administration has also signaled its intent to pursue additional healthcare reform measures, including those aimed at reducing prescription drug prices, through various means, including presidential executive orders and agency action. These efforts include, among other things, proposals to establish a "most favored nation" drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost." Prescription drug affordability boards in several states have begun identifying products for affordability reviews and issuing information request to manufacturers to determine whether upper payment limits may be justified.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies.

Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Additionally, in February 2025 HHS ended a longstanding commitment to voluntarily comply with notice and comment requirements, even when not required by statute, which could contribute to rapid changes in policy without opportunity for public input. The new framework could increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will likely be subject to increased litigation and judicial scrutiny. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process and modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion in the IRA, and reduce Medicaid enrollment and funding. We expect additional health reform measures may be implemented in the future, particularly given the recent change in administration.

The Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additionally, to the extent that we have business operations in foreign countries, sell any of our products in foreign countries and jurisdictions, or engage with officials from other countries, including Canada or the EU, we may be subject to additional, comparable, regulation.

Additional Regulation

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

Other Regulations

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

Human Capital

Our Vision and Culture

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

Employees

As of March 31, 2026, we had 315 full-time permanent employees, primarily in the U.S. Of these employees, approximately 55% have advanced degrees including but not limited to Ph.D., M.D., and M.B.A., and approximately 85% were engaged in research and development activities. More than half of our workforce, as well as our senior management team, is comprised of women. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we have not had any work stoppages. We believe our relationship with our employees is good.

As the clinical development of our product candidates progresses and, if any of our product candidates receives marketing approval, we may grow the number of employees in the areas of sales, marketing, reimbursement and distribution.

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

Available Information

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

Item 1A. Risk Factors

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

Risks Related to Development, Regulatory Approval and Commercialization

Our business is dependent on the successful and timely development, regulatory approval and commercialization of our product candidates.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that our primary efforts and expenditures over the next few years will be devoted to the advancement of our clinical programs. Our business currently depends on the successful completion of our clinical trials for and subsequent regulatory approval and commercialization of our product candidates, which is uncertain. See "Risks Related to Development, Regulatory Approval and Commercialization – Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes."

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

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant foreign regulatory authorities for marketing approval;
- the FDA or other relevant foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including whether the design of our clinical trials is sufficient to support a regulatory approval;
- the FDA or other relevant foreign regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA or other relevant foreign regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of our product candidates or may require additional studies;
- the FDA or other relevant foreign regulatory authorities may not accept data generated from our clinical trial sites;
- if our BLA or other foreign marketing authorization application is referred for review by an advisory committee, the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant foreign regulatory authorities may require development of a REMS drug safety program or similar strategy imposed by foreign regulatory authorities, as a condition of approval;
- the FDA or other relevant foreign regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant foreign regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidate;
- the FDA or other relevant foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant foreign regulatory authorities may change their approval policies or adopt new regulations.

In addition, if our product candidates encounter safety or efficacy problems, such as the observed lipid findings from our clinical trials of batoclimab, developmental delays, regulatory issues, supply issues, or other problems in one of our target indications, our development plans for our product candidates could be significantly harmed in other indications, which would have a material adverse effect on our business. Further, problems encountered by 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 our product candidates could suggest problems with our product candidates that would potentially harm our business. Accordingly, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

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

Our product candidates are 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. For example, we are conducting trials evaluating IMVT-1402 in GD, D2T RA, MG, CIDP, SjD and CLE. Except for D2T RA and CLE, the first top-line data for any of the studies are not expected until sometime in calendar year 2027, assuming we can fully enroll and successfully complete the relevant trials according to our anticipated timelines. We cannot provide any assurance that any clinical trials will be conducted as planned or completed on schedule, if at all. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming and costly and is dependent upon collaboration with many contract research organizations ("CROs") and clinical trial sites.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation delaying the next stage of clinical development or submission of a BLA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit negative safety signals in later stage clinical trials that they did not exhibit in nonclinical or earlier-stage clinical trials. A number of companies in the pharmaceutical industry, including biotechnology and biopharmaceutical companies, have suffered significant setbacks in or the discontinuation of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Likewise, the results of early nonclinical studies and clinical trials of our product candidates, some of which were not conducted by us, may not be predictive of the results of our current or planned development programs.

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

- failure to obtain regulatory authorization to commence a clinical trial or reach a consensus with regulatory authorities regarding the design or implementation of our studies;
- unforeseen safety issues or subjects experiencing severe or unexpected AEs;
- continuation of previously identified safety issues;
- occurrence of AEs in trials of the same class of agents conducted by other sponsors or AEs reported by anti-FcRn product candidates developed by others;
- lack of effectiveness during clinical trials;
- resolving any dosing issues or limitations, including those raised by the FDA or other foreign regulatory authorities;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to identify, qualify, or initiate a sufficient number of clinical trial sites;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an investigational new drug application ("IND") or amendment, a clinical trial application ("CTA") or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from a Good Clinical Practice ("GCP") inspection of our clinical trial operations or trial sites; developments in trials conducted by in-class competitors that raise regulatory concerns about risk to patients of the class broadly; or if the regulator finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- failure to perform in accordance with the FDA's or any other regulatory authority's GCP requirements, or other regulatory guidelines in other countries;
- unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other foreign regulatory authorities;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;
- an institutional review board ("IRB") or ethics committee refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;

- IRBs or ethics committees issuing negative opinions regarding a clinical trial or requiring substantial modifications of a proposed clinical trial;
- premature discontinuation of study participants from clinical trials or missing data at a level that impacts study integrity;
- failure to manufacture or release sufficient quantities of our product candidates or placebo for our clinical trials that in each case meet our and global quality standards for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement, enrollment, or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from our product candidates, if approved, may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue.

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 and we may not be able to enroll patients in our trials on our anticipated timelines.

We may encounter delays or difficulties in enrolling or be unable to enroll a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate or be stopped, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials evaluating IMVT-1402 for MG, CIDP and GD due to existing alternative treatments available, including efgartigimod, rozanolixizumab, and nipocalimab for the treatment of MG, efgartigimod, IVIg, plasma exchange and steroids for the treatment of CIDP, and anti-thyroid drugs and ablative treatments for GD. In addition, patients may decline to enroll or decide to withdraw from our clinical trials due to protocol-required washout periods or the risk of receiving placebo.

Patient enrollment and retention in clinical trials depends on many factors, including the size of the eligible patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, limited trial site capacity and staffing as a result of healthcare worker shortages, the existing body of safety and efficacy data with respect to the study drug or drug class, 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, and our ability to obtain and maintain patient consents. Our product candidates are focused in part on addressing rare autoimmune indications, and we have focused our initial development efforts for batoclimab on the treatment of MG, TED, CIDP and GD with limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. We could be faced with similarly limited patient pools as we pursue certain of these and other indications for IMVT-1402, such as SjD, D2T RA and CLE.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients if a clinical trial is paused and then subsequently resumed. For example, we previously voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some patients treated with batoclimab. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible.

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

Success in preclinical 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 preclinical testing and clinical trials. In particular, we cannot assure you that the reductions in IgG antibodies and favorable analyte profile that we have observed in our Phase 1 trial of IMVT-1402 will be observed in any future clinical trials, including pivotal trials necessary for regulatory approvals, or that such reductions in IgG antibodies will correlate with clinical benefits sufficient to demonstrate that the efficacy endpoints of the study are met. Likewise, promising interim results or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and may lack statistical significance, which would further limit the reliability of such interim or preliminary data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results were seen with their product candidates in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made during clinical trials, including previously unobserved adverse effects.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints may cause us to abandon development of the product candidate in question. For example, our Phase 3 trials evaluating batoclimab in TED failed to meet the primary endpoint, resulting in our decision to discontinue development of batoclimab. Any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates (if approved) and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our expectations for differentiation or the effectiveness or safety of our product candidates. The FDA has substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we may propose. In addition, only a small percentage of biologics under development result in the submission of a BLA to the FDA, or other similar applications with other relevant foreign regulatory authorities, and even fewer are approved for commercialization.

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

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Top-line data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously disclosed. As a result, top-line data should be viewed with caution until the final data is available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete is subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of shares of our common stock.

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

Our product candidates may be associated with adverse events or cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, cause us to abandon further development or limit the commercial viability of any approved label or market acceptance.

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

If an unacceptable frequency or severity of treatment related side effects or new safety signals are reported in our or others' anti-FcRn clinical trials or from post-marketing safety surveillance of approved anti-FcRn products, our ability to obtain regulatory approval may be negatively impacted. Treatment-related side effects arising from, or those potentially arising from, our product candidates or those from other companies targeting similar autoimmune indications or using the same mechanism of action could affect the design of clinical studies, target patient population, enrollment and conduct of the studies, patient recruitment or the ability of enrolled patients to complete our clinical trials, eventual labeling and risk management, or result in potential product liability claims.

For example, treatment-related side effects associated with batoclimab in our clinical trials previously caused us to pause dosing in our clinical trials of batoclimab. We voluntarily paused dosing in our early phase clinical studies of batoclimab to evaluate treatment-induced elevations in total cholesterol and LDL levels observed in some trial subjects. We incurred a delay to evaluate the available safety data and eventually continued our clinical development of batoclimab and adjusted protocols that contained long-term treatment durations to include frequent monitoring of plasma lipids and guidelines for the management of any observed lipid abnormalities. Although our focus is currently on IMVT-1402, which has not been observed to cause the treatment-induced lipid elevations associated with batoclimab, these occurrences harmed, and any similar occurrences may in the future harm, our business, financial condition and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We face intense competition from other biopharmaceutical companies who are marketing and developing agents for the treatment of autoimmune diseases, including multiple agents in the anti-FcRn class. These include efgartigimod (Argenx SE), nipocalimab (Johnson & Johnson) and rozanolixizumab (UCB SA), each of which are approved for the treatment of generalized myasthenia gravis ("gMG"). Efgartigimod is also approved for the treatment of CIDP. Each of efgartigimod and nipocalimab are being evaluated in Phase 3 studies in SjD, and Argenx plans to initiate an efgartigimod study in GD in 2026. Other FcRn inhibitors include Viridian Therapeutics' VRDN-006 and VRDN-008, each of which is currently in Phase 1 development, and have the potential to treat a broad array of autoimmune diseases.

Our product candidates, if approved, may also face competition from agents with different mechanisms of action. 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. A number of C5 complement inhibitors are approved in gMG including SOLIRIS® (eculizumab), ULTOMIRIS® (ravulizumab-cwvz), and ZILBRYSQ® (zilucoplan). UPLIZNA® (inebilizumab), a CD19-targeted humanized monoclonal antibody, is approved for the treatment of gMG.

IMVT-1402 may also face competition in CIDP from agents in Phase 3 development with different mechanisms of action including C1 inhibitors riliprubart (Sanofi), DNTH103 (Dianthus) and C2 inhibitor empasiprubart (Argenx SE).

We are aware of multiple agents with different mechanisms of action that are in early-stage development for the treatment of GD, including TSH antagonists being developed by Crinetics Pharmaceuticals and Lycia Therapeutics (LCA-0321) and currently in IND-enabling studies, Biohaven's IgG degrader (BHV-1300) in a Phase 1 study, Merida Biosciences' FC biotherapeutic targeting TSHR (MER511) in a Phase 1 study, Yarrow Bioscience's anti-TSHR antibody (YB-101) entering a Phase 1b/2b trial, and Sanofi's BTK inhibitor (rilzabrutinib) in a Phase 2 study. Viridian has an anti-TRAb, half-life extended monoclonal antibody candidate in preclinical development with potential use in the treatment of GD, which is intended to be delivered by subcutaneous administration via autoinjector.

CLE is a dermatology focused therapeutic category with no treatment innovation for more than 50 years, but treatment options include prevention of exposure to sunlight with the utilization of both topical and systemic therapies such as antimalarials, immunomodulators, and immunosuppressives (methotrexate, mycophenolate). With the significant unmet need and increasing demand for biologic therapies in dermatology and rheumatology, the competitive landscape for SCLE and CCLE is a growing market for novel therapies and diagnostic tools in development. Biogen is in Phase 2/3 with litifilimab (BDCA2), AstraZeneca is in Phase 3 anifrolumab (IFNAR1) with many other early development programs, and Merck has entered Phase 3 evaluations of enpatoran.

Therapeutic approaches for SjD include a variety of local agents to address the associated dry eye and mouth and/or immunosuppressive treatments to address the systemic manifestations of disease. In addition to the anti-FcRn competitors mentioned above, IMVT-1402 may also face competition from other drug classes, including inhibitors of TYK2 (deucravacitinib), CD40 (dazodalibep), BAFF (ianalumab) or BLyS/APRIL (telitacicept).

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

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

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

- develop and commercialize therapies in our target indications that are superior to other products in the market;
- demonstrate through our clinical trials that IMVT-1402 or any future product candidate is differentiated from existing and future therapies;
- attract qualified scientific, product development, manufacturing and commercial personnel;
- obtain patent or other proprietary protection for IMVT-1402, or any future product candidates;
- obtain required regulatory approvals, including approvals to market IMVT-1402 or any future product candidate we develop, in ways that are differentiated from existing and future products and treatments;
- have commercial quantities of any approved product manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- successfully commercialize IMVT-1402 or any future product candidate, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors and/or competent authorities;
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies; and
- avoid regulatory exclusivities or patents held by competitors that may inhibit our products' entry to the market.

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

Additional time may be required to obtain marketing authorizations for the autoinjector presentation of IMVT-1402 because it would be subject to regulation as a combination product.

Combination products are therapeutic and diagnostic products that combine drugs, devices and/or biological products. The autoinjector presentation of IMVT-1402 would be considered a combination product that requires coordination within the FDA and in similar foreign regulatory authorities for review of its device and biologic components. Although the FDA and similar foreign regulatory authorities have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of these product candidate presentations due to uncertainties in the product development and approval process.

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

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

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

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

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

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

- restrictions on the manufacture of such product;
- restrictions on the labeling or marketing of such product, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS or additional risk management plans (or similar strategy imposed by foreign regulatory authorities);
- Warning or Untitled Letters;
- withdrawal of the product from the market;
- recall of a product;
- fines, restitution or disgorgement of profits or revenues;
- suspension, variation or withdrawal of marketing approvals;
- refusal to permit the import or export of such product;
- product seizure; or
- lawsuits, injunctions or the imposition of civil or criminal penalties.

The FDA and other foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of IMVT-1402 or any future product candidate. For example, in December 2025, the European Union legislators adopted a new Directive and Regulation, revising the existing pharmaceutical legislation. A number of changes to the regulatory framework governing medicinal products in the European Economic Area ("EEA") will now occur, including a one year decrease in data and market exclusivity available in the EEA. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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

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

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

Market acceptance of new products for the treatment of the indications we pursue with our product candidates, including MG, CIDP, GD, RA, SjD and CLE, may also be affected by the perception that existing treatments are sufficient to treat the majority of these patients. In addition, our product candidates, if approved, may compete with other approved FcRn inhibitors or other FcRn inhibitors under development that have demonstrated similar levels of IgG reductions and shown clinical benefit by meeting their efficacy endpoints in completed clinical trials to date. In addition, the potential patient population for certain autoimmune indications that we may target are relatively small. This could affect the rate of adoption and as a result, market acceptance of our product candidates, if approved, could be much slower than anticipated.

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

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

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

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

We do not currently have our own sales or distribution capabilities and our marketing capabilities are limited. The cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to effectively market our product candidates if we obtain regulatory approval, we must successfully build out our sales, marketing, compliance, distribution and related capabilities or make arrangements with third parties to perform these services. We will also need a patient support services organization to ensure patients have appropriate access to our products, once approved.

We expect to build a focused sales, distribution and marketing infrastructure to market our product candidates in the U.S., if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, develop an appropriate and effective compliance function, provide adequate training to sales and marketing personnel and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact its commercialization. If the commercial launch of our first 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. The costs associated with a sales, marketing and distribution infrastructure may exceed the net revenues we are able to generate from the sale of a product candidate following regulatory approval.

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, marketing, reimbursement, patient support, medical affairs and other support personnel;
- the inability of sales personnel to appropriately inform and educate healthcare providers regarding the potential benefits and proper administration of our products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of any product candidate, it could result in a delay to, or reduce the effectiveness of, our commercialization efforts. This could adversely impact the product revenues generated from a product candidate following regulatory approval.

If we decide to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring any product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to any of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenues, including net revenues, may be lower than if we were to market and sell a product candidate through an internal sales force. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion.

If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates following regulatory approval 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 may seek orphan drug designations for IMVT-1402 or other product candidates we develop, but we may be unable to obtain such further designation or to maintain the benefits associated with orphan drug status even if that designation is granted.

As part of our business strategy, we have in the past and may in the future seek orphan drug designations for any product candidates we develop, and we may be unsuccessful. In July 2021, we were granted orphan drug designation in the U.S. by the FDA for batoclimab for the treatment of MG and, in August 2022, we received orphan drug designation from the European Commission for batoclimab for the treatment of MG. We may seek orphan drug designation from the FDA for IMVT-1402 where there is a medically plausible basis for its use. We may also seek orphan drug designations for IMVT-1402 for the treatment of other indications in European countries, where available.

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

It is also possible that current or future litigation or action by Congress could change the scope of available orphan exclusivity. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

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

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

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

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

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

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support programs, 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, a criminal law that 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. The term "remuneration" has been broadly interpreted to include anything of value. The intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act ("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. A claim including items or services resulting from a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act ("FCA"). A conviction for a violation of the federal Anti-Kickback Statute can result in criminal fines and/or imprisonment and requires mandatory exclusion from participation in federal health care programs. Exclusion may also be imposed if the government determines that an entity has committed acts that are prohibited by the federal Anti-Kickback Statute;
- the federal criminal and civil false claims laws and civil monetary penalty laws, including the FCA, which prohibits, among other things, (i) knowingly presenting or causing to be presented, claims for payment of government funds that are false or fraudulent; (ii) knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim; (iii) knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government; or (iv) knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring FCA *qui tam* actions, on behalf of the government and may share in amounts paid by the entity to the government in recovery or settlement;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payment Sunshine Act (as defined below), which requires certain manufacturers of drugs, devices, biologics and medical supplies, among others, to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other "transfers of value" made by such manufacturers to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, certified nurse midwives, and U.S. teaching hospitals, as well as ownership and investment interests held by U.S.-licensed physicians and their immediate family members. Failure to timely, accurately, and completely submit the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties;
- 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; 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; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require the reporting of certain pricing information, including information pertaining to and justifying price increases, prohibit prescription drug price gouging; or impose payment caps on certain pharmaceutical products deemed by the state to be "high cost"; and
- federal, state and foreign laws governing the privacy and security of personal information, including health information, such as HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, which may require us to, among other data protection measures, provide notices, obtain individual consents to use and disclose information, give individuals rights with respect to their information and keep the information secure. Enforcement of such laws could result in civil and criminal penalties as well as, in some circumstances, damages and related costs in defending private actions, including class actions.

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

Legislation targeting biotechnology companies with ties to certain foreign adversaries, including the BIOSECURE Act, could materially adversely affect our business, supply chain and results of operations.

We rely on third-party contract manufacturing organizations ("CMOs") to manufacture drug substance and drug product for our product candidates. The BIOSECURE Act, enacted in December 2025 as Section 851 of the FY2026 National Defense Authorization Act, prohibits U.S. government agencies from procuring or obtaining biotechnology equipment or services from designated "biotechnology companies of concern," and restricts agencies from entering into, extending, or renewing contracts with entities that use such covered equipment or services (the "BIOSECURE Act"). The statute relies on two designation mechanisms: (1) automatic designation through the Department of Defense's Section 1260H list of "Chinese military companies"; and (2) a criteria-based pathway administered through an interagency process led by the Office of Management and Budget, which is required to publish a list of biotechnology companies of concern within one year.

The prohibitions under the BIOSECURE Act take effect following revisions to the Federal Acquisition Regulation, with the timing depending on the basis for a company's designation as a "biotechnology company of concern." Although the statute includes a five-year rule of construction that protects legacy agreements from being invalidated by the new restrictions, a safe harbor for items no longer produced or provided by a biotechnology company of concern, and limited case-by-case waivers in the national security interest, there can be no assurance that we will be able to fully avail ourselves of such provisions or that they will adequately mitigate the impact of the statute's prohibitions on our operations. In such event, we may be required to transition manufacturing activities then performed by CMOs receiving the designation to alternative CMOs, which could be costly, time-consuming and disruptive to our supply chain and clinical development programs.

In addition to the BIOSECURE Act, the introduction or passage of other federal or state legislation, executive orders or regulatory actions further restricting U.S. biotechnology companies' use of certain foreign-based CMOs could impose additional constraints on our manufacturing operations and supply chain. Although we also maintain manufacturing relationships with a number of different CMOs, there can be no assurance that we would be able to identify and qualify alternative manufacturers on commercially reasonable terms or in a timeframe sufficient to avoid material disruption to our business, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

The Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced an "average manufacturer price" calculation for drugs and biologics that are inhaled, infused, instilled, implanted or injected and that are not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) 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; (6) created a licensure framework for follow-on biologic products; and (7) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been amendments to and executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance and eliminating the implementation of certain mandated fees. On June 17, 2021, the U.S. Supreme Court dismissed a legal challenge to the law brought by several states arguing that, without the individual mandate, the entire Affordable Care Act was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments.

On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs. As of January 1, 2024, manufacturers' Medicaid Drug Rebate Program rebate liability is no longer capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs. Further, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. These enhanced subsidies expired on December 31, 2025 but remain the subject of Congressional debate. In the future, there may be additional challenges and/or amendments to the Affordable Care Act. It is unclear how future litigation and the healthcare reform measures of future presidential administrations will impact the Affordable Care Act and our business. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and implementing a manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the current presidential administration will impact the Affordable Care Act and our business. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2032 (with the exception of a temporary suspension, and subsequent reduction, due to the COVID-19 pandemic) unless additional Congressional action is taken. 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.

There is also recent heightened governmental scrutiny over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, the IRA, among other things, (1) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure single-source biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. CMS has and continues to take steps to implement the IRA, including negotiating and publishing "maximum fair prices" for drugs selected under the IRA's price negotiation framework and releasing quarterly lists of Medicare Part B products and annual lists of Medicare Part D products that are subject to adjusted coinsurance rates based on the inflationary rebate provisions of the IRA. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services, the Secretary of the U.S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. Additionally, when originally enacted, the IRA explicitly excluded from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. However, the One Big Beautiful Bill Act ("OBBBA") signed into law on July 4, 2025, amended the applicable statute to broaden the orphan drug exclusion such that products with more than one orphan designation and more than one approved indication will remain exempt from price negotiation, so long as each approved indication is for a rare disease or condition. The OBBBA also postpones the start of price negotiation requirements for drugs and biologics with orphan designations until the product receives approval for a non-orphan indication.

The current presidential administration has also signaled its intent to pursue additional healthcare reform measures, including those aimed at reducing prescription drug prices, through various means, including presidential executive orders and agency action. These efforts include, among other things, proposals to establish a "most favored nation" drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

Further, on December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, individual states in the U.S. are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost." Prescription drug affordability boards in several states have begun identifying products for affordability reviews and issuing information requests to manufacturers to determine whether upper payment limits may be justified. Furthermore, the increased emphasis on managed healthcare will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, other insurers, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained. The current presidential administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business.

Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA, HHS, and CMS. The new framework could increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will likely be subject to increased litigation and judicial scrutiny.

Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion in the IRA, and reduce Medicaid enrollment and funding. We expect additional health reform measures may be implemented in the future.

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

Market acceptance and sales of any approved product that we develop will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. The pricing and reimbursement of our product candidates, if approved, must be adequate to support the costs associated with commercialization efforts. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates following regulatory approval, will be adversely affected. There is no assurance that our product candidates, if approved, would achieve adequate coverage and reimbursement levels.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidate that we develop through approval will be made on a plan-by-plan basis. For example, 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 same product, and payors may periodically review and change their coverage and reimbursement rates. 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, what amount it will pay the manufacturer, 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, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers. Additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. Target patient populations may be small for some of the indications we may pursue with our product candidates. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidate for which we are able to obtain regulatory approval.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the U.S. and in some foreign jurisdictions that could affect our ability to profitably sell any product candidates following regulatory approval. There can be no assurance that our product candidates, if approved, will be considered medically reasonable and necessary or cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the U.S. and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if approved for sale.

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

Regulation No 2021/2282 on HTA boosts cooperation among the EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The Regulation permits the EU Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in selected EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

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

Risks Related to Our Business, Financial Position and Capital Requirements

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to obtain regulatory approval or fail to become commercially viable. We have never generated any product revenue and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was $505.6 million and $413.8 million for the years ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $1,745.1 million.

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

We expect our research and development expenses in connection with our development programs for our product candidates to continue to be significant. For example, we expect our research and development expenses to increase as we conduct evaluations of IMVT-1402, including trials currently underway in GD, D2T RA, MG, CIDP, SjD and CLE. In addition, if we obtain regulatory approval for IMVT-1402, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses had and will continue to have an adverse effect on our results of operations, financial position and working capital.

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, 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 our product candidates we develop. We have never been profitable, have no products approved for commercial sale and have not generated any product revenue.

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

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

- successfully complete clinical trials and obtain regulatory approval for the marketing of IMVT-1402 or any future product candidate in the U.S. and in other jurisdictions;
- add operational, financial and management information systems personnel, including personnel to support our planned future commercialization efforts;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of IMVT-1402 or any future product candidate manufactured at acceptable cost and quality levels and in compliance with FDA and other foreign regulatory requirements;
- attract and retain experienced management and advisory teams;
- raise additional funds when needed and on terms acceptable to us;
- commercially launch IMVT-1402 or any future product candidate, if approved, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;

- set an acceptable price for any approved product and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of any approved product in the medical community and with third-party payors and consumers;
- compete effectively with other biotechnology and pharmaceutical companies targeting autoimmune disease indications; and
- maintain, expand and protect our intellectual property portfolio.

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

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

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

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

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

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

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

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize our product candidates. For example, we will require substantial capital to execute our plans to conduct studies evaluating IMVT-1402, including those currently underway in GD, D2T RA, MG, CIDP, SjD and CLE. Our expenditures may also include costs associated with the HanAll Agreement, including payments in connection with the resolution of any potential dispute with HanAll relating to our development of batoclimab, the achievement of certain future regulatory milestones for IMVT-1402 prior to generating any product sales, significant further payments upon the achievement of certain sales milestones and tiered royalty payments in connection with the commercial sale of IMVT-1402, if approved.

We will require additional capital to complete the development and potential commercialization of our product candidates. Because the length of time and activities associated with successful development of our product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all, and our ability to raise additional capital may be adversely impacted by global economic conditions, including disruptions to and volatility in the credit and financial markets in the U.S. and worldwide, geopolitical tensions, including the rising tensions between China and Taiwan, tensions in Venezuela, the ongoing military conflicts between Russia and Ukraine and in the Middle East, including the recent hostilities involving Iran, changes in inflation, interest rates, international trade policies and tariffs and other factors. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the timing, progress, costs and results of our clinical trials for our product candidates;
- 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-1402 or any future product candidate in regions where we choose to commercialize such product candidate, if approved, on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

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

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

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs, or batoclimab, IMVT-1402 or any future product candidate or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves. Although we were able to raise additional funds through an underwritten offering of our common stock completed in December 2025, there can be no assurances that we will be able to raise additional capital on favorable terms (if at all) in the future.

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

We have licensed our core intellectual property relating to IMVT-1402 and batoclimab from HanAll under the HanAll Agreement. The HanAll Agreement imposes a variety of obligations on us, including those relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we materially breach any of our obligations under the HanAll Agreement and are unable to cure that breach within the time frame specified under the HanAll Agreement, we may be required to pay damages to HanAll and they may have the right to terminate the HanAll Agreement, which would result in us being unable to develop or manufacture our product candidates. We have commenced discussions with HanAll regarding the potential return of certain rights for batoclimab.

Biotechnology and pharmaceutical license agreements are complex and certain provisions in the HanAll Agreement may be susceptible to multiple interpretations. The resolution of any dispute or disagreement involving contract interpretation that may arise in relation to the HanAll Agreement could affect the scope of our rights to our product candidates or affect financial or other obligations under the HanAll Agreement or other agreements related to the development and commercialization of our product candidates, either of which could harm our business, financial condition, results of operations and prospects.

We shared top-line results from the two batoclimab Phase 3 TED studies concurrently in April 2026. Neither study achieved its primary endpoint, leading us to make a decision to discontinue further development of batoclimab across all indications to focus fully on IMVT-1402. HanAll has a variety of interests in the licensed products including under the HanAll Agreement and outside of our Licensed Territory and may, as a result of those interests, disagree with, or initiate a dispute with respect to, our plans for batoclimab. While the HanAll Agreement gives us final decision-making authority over development and regulatory matters for licensed products in our Licensed Territory, and we believe we have satisfied our obligations under the HanAll Agreement, including with respect to batoclimab, HanAll may disagree with our interpretation of the agreement or our actions thereunder, and we may be unable to reach an agreement with HanAll regarding the future of batoclimab. This could result in a dispute with HanAll involving arbitration or litigation. In the event that HanAll asserts a breach, we do not believe there would be any basis for such a claim, and we would vigorously contest such a claim if made. Any potential dispute with HanAll could be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could materially impact our business. In addition, discontinuing further development of and regulatory submissions for batoclimab could impact and result in disputes with third parties, such as with respect to the contract manufacturing of batoclimab, which may be time-consuming and expensive to resolve.

The HanAll Agreement obligates us to make milestone payments, some of which may be triggered prior to our potential commercialization of any product candidate.

We will be responsible for future contingent payments and royalties under the HanAll Agreement, including up to an aggregate of $420.0 million (after an aggregate amount of $32.5 million paid for milestone events achieved as of March 31, 2026), certain of which will occur prior to commercialization of any product candidate. 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-1402. As disclosed, we have discontinued development of batoclimab. Following commercialization (if achieved), we may be required to make significant further payments upon the achievement of sales milestones and make tiered royalty payments in connection with the commercial sale of IMVT-1402, if approved. There can be no assurance that we will have the funds necessary to make such payments or be able to raise such funds when needed on terms acceptable to us or at all. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts. We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management, scientific, clinical and commercial personnel due to the intense competition for qualified individuals among biotechnology, pharmaceutical and other businesses.

If we are not able to recruit, retain, manage and motivate necessary personnel to accomplish our business objectives, including our plan to focus on the execution of clinical trials of IMVT-1402 in the current six indications, 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.

Many of the other pharmaceutical companies with which we compete for qualified personnel 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 than what we offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop IMVT-1402 and our business will be harmed.

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

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

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

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

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

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

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

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

We and the third parties with whom we work are subject to stringent and changing privacy, data protection and information security laws, contractual obligations, self-regulatory schemes, government regulation, industry standards and other obligations related to data privacy and security. The actual or perceived failure by us or the third parties with whom we work to comply with such obligations could result in harm to our reputation, regulatory investigations or actions, significant fines and liability, disruption of our clinical trials or other material adverse effects on our business.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect about patients and healthcare providers in connection with clinical trials in the U.S. and abroad ("Process" or "Processing") necessary to operate our business and for legal, marketing and other business-related purposes. These activities subject us to numerous federal, state, local and foreign laws, regulations and guidance regarding privacy, data protection, information security and Processing ("Data Protection Laws"), the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or Data Protection Obligations (as defined below).

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to conduct our clinical trials and commercialize our product candidates, if approved. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA"), applies to personal data of consumers, business representatives and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,988 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work.

We also expect that there will continue to be new or amended laws, regulations and industry standards concerning privacy, data protection and information security proposed and enacted in various foreign jurisdictions. For example, under the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR"), companies can face private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests; temporary or definitive bans on data processing and other corrective actions; and fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or 4% of their worldwide annual revenue, whichever is greater. Our or our CROs', or other third party vendors' failure to comply with the GDPR could lead to significant fines imposed by regulators or restrictions on our ability to process personal information as needed to conduct clinical trials in the EEA and/or the UK (as applicable) or commercialize our product candidates, if approved. We may also be obligated to assist our clinical trial sites, CROs and vendors with their own compliance obligations under the GDPR, which could require expenditure of significant resources. Assisting our clinical trial sites, CROs and vendors in complying with the GDPR or complying with the GDPR ourselves may cause us to incur substantial operational costs or require us to change our business practices.

In the ordinary course of business, we may transfer personal information from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the United States. If there is no lawful manner for us to transfer personal information from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Additionally, companies that transfer personal information out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. For example, regulators in the United States including the Department of Justice are increasingly scrutinizing certain personal data transfers and taking steps to enact certain data localization requirements, such as the Department of Justice's recently finalized rule implementing the Biden Administration's executive order "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern."

We are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications and frameworks ("Privacy Policies") and to contractual obligations to third parties related to privacy, data protection, information security and Processing ("Data Protection Obligations"). We may be contractually subject to industry standards adopted by industry groups and may become subject to additional such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, may require our vendors to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements regarding our data privacy and security practices. Regulators in the United States are increasingly scrutinizing such statements, and if they are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

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

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations, or if our Privacy Policies are, in whole or part, found to be inaccurate, incomplete, deceptive, unfair or misrepresentative of our actual practices, it could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, interrupt or stop clinical trials, result in litigation and liability, result in an inability to process personal information or to operate in certain jurisdictions, cause a material adverse effect on our business operations or financial results or otherwise result in a material adverse effect on our business. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

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

We may in the future receive inquiries or be subject to investigations, proceedings or actions by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect on our reputation, business or financial condition, including without limitation: interruptions or stoppages in our business operations (including, as relevant, clinical trials); the diversion of resources and the attention of management from our business to defend any claim or inquiry; limited ability to commercialize our products; discontinuance of necessary processing; adverse publicity; or substantial changes to our business model or operations.

If our information technology systems or data, or those of our affiliates, service providers or other third parties with whom we work, are or were compromised now or in the future, this could result in a material adverse effect on our business, including without limitation, a material interruption to our operations, harm to our reputation, regulatory investigations or actions, significant fines, penalties and liability, breach or triggering of Data Protection Laws, Privacy Policies and Data Protection Obligations or material disruption of our clinical trials or other business activity.

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

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

Cyberattacks, malicious internet-based activity and online and offline fraud threaten the confidentiality, integrity and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists", organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-state and nation-state-supported actors. Some actors now engage and are expected to continue to engage in attacks, including without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work (including our CROs and trial sites) are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), software bugs, malicious code (such as viruses and worms), adware, employee theft or misuse, supply chain attacks, denial-of-service attacks (such as credential stuffing) and ransomware attacks, phishing attacks, viruses, malware installation (including as a result of advanced persistent threat intrusions), server malfunction, software or hardware failures, loss of data or other information technology assets, telecommunications failures, earthquakes, fires, floods, attacks, enhanced or facilitated by AI or other similar issues. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

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

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, clinical trial operations, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a Security Breach or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. A Security Breach or other interruption could disrupt our ability (and that of third parties with whom we work) to conduct our business operations. We may be required to expend significant resources, fundamentally change our business activities and practices or modify our operations (including our clinical trial activities) or information technology in an effort to protect against Security Breaches and to mitigate, detect and remediate actual and potential vulnerabilities. Applicable Data Protection Laws, Privacy Policies and Data Protection Obligations also require us to implement and maintain specific security measures or use industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against Security Breaches, there can be no assurance that our security measures or those of our service providers, partners and other third parties with whom we work will be effective in protecting against all Security Breaches and adverse effects on our business that may arise from such breaches. The recovery systems, security protocols, network protection mechanisms and other security measures that we (and our third parties) have integrated into our platform, systems, networks and physical facilities, which are designed to protect against, detect and minimize Security Breaches, may not be adequate to prevent or detect service interruption, system failure or data loss.

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

Applicable Data Protection Laws, Privacy Policies and Data Protection Obligations may require us to notify relevant stakeholders of Security Breaches, including affected individuals, customers, regulators and credit reporting agencies. Such disclosures are costly and the disclosures or the failure to comply with such requirements could lead to adverse effects on our business including, without limitation, government enforcement actions (for example, investigations, fines, penalties, audits and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable Data Protection Laws, Privacy Policies or Data Protection Obligations related to information security or Security Breaches.

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

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

In addition to experiencing a Security Breach, third parties may gather, collect or infer sensitive information about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed or revealed as a result of or in connection with the use of generative AI technologies by our employees, personnel or vendors, even if such use is not authorized by us or permitted by our internal policies.

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

- impairment of our business reputation and significant negative media attention;
- delay or termination of clinical trials or withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize any product candidate, if approved;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for any product candidate, if approved; and
- loss of revenue.

The product liability insurance we currently carry and any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for IMVT-1402 or any future product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any approved product.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (the "APA") "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision has had and will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the Department of Health and Human Services (HHS), CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles and legislative developments. For example, the current presidential administration's commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to the use of artificial intelligence to review product applications. And, the recent federal government shutdown may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. These developments may lead to greater uncertainty regarding FDA policies, slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

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

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

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

Our business could be adversely affected by economic downturns, changes in inflation and interest rates, changes in international trade policies and tariffs, natural disasters, political crises, geopolitical events, such as the crises and conflicts in Ukraine and the Middle East, or other macroeconomic conditions, which may negatively impact our business and financial performance in the future.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, changes in inflation and interest rates and uncertainty about economic stability. For example, during 2022 and 2023, the Federal Reserve raised interest rates multiple times in response to concerns about inflation. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Trade policies and geopolitical disputes and conflicts can result in tariffs, sanctions and other measures that restrict international trade, and may adversely affect our costs of doing business, particularly if these measures occur in regions where our suppliers source components or raw materials. For example, in April 2025 the U.S. and China implemented reciprocal tariffs on a variety of goods, including pharmaceutical products. Similarly, the ongoing military conflicts between Russia and Ukraine, the Israel/Hamas conflict in the Middle East, and the conflict in Iran have created volatility in the global capital markets and are expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and rely on third parties to produce clinical supplies and commercial supplies of our product candidates. The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production or our quality management program may fail to detect quality issues at our third-party manufacturers, which may delay or prevent our ability to obtain marketing approval or commercialize 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. We rely on third parties for the manufacture of our drug substance, drug product, and delivery devices. With respect to IMVT-1402, we have established arrangements with CMOs to supply drug substance and drug product to support our current and planned clinical trial programs, as well as anticipated commercial supply to support the potential launch of IMVT-1402, if approved. Additional third-party vendors may be difficult to identify for our product candidate process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our preclinical studies, clinical trials, research and development activities and, following regulatory approval, commercialization. Any significant delay in the supply of IMVT-1402 or the raw material components thereof, or in placebo controls for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of IMVT-1402 or any future product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for IMVT-1402 or any future product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of such product candidate and may require notification to the FDA or other regulatory authorities. In addition, our product candidates are biologics and require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Our future success depends on our ability to maintain and continuously improve our quality management program to monitor the manufacturing processes used by third-party manufacturers and our reliance on third-party manufacturers does not relieve us of our regulatory responsibilities. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims and insufficient inventory. A quality or safety issue emanating from manufacturing failures may result in adverse inspection reports, warning letters, monetary sanctions, injunction to halt manufacture and distribution of drugs or drug products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses.

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

Further, our reliance on third-party manufacturers entails risks, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing, which can be difficult for a biologic product;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- potential disputes with third parties that might delay work under third-party contracts;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell any product candidate, if approved, in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacture of another company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

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

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

We currently and expect to continue to engage in contract manufacturing, conduct clinical trials, and perform laboratory research activities outside the U.S., including in Asia. Any disruption in production or inability of our manufacturers in Asia to produce adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. In particular, trade tensions and conflict between the United States and China remain high, and could result in changes to the laws, rules, regulations and policies of the governments of the United States or China that impact the ability of U.S. biotechnology companies to partner with entities in China. For example, in April 2025, the U.S. and China implemented reciprocal tariffs on a variety of goods, including pharmaceutical products. We also conduct certain laboratory research and expect to have clinical trial sites in Asia. We are exposed to the possibility of product supply disruption, clinical trial delays and increased costs in the event of changes in governmental policies, political unrest or unstable economic conditions in Asia. Any disruption of these activities could materially and adversely affect our business and results of operations.

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

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

We rely upon CROs to monitor and manage data for our clinical programs, as well as for the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GLP and GCP regulations and guidelines enforced by the FDA and equivalent foreign regulations and guidelines, including the International Council for Harmonization guidelines, enforced by foreign regulatory authorities for IMVT-1402 or any of our future product candidates that are in nonclinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations and our reliance on the CROs does not relieve us of our regulatory responsibilities. Therefore, the success of our clinical trials depends on our ability to maintain and continuously improve our quality management program to monitor our CROs' compliance with applicable regulations. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical trials before approving our marketing applications. Accordingly, if we or our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the relevant regulatory approval process. Failure by our CROs to properly execute study protocols in accordance with applicable law could also create product liability and regulatory risks for us as sponsors of those studies. Further, our or our CROs' inability to address a quality or safety issue may result in, among others, adverse inspection reports, warning letters, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses.

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

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

Risks Related to Our Intellectual Property

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

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

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

The validity, scope and enforceability of any patents that cover a biologic subject to approval by the FDA via a BLA, such as IMVT-1402 or batoclimab, can be challenged by third parties.

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

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

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

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

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

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

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

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

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our patent rights, allow third parties to commercialize IMVT-1402, batoclimab, 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-1402, batoclimab, or any future product candidates.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices, both in the U.S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Moreover, patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Without patent protection for IMVT-1402, batoclimab, 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.

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

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

We may decide to abandon national and regional patent applications while they are still pending. The examination and issuance of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by a patent office in one jurisdiction, while substantively similar applications are granted by patent offices in other jurisdictions. For example, relative to other countries, India has a heightened requirement for patentability and specifically does not allow patenting of medical treatment methods. It is also common that, depending on the country, the scope of patent protection may vary for the same product candidate or technology. If we are unable obtain claims that we feel are commercially relevant in a particular jurisdiction, we may abandon that patent application and forego obtaining patent protection for that product in the relevant jurisdiction, which may allow competitors in that jurisdiction to develop their own products that may compete with our products without infringing our patent claims in that jurisdiction.

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 certain countries in the European Union, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to other parties. EU legislators are currently negotiating a Regulation on Critical Medicines which, among other measures, envisages the conclusion of voluntary agreements for certain in-scope medicines, and – as a measure of last resort – the possibility of allowing third-party production of patented medicines without the consent of the license holder. The Regulation is expected to be adopted in 2026. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the statutory expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent and the protection it affords is limited. Even if patents covering our product candidates are obtained, once the patent has expired, we may be open to competition from competitive products, including generics or biosimilars. The patent family directed to the composition of matter of batoclimab has a statutory projected expiration date in 2035 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent family directed to the composition of matter of IMVT-1402 and its use in treating autoimmune diseases has a statutory projected expiration date in 2043 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent family directed to methods of improving anti-FcRn therapies, which describes specific dosing regimens for IMVT-1402 including for the treatment of rheumatoid arthritis, has a statutory projected expiration date in 2044 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent family directed to methods of treating skin diseases using anti-FcRn antibodies including IMVT-1402 and batoclimab has a statutory projected expiration date in 2046 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent family directed to the formulation of batoclimab has a statutory projected expiration date in 2041 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent families directed to the use of IMVT-1402 and batoclimab for treating GD and the use of IMVT-1402 and batoclimab for treating CIDP each have a statutory projected expiration date in 2043 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent family directed to the method of manufacturing of, and formulations produced by such method, covering manufacturing and formulations of batoclimab, has a statutory projected expiration date in 2044 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The patent family directed to formulations for anti-FcRn antibodies has a statutory projected expiration date in 2045 in the U.S. and in foreign jurisdictions, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Given the amount of time required for the development, testing and regulatory review of any new product candidate, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property rights in the U.S. and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. Depending upon the timing, duration and specifics of FDA marketing approval of IMVT-1402, batoclimab or other product candidates that we may identify, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA premarket regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries, including the EU where it is known as a Supplementary Protection Certificate ("SPC"), upon regulatory approval of our product candidates, based on similar legislation. Nevertheless, we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

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

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

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

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

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

We have licensed certain intellectual property rights, including certain intellectual property rights covering IMVT-1402 and batoclimab from HanAll. We depend, and will continue to depend, on the HanAll Agreement for the rights to develop, manufacture and commercialize our product candidates. If, for any reason, the rights granted to us under the HanAll Agreement are terminated or we otherwise lose those rights, it would adversely affect our business. The HanAll Agreement also 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 materially breach any of those 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 HanAll Agreement, which could result in us being unable to develop, manufacture and sell products that are covered by the HanAll Agreement or having to negotiate new or reinstated licenses on less favorable terms or enable a competitor to gain access to the licensed technology.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and fee payment during the life of a patent. While an inadvertent lapse in compliance with these provisions 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, underpayment or non-payment of fees and failure to properly legalize and submit formal documents within the prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering batoclimab, IMVT-1402 or any of our future product candidates, our competitors might be able to enter the market earlier than anticipated, which would have an adverse effect on our business.

We may 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.

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development of any of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize batoclimab, IMVT-1402 or any future product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. If we are unable to obtain a license, we may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible.

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

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have an adverse effect on the price of shares of our common stock. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock. The occurrence of any of these events may have an adverse effect on our business, results of operation, financial condition or cash flows.

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

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

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

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

If we fail to identify or correctly interpret relevant patents to which we do not have a license or we are unable to obtain a license, 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, the infringer may file an appeal and the district court judgment may be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents.

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

Third parties may also raise similar unpatentability claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of unpatentability is unpredictable. We cannot be certain that there is no prior art of which we and the patent examiner were unaware during prosecution and which renders the claims unpatentable or invalid. 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 unpatentability, invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on batoclimab, IMVT-1402 or any future product candidates. Such a loss of patent protection could harm our business.

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

Even if we establish a party has infringed our intellectual property rights, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock.

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

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

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

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

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

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

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

In addition to seeking patents for our product candidate, we also rely, and will continue to 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 and information 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 and having an adverse effect on our business.

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

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

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

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

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

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

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

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.

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

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

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 IMVT-1402 or future product candidates but that are not covered by the claims of the patents that we own or have licensed;
- others may be able to make a product that is similar to our product candidates and not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we, our licensor or any collaborators might not have been the first to file patent applications covering certain of our or our licensor's inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- patents that we own or have exclusively licensed may not provide us with any competitive advantage or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

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

General Risks Related to an Investment in Our Securities

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

As of May 14, 2026, RSL beneficially owned approximately 55.2% of the voting power of our outstanding shares of common stock. Therefore, we are controlled by RSL and RSL has the ability to substantially influence us and exert significant control through this ownership position. It is possible RSL may be able to control elections of directors, the issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL is publicly traded and its interests may not always coincide with our corporate interests or the interests of other stockholders and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. There may be changes to the management or ownership of RSL, or to RSL's business model, that could impact RSL's interests in a way that may not coincide with our corporate interests or the interests of other stockholders. Any such changes may diminish or eliminate entirely any benefits we expect to derive from our membership in the Roivant family of companies. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

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

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

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

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

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

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

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

- results of clinical trials for IMVT-1402 or any future product candidate or those of our competitors;
- sales of shares of our common stock by us or sales or purchases of our common stock by our stockholders in the future, including RSL;
- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- any delay in filing a BLA or similar application for IMVT-1402 or any future product candidate and any adverse development or perceived adverse development with respect to the FDA or other foreign regulatory authority's review of that BLA or similar application, as the case may be;

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

Certain shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered or intend to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance once vested, subject to volume limitations applicable to affiliates. In addition, certain of our directors, executive officers and certain affiliates have established, or may establish, programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, or if it is perceived that a large number of our shares will be sold, the market price of our common stock could decline.

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

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

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, in February 2021, a securities class action complaint was filed against us, certain of our officers and a board member of HSAC alleging violations of the Exchange Act. In April 2024, the court overseeing the litigation entered judgment in favor of the defendants. Plaintiffs did not appeal the court's judgment, so the litigation is now concluded. Any future securities litigation could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

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

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

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

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

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

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

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

We have never declared or paid any cash dividends on shares of our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of shares of our common stock would be your sole source of gain on an investment in shares of our common stock for the foreseeable future.

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

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

If we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm 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 the capital markets.

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

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

Our wholly owned subsidiary, 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 UK and, under current UK tax law, a company which is centrally managed and controlled in the UK is regarded as resident in the UK for taxation purposes. Accordingly, we expect ISL to be subject to UK taxation on its income and gains and subject to the UK's controlled foreign company rules, except where an exemption applies. ISL may be treated as a dual resident company for UK tax purposes. As a result, ISL's right to claim certain reliefs from UK tax may be restricted, and changes in law or practice in the UK could result in the imposition of further restrictions on ISL's right to claim UK tax relief. 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.

Our 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 UK. Further, we currently have other subsidiaries that are domiciled in the UK, Switzerland and the U.S. If any of our product candidates receive approval by applicable regulatory bodies, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions where such approvals have been granted, in part through intercompany service agreements between us, our parent company and our subsidiaries. In that case, we anticipate that 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 and determinations are not binding on applicable tax authorities. If tax authorities in any country were to successfully challenge our transfer pricing procedures and determinations as not reflecting arms' length transactions, they could require us to adjust our transfer pricing procedures and determinations and thereby could require us to 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 could increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which an ultimate tax determination is uncertain. As such, there can be no assurance that the relevant taxing authorities will not assert that the actual tax treatment of such transactions differs from our intended tax treatment. The application of tax laws across countries and taxing jurisdictions 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 arms' length standard is applied for transfer pricing purposes or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. Moreover, certain relevant tax, accounting and other laws have special application with respect to "affiliated," "combined" or similar groups, which may include RSL, ISL and their respective subsidiaries and which may impact the tax liabilities of the companies. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice or tax positions are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could harm our financial condition, results of operations and cash flows.

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

New income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect us. Further, our tax position could be adversely impacted by changes in existing tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the UK and Switzerland), the U.S., Bermuda and other jurisdictions as well as being affected by certain international tax developments, including certain changes currently proposed by the Organization for Economic Co-operation and Development ("OECD") and their action plan on Base Erosion and Profit Shifting ("BEPS"), as well as other initiatives led by the OECD and the European Commission. For example, the OECD continues to lead work on proposals, commonly referred to as "BEPS 2.0", which, to the extent implemented, would make important changes to the international tax system. These proposals are based on two "pillars", involving the allocation of taxing rights in respect of certain multinational enterprises above a fixed profit margin to the jurisdictions in which they carry on business (referred to as the Pillar One rules) and imposing a minimum effective tax rate on certain multinational enterprises (referred to as the Pillar Two rules). A number of countries in which we have group entities or conduct business (including, the UK, Switzerland and Bermuda) have enacted, or are in the process of enacting, core elements of the Pillar Two rules. We may face an increase in our tax obligations under the OECD BEPS 2.0, which could also require us to incur additional costs to ensure compliance with any such rules in the countries where we do business or have group entities.

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

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

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

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

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

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

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

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

- provide that the number of directors is set at seven and may only be changed by resolution of the board of directors, including a majority of Series A Preferred Directors then serving;
- prohibit cumulative voting in the election of directors; and
- provide that, subject to the rights of our Series A preferred stockholder, vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

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

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

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law (the "DGCL"), our Certificate of Incorporation or our Bylaws; any action as to which DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended (the "Securities Act") creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established certain processes designed to assess, identify and manage cybersecurity risks, which are built into our information technology functions and are designed to help protect our information assets and operations from internal and external cyber threats. Our cybersecurity risk management processes target integral areas such as data protection, access control, incident response and vulnerability management and are integrated into our overall enterprise risk management process. As part of our overall enterprise risk management process, our company's information technology functions, including our Information Technology department leaders and third-party service providers, identify, assess and evaluate cybersecurity risks impacting our operations across the Company.

Depending on the information systems and environment, our cybersecurity program includes various administrative, physical, and technical safeguards designed to manage and mitigate material risks from cybersecurity threats, including, for example: an incident response plan, incident detection and response, disaster recovery plan, risk assessments, encryption of data, network security controls, data segregation, access controls, physical security, systems monitoring, a vendor risk management program, penetration testing, cybersecurity insurance, dedicated cybersecurity staff, and asset management, tracking and disposal. Additionally, we provide all employees, including part-time and temporary employees, with annual and ad hoc cybersecurity awareness training.

Our information technology functions identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods, including internal and external audits, penetration and vulnerability tests, automated tools, subscriptions to reports and services that identify cybersecurity threats, analysis of reports of threats and actors, use of external intelligence feeds, evaluations of our and our industry's risk profile, evaluation of threats reported to us, threat assessments for internal and external threats, scans of internal systems for threats and incident response simulations (including third-party-conducted tabletop incident response exercises). We engage certain external service providers, including consultants, independent privacy assessors and computer security firms, as appropriate, to assess, test or otherwise assist with aspects of our security controls, including cybersecurity incident containment and remediation efforts, and enhance our cybersecurity oversight. We also use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example penetration testing firms, cybersecurity consultants, forensic investigators, cybersecurity software providers, managed cybersecurity service providers and professional services firms (including legal counsel).

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors and supply chain resources. With respect to our use and oversight of third-party service providers, we use a risk-based approach to apply our cybersecurity processes according to the nature and sensitivity of the data accessed, processed, or stored by such third-party service provider and perform additional risk screenings and procedures, as appropriate. We use a number of means to assess cyber risks related to our third-party service providers, including risk assessments for each vendor, vendor security questionnaires and due diligence in connection with onboarding new vendors and ongoing reviews and due diligence with key or high-risk third-party vendors. We also seek to collect and assess cybersecurity audit reports and other supporting documentation when available and include appropriate security terms in our contracts where applicable as part of our oversight of third-party providers.

For additional information regarding cybersecurity risks and their potential impacts on our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A. Risk Factors in this Annual Report, including the risk factor captioned "*We and the third parties with whom we work are subject to stringent and changing privacy, data protection, and information security laws, contractual obligations, self-regulatory schemes, government regulation, industry standards and other obligations related to data privacy and security. The actual or perceived failure by us or the third parties with whom we work to comply with such obligations could result in harm to our reputation, regulatory investigations or actions, significant fines and liability, disruption of our clinical trials or other material adverse effects on our business.*"

Governance

The Audit Committee of our Board of Directors oversees our cybersecurity and data privacy risk management activities, and reports to the Board regarding such oversight as appropriate. The Audit Committee receives updates from management regarding cybersecurity matters not less than twice per year, and is notified between such updates regarding any significant new cybersecurity threats or incidents.

Our Vice President of Information Technology and Facilities, together with our Head of Cybersecurity, is responsible for the operational oversight of our enterprise cybersecurity strategy, including the development and implementation of policies, standards, and processes designed to identify, assess and manage cybersecurity risks. These leaders work in coordination with cross-functional stakeholders to support enterprise risk management activities and to enhance the organization's preparedness to prevent, detect, and respond to cybersecurity incidents. Our Vice President of Information Technology and Facilities has over 25 years of experience in information technology leadership, including within life sciences organizations. His experience includes the implementation and operation of enterprise systems supporting research and development, clinical, and commercial functions, as well as the management of infrastructure, cloud-based software solutions, and data integration platforms. He has also been involved in supporting technology capabilities associated with commercialization activities and regulated environments. In addition, he has over ten years of experience incorporating cybersecurity considerations into enterprise systems, risk management practices, and operational processes.

Our Head of Cybersecurity has approximately 15 years of experience in cybersecurity and holds Certified Information Security Manager (CISM), Certified Information Systems Security Professional (CISSP), and Certified in Risk and Information Systems Controls (CRISC) certifications.

In the event of a cybersecurity incident, we maintain a cybersecurity incident response plan designed to govern the actions required for responding to and reporting security incidents involving our information assets, including by escalating certain incidents to members of management, including the Vice President of Information Technology and Facilities and the Head of Cybersecurity. Pursuant to the plan and its escalation protocols, and depending on the nature, severity and other circumstances of each potential cybersecurity incident, designated personnel may be responsible for assessing the severity of an incident and associated threat, containing the threat, remediating the threat, including recovery of data and access to systems, analyzing any reporting obligations associated with the incident, and performing post-incident analysis.

Item 2. Properties

We conduct business operations at 1000 Park Forty Plaza, Suite 210, Durham, North Carolina 27713. ISL's registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda and ISL's principal office is located at 7th Floor, 50 Broadway, London, SW1H 0DB. ISG conducts business operations at Viaduktstrasse 8, 4051 Basel, Switzerland.

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

Item 3. Legal Proceedings

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

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

Holders of Record

Continental Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on May 14, 2026, we had three holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

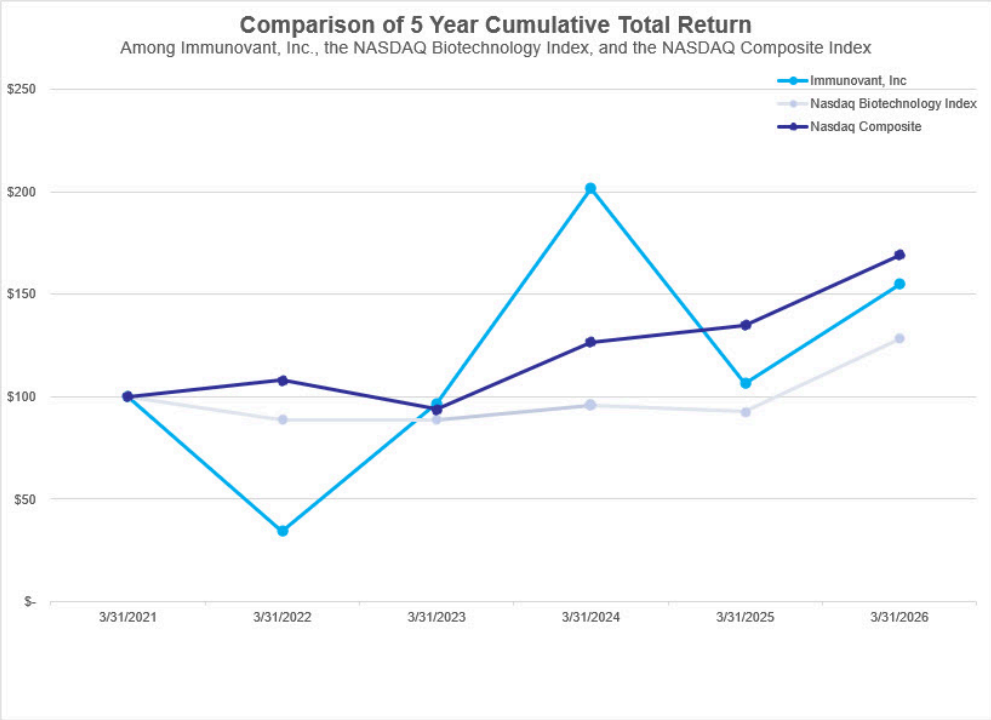
Dividend Policy

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

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act.

The following graph shows a comparison from March 31, 2021 through March 31, 2026 of the cumulative total return for an investment of $100 in our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index and assumes the reinvestment of dividends. The returns shown are based on historical results and are not intended to suggest future performance.



Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

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

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

Overview

Immunovant, Inc. ("Immunovant," "we" or the "Company") is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. Our focus is on developing IMVT-1402, a potentially best-in-class inhibitor of the neonatal fragment crystallizable receptor ("FcRn"), to address autoimmune diseases driven by high levels of pathogenic immunoglobulin G ("IgG") antibodies. FcRn is involved in preventing the degradation of IgG antibodies, and inhibition of FcRn has been shown to reduce levels of total IgG and pathogenic IgG antibodies.

We believe that FcRn inhibition has broad therapeutic and commercial potential to address pathogenic IgG-mediated autoimmune diseases in several therapeutic areas, including but not limited to, endocrinology, neurology, rheumatology and dermatology. Third-party estimates suggest over four million patients in the United States and Europe could benefit from anti-FcRn treatments across more than 20 indications that have been publicly announced for research and development by multiple companies, with two indications that are already approved and launched quickly reaching multi-billions of dollars in global annual sales.

Consistent evidence observed across the class in eight indications in Phase 2 and 3 trials with FcRn inhibitors has indicated that deeper IgG reductions correlate with meaningful improvements in clinical outcomes. This has also been validated with Immunovant's own Phase 2 and 3 studies evaluating its first-generation anti-FcRn antibody, batoclimab, in Graves' disease ("GD"), myasthenia gravis ("MG") and chronic inflammatory demyelinating polyneuropathy ("CIDP") which showed that IgG reductions of greater than or equal to 70% led to meaningfully better outcomes compared to reductions below 70% across a range of clinical measures.

In a Phase 1 clinical trial, healthy adults dosed with IMVT-1402 showed deep, dose-dependent IgG reductions. We expect to be able to reach approximately 80% IgG reductions with continued weekly dosing of 600 mg of IMVT-1402, offering deeper IgG reductions than observed with other competitor anti-FcRn programs, therefore representing a potential best-in-class opportunity. In the Phase 1 clinical trial, across all evaluated doses, IMVT-1402 demonstrated no or minimal reductions in albumin and no or minimal increases in LDL cholesterol levels, which are off-target effects observed in some anti-FcRn antibodies, including batoclimab. We believe IMVT-1402's profile has the potential to offer best-in-class efficacy, in addition to its potentially favorable safety profile and convenient administration with a simple self-administered auto-injector expected at launch.

We are currently progressing a broad set of programs for IMVT-1402 and have ongoing studies in six indications, including potentially registrational trials in GD, difficult-to-treat rheumatoid arthritis ("D2T RA"), MG, CIDP and Sjögren's disease ("SjD"), and a proof-of-concept trial in cutaneous lupus erythematosus ("CLE"). Our primary focus is to execute these six indications first, with plans to assess new indications for IMVT-1402 in the future. All studies evaluating IMVT-1402 are being conducted using the intended commercial drug formulation and delivery device, the YpsoMate® autoinjector developed by Ypsomed AG, which is utilized for multiple approved products.

IMVT-1402 and batoclimab are fully human monoclonal antibodies that target FcRn. These antibodies are the result of a multi-step, multi-year research program conducted in collaboration with HanAll to design highly potent anti-FcRn antibodies that may be optimized as a simple, subcutaneous injection with dosing that has been shown to deliver better efficacy at the high dose and similar efficacy at the low dose compared to standard FcRn inhibition by competitors.

In April 2026, we announced top-line results from two Phase 3 clinical studies evaluating batoclimab as an investigational treatment for adults with active, moderate-to-severe thyroid eye disease ("TED"), neither of which met the primary endpoint. The safety profile observed in these studies was consistent with prior batoclimab studies, with no new safety signals identified. Following these results, we made a decision to discontinue further development of batoclimab across all indications to focus fully on IMVT-1402. Learnings from the batoclimab program, including clinical data, operational trial experience, and relationships with investigators, have been and continue to be leveraged to inform the development of IMVT-1402.

Recent Developments in Our Clinical Programs

Endocrine Diseases

IMVT-1402 Trials in GD

In December 2024 and June 2025, we initiated two potentially registrational trials (NCT06727604 and NCT07018323, respectively) evaluating IMVT-1402 in adults with GD. We expect to report top-line results from these trials in calendar year 2027.

Proof-of-Concept Trial with Batoclimab in GD

We initially tested the potential of FcRn inhibition for the treatment of GD in a Phase 2 proof-of-concept trial (NCT05907668) evaluating our first-generation FcRn inhibitor, batoclimab.

The study included a 24-week batoclimab treatment period with a dose step-down midway through the treatment period (Weeks 0-12 at 680 mg weekly ("QW") subcutaneously ("SC") and Weeks 13-24 at 340 mg QW SC), followed by a 24-week off-treatment follow-up period. The study enrolled participants with active GD as documented by presence of elevated TRAb and who were hyperthyroid despite current treatment with standard of care ATD therapy. The primary endpoint of the study measured response as the proportion of participants who at Week 24 achieved normalization of free triiodothyronine ("T3") and free thyroxine ("T4"), or have T3/T4 below the lower limit of normal ("LLN"), without an increase in ATD dose from baseline. A total of 25 subjects were enrolled in the treatment period, and 21 subjects entered the 24-week off-treatment follow-up period and could be assessed for maintenance of response. In data previously disclosed in September 2024 that was reanalyzed to include an additional patient who discontinued prior to Week 12 but remained in off-drug follow-up, at the end of the first 12 weeks, a mean IgG reduction of 77% and an 80% response rate (defined as T3 and T4 falling below the upper limit of normal ("ULN") without increasing the ATD dose) were observed. 60% of subjects treated with higher dose batoclimab were observed to have an ATD-Free Response (defined as T3 and T4 falling below the ULN and the patient simultaneously tapering completely off their ATD) at the end of the first 12 weeks. During weeks 13 to 24, patients receiving lower dose batoclimab were observed to have mean IgG reduction of 65% with a correspondingly lower responder rate of 72% and a lower ATD-Free Response rate of 40% at the end of the second 12 weeks. Patients who were observed to have at least a 70% IgG reduction at the end of the evaluation period had nearly a threefold higher ATD-Free Response rate than those who did not (64% vs. 23%).

Six-month off-treatment data was presented at the American Thyroid Association Annual Meeting in September 2025. At completion of the follow-up period at Week 48 (i.e., subjects off-treatment for 24 weeks), approximately 80% (17/21) of those subjects maintained T3/T4 values ≤ upper limit of normal ("ULN"), suggestive of strong durability of the response observed at Week 24 as evaluated at approximately six months off treatment at Week 48. Of these 17 subjects, approximately 50% (8/17) were ATD-free and an additional approximately 30% (5/17) were on ATD doses of 2.5 mg/day at six months off batoclimab treatment. Total IgG and TRAb levels declined through Week 24, consistent with previous observations, and while total IgG rebounded after treatment ended, pathogenic TRAb levels remained suppressed at Week 48. Safety and tolerability were observed to be consistent with prior batoclimab studies.

This study is now completed, with its data suggesting the potential of FcRn inhibition for the treatment of GD by modifying the underlying disease pathology, which is driven by TRAb. As such, GD is a key strategic priority for our development of IMVT-1402.

Neurological Diseases

IMVT-1402 Trial in MG

In March 2025, we initiated a potentially registrational trial (NCT07039916) evaluating IMVT-1402 in adults with MG. This trial is a randomized, placebo-controlled, 26-week trial. We expect to report top-line results from this trial in calendar year 2027.

IMVT-1402 Trial in CIDP

In March 2025, we initiated a potentially registrational trial (NCT07032662) evaluating IMVT-1402 in adults with CIDP. This trial is a randomized, placebo-controlled, 24-week trial in participants with active CIDP. We expect to report top-line results from this trial in calendar year 2028.

Rheumatology Diseases

IMVT-1402 Trial in D2T RA

In December 2024, we initiated a potentially registrational trial (NCT06754462) evaluating IMVT-1402 in anti-citrullinated protein autoantibody ("ACPA") positive D2T RA.

The trial is currently ongoing and has enrolled a total of 170 participants in Period 1. At the completion of Period 1, 165 of the 170 enrolled patients were evaluable for ACR20 response to determine eligibility to continue to Period 2 and the primary efficacy analysis for the study. The enrollment inclusion criteria described above resulted in a heavily pretreated population: 86.7% (143/165) had failed two prior mechanisms of advanced therapies (i.e., biologic or targeted synthetic DMARDs), and the mean time from disease diagnosis was 12.8 years. Baseline disease activity was high, with a mean of 24.2 tender joints, 16.7 swollen joints, and DAS28-CRP score of 6.1.

At Week 16, the ACR20, ACR50, and ACR70 response rates observed were 72.7%, 54.5%, and 35.8%, respectively; participants who discontinued prior to Week 16 were imputed as non-responders. Among the subset of participants who had failed at least a JAK inhibitor and an anti-TNF inhibitor (N=107), the ACR20, ACR50, and ACR70 response rates observed at Week 16 were 72.0%, 53.3%, and 37.4%, respectively. ACR20 response is defined as a $\geq$ 20% improvement from baseline in tender joint count and swollen joint count and a $\geq$ 20% improvement from baseline in at least 3 of 5 additional clinical parameters. Similarly, ACR50 and ACR70 responses are a calculation of 50% or 70% improvement, respectively, in the number of swollen and tender joints and 3 of 5 assessment parameters.

Period 1 was conducted in an open-label setting, with joint assessments performed by independent assessors blinded to treatment status to control for the potential for assessor bias in the response measures. IMVT-1402 was observed to be safe and well-tolerated in Period 1, and no new drug-related safety signals were identified. Study participants meeting the criteria for an ACR20 response at Week 16 are eligible to advance to Period 2 of the trial, where the primary endpoint will be assessed at Week 28. Further updates on this program are expected in the second half of calendar year 2026.

IMVT-1402 Trial in SjD

In June 2025, we initiated a potentially registrational trial (NCT06979531) evaluating IMVT-1402 in SjD. We expect to report top-line results from this trial in calendar year 2028.

Dermatology Diseases

IMVT-1402 Proof-of-Concept Trial in CLE

In February 2025, we initiated a proof-of-concept trial (NCT6980805) evaluating IMVT-1402 in CLE. We expect to report top-line results from this trial in the second half of calendar year 2026.

For more information on our clinical trials, refer to Part I, Item 1. Business, "*Overview.*"

Macroeconomic Considerations

Unfavorable conditions in the economy in the U.S., Canada and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including changes in inflation and interest rates, changes in international trade policies and tariffs and geopolitical tensions, such as the Russia-Ukraine war and conflicts in the Middle East, including the recent hostilities involving Iran, have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

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

Our Key Agreements

License Agreement with HanAll ("HanAll Agreement")

We have commenced discussions with HanAll regarding the future disposition of batoclimab, including the potential return to HanAll of certain rights for batoclimab. In April 2026, we notified HanAll of our decision to indefinitely delay further development of batoclimab and focus our resources fully on IMVT-1402. Under the HanAll Agreement, we retain final decision-making authority over development and regulatory matters for licensed products in our Licensed Territory, and we believe we have satisfied our obligations under the HanAll Agreement, including with respect to batoclimab. HanAll may disagree with our interpretation of the agreement or our actions thereunder, and we may be unable to reach an agreement with HanAll regarding the future of batoclimab. This could result in a dispute with HanAll involving arbitration or litigation.

For a description of our transactions under the HanAll Agreement, refer to Part II, Item 8. Financial Statements and Supplementary Data, Note 3 – Material Agreements.

Related Party Transactions

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

Financial Operations Overview

Revenue

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

Research and Development Expenses

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

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

Unallocated costs include:

- personnel-related expenses, such as salaries, stock-based compensation and benefits, for research and development personnel;
- costs allocated to us under our services agreements with Roivant Sciences Ltd. ("RSL") and Roivant Sciences GmbH ("RSG") (the "Services Agreements");
- contractual costs related to discontinued batoclimab programs; and
- other expenses, which include the cost of consultants and information technology related to our research and development but are not allocated to a specific therapeutic area.

Research and development activities will continue to be central to our business model. We expect to incur research and development expenses with respect to our IMVT-1402 development activities and we have ongoing clinical trials evaluating IMVT-1402 in GD, D2T RA, MG, CIDP, SjD and CLE. We expect to continue to incur research and development expenses over the next several years as we execute IMVT-1402 trials, manufacture IMVT-1402 and prepare to seek regulatory approval. It is not possible to determine with certainty the duration and completion costs of any clinical trial we may conduct.

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

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory authorities;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals;
- the potential impact of macroeconomic events, including changes in inflation, interest rates and international trade policies and tariffs and geopolitical tensions, such as the Russia-Ukraine war and the conflicts in the Middle East, including the recent hostilities involving Iran;
- the efficacy and safety profile of the product candidate; and
- the cost of manufacturing.

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

Acquired In-Process Research and Development Expenses

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will continue to support our ongoing research and development activities. These expenses will likely include patent-related costs, including legal and professional fees for filing, prosecution and maintenance of patents and patent applications claiming our product candidates and fees to outside consultants for professional services. In addition, if IMVT-1402 or any other product candidate obtains regulatory approval, we expect that we would incur significant additional expenses associated with market research activities and building commercial teams.

Results of Operations

Comparison of the Years Ended March 31, 2026, 2025 and 2024

The following table sets forth our results of operations for the years ended March 31, 2026, 2025 and 2024 (in thousands):

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
Operating expenses:					
Research and development	$ 456,660	$ 360,917	$ 212,928	$ 95,743	$ 147,989
Acquired in-process research and development	—	—	12,500	—	(12,500)
General and administrative	76,242	77,235	57,281	(993)	19,954
Total operating expenses	532,902	438,152	282,709	94,750	155,443
Interest income, net	(25,330)	(24,732)	(24,948)	(598)	216
Other (income) expense, net	(2,181)	(471)	1,008	(1,710)	(1,479)
Loss before provision for income taxes	(505,391)	(412,949)	(258,769)	(92,442)	(154,180)
Provision for income taxes	215	891	567	(676)	324
Net loss	**$ (505,606)**	**$ (413,840)**	**$ (259,336)**	**$ (91,765)**	**$ (154,504)**

Research and Development Expenses

The following table summarizes the year-over-year changes in research and development expenses for the years ended March 31, 2026, 2025 and 2024 (in thousands):

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
Therapeutic area-specific costs:					
Endocrine diseases	$ 90,359	$ 63,073	$ 33,205	$ 27,286	$ 29,868
Neurological diseases	82,515	93,224	41,060	(10,709)	52,164
Rheumatology diseases	48,813	23,897	—	24,916	23,897
Dermatology diseases	20,264	15,633	—	4,631	15,633
Other clinical and nonclinical	3,367	9,327	39,811	(5,960)	(30,484)
Total therapeutic area-specific costs	**245,318**	**205,154**	**114,076**	**40,164**	**91,078**
Unallocated costs:					
Personnel-related expenses including stock-based compensation	128,534	111,499	74,290	17,035	37,209
Contractual costs related to batoclimab program discontinuation	38,952	—	—	38,952	—
Other	43,856	44,264	24,562	(408)	19,702
Total research and development expenses	**$ 456,660**	**$ 360,917**	**$ 212,928**	**$ 95,743**	**$ 147,989**

Fiscal 2026 vs. Fiscal 2025

For the year ended March 31, 2026, research and development expenses increased $95.7 million as compared with the prior year.

For the year ended March 31, 2026, therapeutic area-specific research and development costs, including contract manufacturing costs, increased $40.2 million as compared with the prior year. Research and development costs related to endocrine diseases, which include GD and TED, increased $27.3 million. This increase was primarily due to our ongoing clinical trials of IMVT-1402 in endocrine diseases, partially offset by lower overall clinical trial costs related to our batoclimab clinical trials. Research and development costs related to neurological diseases, which include MG and CIDP, decreased $10.7 million, primarily due to lower overall clinical trial costs related to our batoclimab Phase 3 and Phase 2b clinical trials, partially offset by clinical trial costs related to our clinical trials of IMVT-1402 in neurological diseases. Research and development costs related to rheumatology diseases increased $24.9 million, reflecting expenses incurred with our clinical trials of IMVT-1402 in D2T RA and SjD. Research and development costs related to dermatology diseases increased $4.6 million, reflecting the initiation of our proof-of-concept trial in CLE. Research and development costs related to other clinical and nonclinical activities decreased $6.0 million, primarily reflecting the transition of IMVT-1402 clinical activities targeting specific therapeutic areas.

For the year ended March 31, 2026, unallocated research and development costs increased $55.6 million as compared with the prior year. This increase included the impact of costs incurred in connection with batoclimab discontinuation of $39.0 million, as well as higher personnel-related expenses of $17.0 million, reflecting a higher average headcount to execute an increased number of clinical trials.

Fiscal 2025 vs. Fiscal 2024

For the year ended March 31, 2025, research and development expenses increased $148.0 million as compared with the prior year.

For the year ended March 31, 2025, therapeutic area-specific research and development costs, including contract manufacturing costs, increased $91.1 million as compared with the prior year. Research and development costs related to endocrine diseases, which include GD and TED, increased $29.9 million. This increase was primarily due to preparation and initiation of our clinical trial of IMVT-1402 in endocrine diseases and higher overall clinical trial costs related to our batoclimab Phase 3 clinical program. Research and development costs related to neurological diseases, which include MG and CIDP, increased $52.2 million. This increase was primarily due to preparation for our clinical trials of IMVT-1402 in neurological diseases and higher overall clinical trial costs related to our batoclimab Phase 3 and Phase 2b clinical trials. Research and development costs related to rheumatology diseases of $23.9 million in fiscal 2025 reflected the initiation of our clinical trial of IMVT-1402 in D2T RA, as well as preparation for our clinical trial of IMVT-1402 in SjD. Research and development costs related to dermatology diseases of $15.6 million in fiscal 2025 reflected the initiation of our proof-of-concept trial in CLE. Research and development costs related to other clinical and nonclinical activities decreased $30.5 million, reflecting the current year transition to clinical activities targeting specific therapeutic areas, as well as lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies.

For the year ended March 31, 2025, unallocated research and development costs increased $56.9 million as compared with the prior year. This increase reflected higher personnel-related expenses of $37.2 million, driven by higher headcount and enhancement of our capabilities to support our strategic objectives as we progress our clinical activities. In addition, other expenses increased $19.7 million, primarily reflecting higher costs to support our research and development activities to advance the clinical development of IMVT-1402 that are not related to a specific therapeutic area.

Acquired In-Process Research and Development Expenses

There were no acquired in-process research and development expenses for the years ended March 31, 2026 and March 31, 2025. During the year ended March 31, 2024, acquired in-process research and development expenses were $12.5 million related to the achievement of our third and fourth development and regulatory milestone events for batoclimab under the terms of the HanAll Agreement.

General and Administrative Expenses

For the year ended March 31, 2026, general and administrative expenses decreased $1.0 million from the year ended March 31, 2025, primarily reflecting lower information technology costs and market research costs, partially offset by higher personnel-related expenses, including stock-based compensation. For the year ended March 31, 2025, general and administrative expenses increased $20.0 million from the year ended March 31, 2024, primarily reflecting higher personnel-related expenses, professional fees, information technology costs and market research costs.

Interest Income, net

For the year ended March 31, 2026, interest income, net increased $0.6 million as compared with the year ended March 31, 2025, primarily reflecting higher average money market balances, partially offset by slightly lower interest rates on our money market balances. For the year ended March 31, 2025, interest income, net decreased $0.2 million as compared with the year ended March 31, 2024, primarily reflecting lower average money market balances throughout the year, mostly offset by interest earned on money market fund balances as a result of the proceeds from our January 2025 private placement.

Liquidity and Capital Resources

Sources of Liquidity

We had cash and cash equivalents of $902.1 million and $714.0 million as of March 31, 2026 and 2025, respectively. For the years ended March 31, 2026, 2025 and 2024, we had net losses of $505.6 million, $413.8 million and $259.3 million, respectively. We expect to continue to incur significant expenses 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-1402 or any future product candidate.

To date, we have financed our operations primarily from equity offerings. Until such time, if ever, as we can generate substantial product revenue from sales of IMVT-1402 or any other product candidate, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the continuing disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide, disruptions resulting from geopolitical tensions, including the ongoing military conflicts between Russia and Ukraine and in the Middle East, including the recent hostilities involving Iran, and changes in inflation, interest rates and international trade policies and tariffs.

We do not currently have any committed external source of funds. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We have a sales agreement with Leerink Partners LLC (“Leerink Partners”), as sales agent, pursuant to which we may offer and sell, from time to time, shares of our common stock (the “ATM Shares”), subject to certain conditions as specified in the sales agreement. We agreed to pay Leerink Partners up to 3% of the gross proceeds from each sale of ATM Shares sold through the sales agreement. The ATM Shares would be sold at prevailing market prices at the time of the sale and, as a result, prices may vary. The ATM Shares to be sold under the sales agreement, if any, would be issued and sold pursuant to an automatic shelf registration statement on Form S-3, which we filed with the SEC on November 9, 2023, along with a prospectus supplement relating to the offer and sale of up to $150.0 million of ATM Shares pursuant to the sales agreement. We have not issued or sold any ATM Shares pursuant to the ATM offering program.

In December 2025, we completed an underwritten offering of 26,200,000 shares of our common stock (including 16,666,666 shares of common stock purchased by RSL on the same terms as other investors in the offering) at an offering price of $21.00 per share. The underwriter did not receive any underwriting discounts or commissions with respect to shares sold to RSL in the offering. The net proceeds to us were $543.7 million after deducting underwriting discounts and commissions and other offering expenses.

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

Cash Flows

The following table sets forth a summary of our cash flows for the years ended March 31, 2026, 2025 and 2024 (in thousands):

	Years Ended March 31,		
	2026	2025	2024
Net cash used in operating activities	$ (407,310)	$ (375,874)	$ (214,227)
Net cash used in investing activities	(8)	(759)	(360)
Net cash provided by financing activities	595,756	454,492	472,427

Operating Activities

For the year ended March 31, 2026, $407.3 million of cash was used in operating activities, primarily reflecting a net loss from operations for the year of $505.6 million, partially offset by non-cash charges of $56.2 million and a net change in operating assets and liabilities of $42.1 million. The non-cash charges consisted mainly of stock-based compensation of $55.7 million, reflecting the higher average headcount and incentive equity awards as compared with the prior year. The change in operating assets and liabilities primarily reflected an increase in accrued expenses of $45.0 million, which includes $39.0 million for charges related to batoclimab discontinuation, as well as $6.0 million reflecting the timing of payments and services related to our ongoing clinical trials and contract manufacturing. Other changes in operating assets and liabilities, including lower prepaid and other current assets of $8.8 million and a decrease in accounts payable of $10.3 million, were driven mostly by the timing of payments and services related to our ongoing clinical trials.

For the year ended March 31, 2025, $375.9 million of cash was used in operating activities, primarily reflecting a net loss from operations for the year of $413.8 million and a net change in operating assets and liabilities of $12.1 million, partially offset by non-cash charges of $50.0 million. The non-cash charges consisted mainly of stock-based compensation of $49.5 million, reflecting the higher headcount and incentive equity awards as compared with the prior year. The change in operating assets and liabilities reflected higher prepaid expenses and other current assets of $27.0 million, driven primarily by the timing of payments and services performed related to our ongoing and planned clinical trials, as well as an increase in other assets of $7.7 million as a result of prepaid expenses related to planned contract manufacturing activities. These changes were partially offset by an increase in accounts payable of $10.7 million, primarily related to clinical trial costs. Accrued expenses increased $8.9 million, primarily reflecting the timing of payments and services related to our ongoing clinical trials and contract manufacturing. In addition, accounts receivable decreased $3.2 million, reflecting the collection of amounts owed to us under research and development cost-sharing arrangements with a third party.

For the year ended March 31, 2024, $214.2 million of cash was used in operating activities, primarily reflecting a net loss from operations for the year of $259.3 million, partially offset by non-cash charges of $42.5 million and a net change in operating assets and liabilities of $2.6 million. The non-cash charges consisted mainly of stock-based compensation of $41.1 million, reflecting the higher headcount and incentive equity awards as compared with the prior year. The change in operating assets and liabilities reflected an increase in accounts payable and accrued expenses of $7.1 million, primarily reflecting the timing and level of payments for contract manufacturing and other research and development costs, and lower prepaid expenses and other current assets of $1.6 million, driven primarily by the timing of payments and services performed related to our ongoing clinical trials. These changes were partially offset by an increase in accounts receivable of $4.6 million, reflecting amounts owed to us under a research and development cost-sharing arrangement with a third party.

Investing Activities

For the years ended March 31, 2026, 2025 and 2024, cash used in investing activities was related to the purchase of property and equipment.

Financing Activities

For the year ended March 31, 2026, $595.8 million of cash provided by financing activities primarily consisted of net proceeds from our December 2025 underwritten offering of $543.7 million, after deducting underwriting discounts and commissions and other offering expenses. Cash provided by financing activities also reflected $52.1 million of proceeds from the exercise of stock options, primarily from our former executive officers.

For the year ended March 31, 2025, $454.5 million of cash provided by financing activities primarily consisted of proceeds from our January 2025 private placement of $450.0 million. Cash provided by financing activities also reflected $4.8 million of proceeds from the exercise of stock options.

For the year ended March 31, 2024, $472.4 million of cash provided by financing activities primarily consisted of proceeds from our October 2023 underwritten public offering and concurrent private placement of $466.7 million, combined, after deducting underwriting discounts and commissions, placement agent fees and offering expenses. Cash provided by financing activities also reflected $5.7 million of proceeds from the exercise of stock options.

Material Cash Requirements

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

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

Our short-term and long-term material cash requirements as of March 31, 2026 primarily consisted of those related to our clinical trials and clinical development activities, which we expect to fund primarily with our existing cash balance. Our most significant cash requirements are described below:

Commitments

As of March 31, 2026, we had an accumulated accrual of $42.5 million of non-cancelable contractual costs recognized in connection with the discontinuation of batoclimab, of which $39.0 million was recognized as research and development expenses during the year ended March 31, 2026.

We enter into agreements with vendors in the ordinary course of business that include unconditional purchase obligations for manufacturing and other services. In April 2026, we entered into an agreement that includes provisions for minimum obligations for the contract manufacturing of IMVT-1402 drug substance. As of May 20, 2026, the minimum commitment was approximately $22.8 million, of which $4.2 million and $18.6 million is expected to be paid during the fiscal years ending March 31, 2027 and 2028, respectively. The agreement includes a variable component whereby service prices may be adjusted based on related commitments for raw materials and other costs, and annual inflationary changes in an applicable price index.

HanAll Agreement

Potential future payments due under the HanAll Agreement are contingent upon future events. As of March 31, 2026, the aggregate maximum amount of milestone payments we could be required to make under the HanAll Agreement is $420.0 million (after an aggregate amount of $32.5 million paid for milestone events achieved as of March 31, 2026) upon the achievement of certain regulatory and sales milestone events. We have commenced discussions with HanAll regarding the future disposition of batoclimab, including the potential return to HanAll of certain rights for batoclimab, which could impact the aggregate amount (if any) of potential future payments under the HanAll Agreement. In April 2026, we notified HanAll of our decision to indefinitely delay further development of batoclimab and focus our resources fully on IMVT-1402. For additional considerations regarding associated risks, see Part I, Item 1—Key Agreements and Part I, Item 1A—Risk Factors of this annual report on Form 10-K.

Outlook

We currently expect that our existing cash and cash equivalents as of March 31, 2026 of $902.1 million will be sufficient to fund our operating expenses and capital expenditure requirements for announced indications to date through the potential commercial launch of IMVT-1402 in GD.

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

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

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

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

Critical Accounting Estimates

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

We define our critical accounting estimates as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in "Note 2 — Summary of Significant Accounting Policies" to our consolidated financial statements in Part II, Item 8 of this Annual Report, we believe the following critical accounting estimate used in the preparation of our consolidated financial statements requires significant estimates and judgments. We did not make any material changes to these assumptions for the year ended March 31, 2026. We do not expect any material changes in the near term to the underlying assumptions during the year ended March 31, 2026.

Research and Development Expenses and Related Accruals

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of March 31, 2026, we had cash and cash equivalents of $902.1 million, all of which are maintained in accredited financial institutions. Our cash equivalents consist of money market funds invested in high-quality, short-term securities that are issued and guaranteed by the U.S. government. Our primary exposure to market risk is interest income volatility, which is sensitive to changes in the general level of interest rates; however, due to the nature of our account portfolio, an immediate hypothetical 10% change in interest rates would not have a material effect on our financial condition or consolidated financial statements.

Foreign Currency Exchange Rate Risk

Our employees and our operations are currently primarily located in the U.S. and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we are exposed to fluctuations in foreign currency exchange rate risk as a result of entering into transactions denominated in currencies other than U.S. dollars as we have contracted with and may continue to contract with foreign vendors. An immediate hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our liquidity or consolidated financial statements.

Effects of Inflation

Inflation generally affects us by increasing our research and development and contract manufacturing costs. We do not believe that inflation had a material effect on our business, financial condition or consolidated financial statements as of March 31, 2026.

Item 8. Financial Statements and Supplementary Data

Immunovant, Inc.
Index to Consolidated Financial Statements

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	118
Consolidated Financial Statements:	
Consolidated Balance Sheets as of March 31, 2026 and 2025	120
Consolidated Statements of Operations for the Years Ended March 31, 2026, 2025 and 2024	121
Consolidated Statements of Comprehensive Loss for the Years Ended March 31, 2026, 2025 and 2024	122
Consolidated Statements of Stockholders' Equity for the Years Ended March 31, 2026, 2025 and 2024	123
Consolidated Statements of Cash Flows for the Years Ended March 31, 2026, 2025 and 2024	124
Notes to Consolidated Financial Statements	125

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Immunovant, Inc. (the Company) as of March 31, 2026 and 2025, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended March 31, 2026, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2026 and 2025, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2026, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of March 31, 2026, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated May 20, 2026 expressed an unqualified opinion thereon.

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Clinical Trial Accrual

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by contract research organizations. In making these estimates, the Company considers various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment.

Auditing the Company's accrual for clinical trial costs requires a greater extent of audit effort due to the fact that information necessary to estimate the accruals is accumulated from clinical research organizations and the Company's assessment of that information is subject to variability and uncertainty. In addition, in certain circumstances, the determination of the nature and amount of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing does not correspond to the level of services provided and there may be delays in invoicing from clinical study sites and other vendors.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls that addressed the identified risks related to the information used in the Company's process for recording clinical trial accruals. For example, we tested controls over management's review of clinical trial progress in comparison to information and invoices received from third parties, and over the completeness and accuracy of data used to calculate the accrual.

To test the clinical trial accrual, our audit procedures included, among others, reading a sample of the Company's agreements with the service providers to understand key financial and contractual terms and testing the accuracy and completeness of the underlying data used in the accrual computations. We also evaluated management's estimates of the vendor's progress for a sample of clinical trials by making direct inquiries of the Company's operations personnel overseeing the clinical trials and obtaining information directly from certain service providers about the service providers' estimate of costs that had been incurred through March 31, 2026. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

/s/ Ernst & Young LLP

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

Iselin, New Jersey

May 20, 2026

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

	March 31, 2026	March 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 902,110	$ 713,971
Accounts receivable	1,133	2,084
Prepaid expenses and other current assets	42,763	51,180
Income tax receivable	2,813	427
Total current assets	948,819	767,662
Operating lease right-of-use assets	72	98
Property and equipment, net	443	844
Other assets	7,680	7,618
Total assets	**$ 957,014**	**$ 776,222**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,541	$ 17,656
Accrued expenses	96,634	50,748
Current portion of operating lease liabilities	72	98
Due to Roivant Sciences Ltd.	175	273
Total current liabilities	104,422	68,775
Total liabilities	104,422	68,775
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Series A preferred stock, par value $0.0001 per share, 10,000 shares authorized, issued and outstanding at March 31, 2026 and March 31, 2025	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2026 and March 31, 2025	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 203,940,353 shares issued and outstanding at March 31, 2026 and 500,000,000 shares authorized, 170,111,593 shares issued and outstanding at March 31, 2025	20	16
Additional paid-in capital	2,596,971	1,945,495
Accumulated other comprehensive income	730	1,459
Accumulated deficit	(1,745,129)	(1,239,523)
Total stockholders' equity	852,592	707,447
Total liabilities and stockholders' equity	**$ 957,014**	**$ 776,222**

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

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

	Years Ended March 31,		
	2026	**2025**	**2024**
Operating expenses:			
Research and development	$ 456,660	$ 360,917	$ 212,928
Acquired in-process research and development	—	—	12,500
General and administrative	76,242	77,235	57,281
Total operating expenses	532,902	438,152	282,709
Interest income, net	(25,330)	(24,732)	(24,948)
Other (income) expense, net	(2,181)	(471)	1,008
Loss before provision for income taxes	(505,391)	(412,949)	(258,769)
Provision for income taxes	215	891	567
Net loss	**$ (505,606)**	**$ (413,840)**	**$ (259,336)**
Net loss per common share — basic and diluted	$ (2.77)	$ (2.73)	$ (1.88)
Weighted average common shares outstanding — basic and diluted	182,421,233	151,573,553	138,100,577

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

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

	Years Ended March 31,		
	2026	**2025**	**2024**
Net loss	$ (505,606)	$ (413,840)	$ (259,336)
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(729)	(449)	1,056
Total other comprehensive (loss) income	(729)	(449)	1,056
Comprehensive loss	**$ (506,335)**	**$ (414,289)**	**$ (258,280)**

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

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

	Series A preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at March 31, 2023	**10,000**	**$ —**	**130,329,863**	**$ 13**	**$ 927,976**	**$ 852**	**$ (566,347)**	**$ 362,494**
Issuance of common stock upon underwritten offering and private placement	—	—	12,949,184	1	466,732	—	—	466,733
Stock options exercised and restricted stock units vested and settled	—	—	2,303,952	—	5,694	—	—	5,694
Capital contribution – stock-based compensation	—	—	—	—	103	—	—	103
Stock-based compensation	—	—	—	—	41,013	—	—	41,013
Foreign currency translation adjustments	—	—	—	—	—	1,056	—	1,056
Net loss	—	—	—	—	—	—	(259,336)	(259,336)
Balance at March 31, 2024	**10,000**	**$ —**	**145,582,999**	**$ 14**	**$ 1,441,518**	**$ 1,908**	**$ (825,683)**	**$ 617,757**
Issuance of common stock upon private placement	—	—	22,500,000	2	449,679	—	—	449,681
Stock options exercised and restricted stock units vested and settled	—	—	2,028,594	—	4,811	—	—	4,811
Capital contribution – stock-based compensation	—	—	—	—	24	—	—	24
Stock-based compensation	—	—	—	—	49,463	—	—	49,463
Foreign currency translation adjustments	—	—	—	—	—	(449)	—	(449)
Net loss	—	—	—	—	—	—	(413,840)	(413,840)
Balance at March 31, 2025	**10,000**	**$ —**	**170,111,593**	**$ 16**	**$ 1,945,495**	**$ 1,459**	**$ (1,239,523)**	**$ 707,447**
Issuance of common stock upon underwritten offering	—	—	26,200,000	3	543,687	—	—	543,690
Stock options exercised and restricted stock units vested and settled	—	—	7,628,760	1	52,065	—	—	52,066
Capital contribution – stock-based compensation	—	—	—	—	832	—	—	832
Stock-based compensation	—	—	—	—	54,892	—	—	54,892
Foreign currency translation adjustments	—	—	—	—	—	(729)	—	(729)
Net loss	—	—	—	—	—	—	(505,606)	(505,606)
Balance at March 31, 2026	**10,000**	**$ —**	**203,940,353**	**$ 20**	**$ 2,596,971**	**$ 730**	**$ (1,745,129)**	**$ 852,592**

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

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

	Years Ended March 31,		
	2026	**2025**	**2024**
Cash flows from operating activities			
Net loss	$ (505,606)	$ (413,840)	$ (259,336)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	55,724	49,487	41,116
Depreciation on property and equipment	409	377	231
Non-cash lease expense	99	133	1,130
Changes in operating assets and liabilities:			
Accounts receivable	986	3,232	(4,577)
Prepaid expenses and other current assets	8,844	(26,990)	1,558
Income tax receivable	(2,386)	(261)	19
Other assets	69	(7,736)	—
Accounts payable	(10,252)	10,684	5,784
Accrued expenses	45,000	8,923	1,349
Operating lease liabilities	(99)	(138)	(1,172)
Due to Roivant Sciences Ltd.	(98)	255	(329)
Net cash used in operating activities	**(407,310)**	**(375,874)**	**(214,227)**
Cash flows from investing activities			
Purchases of property and equipment	(8)	(759)	(360)
Net cash used in investing activities	**(8)**	**(759)**	**(360)**
Cash flows from financing activities			
Proceeds from issuance of common stock upon underwritten offering, net of underwriter discounts and commissions, and private placement	544,194	450,000	472,745
Payment of offering and private placement costs	(504)	(319)	(6,012)
Proceeds from stock options exercised	52,066	4,811	5,694
Net cash provided by financing activities	**595,756**	**454,492**	**472,427**
Effect of exchange rate changes on cash and cash equivalents	**(299)**	**747**	**993**
Net change in cash and cash equivalents	188,139	78,606	258,833
Cash and cash equivalents – beginning of period	713,971	635,365	376,532
Cash and cash equivalents – end of period	**$ 902,110**	**$ 713,971**	**$ 635,365**
Non-cash operating activity			
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	**$ 73**	**$ 98**	**$ 91**
Supplemental disclosure of cash paid:			
Income taxes	**$ 2,386**	**$ 1,202**	**$ 509**

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

IMMUNOVANT, INC.
Notes to Consolidated Financial Statements

Note 1 — Organization and Nature of Business

[A] Description of Business

Immunovant, Inc. (together with its wholly-owned subsidiaries, the "Company" or "Immunovant") is a clinical-stage immunology company dedicated to enabling normal lives for people with autoimmune diseases. The Company is pursuing a broad anti-FcRN strategy based on its lead asset, IMVT-1402, a novel, fully human, monoclonal antibody that targets the neonatal fragment crystallizable receptor ("FcRn"). Designed to be optimized as a simple, subcutaneous injection, IMVT-1402 has been observed to reduce immunoglobulin G ("IgG") antibody levels, which has provided evidence supporting the use of an anti-FcRn antibody in disease areas associated with high levels of pathogenic IgG antibodies. The Company discontinued further development of batoclimab (formerly referred to as IMVT-1401) across all indications to focus fully on the development of IMVT-1402.

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

In January 2026, the Company completed an internal reorganization and transfer of intellectual property rights related to the Company's product candidates between two wholly-owned subsidiaries of the Company. Ownership and rights to such intellectual property remain with the Company and its subsidiaries. See Note 6 - Income Taxes for additional details.

[B] Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of March 31, 2026, the Company's cash and cash equivalents totaled $902.1 million and its accumulated deficit was $1,745.1 million.

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

The Company intends to raise such additional capital through the issuance of equity securities, debt financings, potential collaboration, license or development agreements 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.

Note 2 — Summary of Significant Accounting Policies

[A] Basis of Presentation

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

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

[B] Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to stock-based compensation, litigation accruals, clinical trial accruals, prepaid expenses, 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 macroeconomic and geopolitical factors on its operations and financial results as of March 31, 2026 and through the issuance of this report. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact that these uncertainties may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

[C] Risks and Uncertainties

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

[D] Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents. As of March 31, 2026, the cash and cash equivalents balance is kept in banking institutions that the Company believes are of high credit quality and are in excess of federally insured levels. The Company maintains its cash and cash equivalents with accredited financial institutions and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses on its cash and cash equivalents.

[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, 2026 and 2025, cash and cash equivalents included $877.8 million and $687.6 million, respectively, of money market funds invested in high-quality, short-term securities that are issued and guaranteed by the U.S. government and its agencies that are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices.

[F] Property and Equipment

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

[G] Impairment of Long-lived Assets

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

[H] Contingencies

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

[I] Research and Development Expenses

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

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

[J] Acquired In-Process Research and Development Expenses

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

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

[K] Leases

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

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

[L] Income Taxes

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

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

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

[M] Stock-based Compensation

Stock-based awards to employees and directors, including stock options, restricted stock units ("RSUs"), performance restricted stock units ("PSUs") and capped value appreciation rights ("CVARs"), are valued at fair value on the date of grant and that fair value is recognized as stock-based compensation expense over the requisite service period. For awards with only service conditions, 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. If awards with graded vesting contain performance or market conditions, then the Company records share-based compensation expense using the accelerated attribution method. The estimated fair value of awards that contain performance conditions is expensed when the Company concludes that it is probable that the performance conditions will be achieved.

The Company values its stock options that only have service vesting requirements using the Black-Scholes option pricing model. Stock-based compensation related to RSUs and PSUs without market conditions is based on the fair value of the Company's common stock on the date of grant. For CVARs with market conditions, the Company determines the fair value of the awards on the date of grant using a Monte Carlo simulation model. When determining the grant-date fair value of stock-based awards, management further considers whether an adjustment is required to the observable market price or volatility of the Company's common stock that is used in the valuation as a result of material non-public information, if that information is expected to result in a material increase in share price.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model and the Monte Carlo simulation model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate, expected dividend yield and the fair value of the Company's common stock. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time as the Company has sufficient exercise history. The expected share price volatility for the Company's common stock was estimated using the average historical price volatility for comparable publicly traded peer companies in fiscal year 2024 and a weighted blend of the Company's historical price volatility and the average historical price volatility for comparable publicly traded peer companies in fiscal year 2025. Beginning on April 1, 2025, the Company determined that its common stock had sufficient trading activity to solely utilize the Company's historical price volatility. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. As the Company has never paid and does not anticipate paying cash dividends on its common stock, the expected dividend yield is assumed to be zero. The Company accounts for pre-vesting award forfeitures when they occur.

[N] Fair Value of Financial Instruments

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

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

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

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and amounts due to Roivant Sciences Ltd. ("RSL"). These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. There were no Level 2 or Level 3 financial instruments as of March 31, 2026 or 2025.

[O] Foreign Currency

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

[P] Net Loss per Common Share

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

The following potentially dilutive securities, presented based on amounts outstanding at period end, have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Years Ended March 31,		
	2026	2025	2024
Preferred stock as converted	10,000	10,000	10,000
Stock options	9,993,443	12,963,834	13,026,329
Restricted stock units	3,485,074	3,239,901	3,466,057
Capped value appreciation rights	136,574	—	—
Total	**13,625,091**	**16,213,735**	**16,502,386**

[Q] Segment Information

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company operates in a single operating segment and has one reportable segment, which includes all activities related to the research, development and manufacturing of its product candidates. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. See Note 9 – Segment Information for additional details.

[R] Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures" ("ASU 2023-09"), which requires disaggregated information on the effective rate reconciliation as well as information on income taxes paid by jurisdiction. The amendments are effective for fiscal years beginning after December 15, 2024 for public entities, with early adoption permitted, and may be applied prospectively, with the option to apply them retrospectively. The Company adopted this ASU for the fiscal year ended March 31, 2026 and applied the new disclosure requirements on a prospective basis. See Note 6 - Income Taxes for the additional disclosures required by ASU 2023-09.

[S] Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. The amendments are effective for public entities for fiscal years beginning after December 15, 2026, and will be applicable for the Company's Annual Report on Form 10-K for the fiscal year ending March 31, 2028 and subsequent interim periods. Early adoption is permitted. The guidance is to be applied prospectively, with the option for retrospective application. The Company expects adoption of this ASU will result in additional disclosures in line with the requirements of ASU 2024-03.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), 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 consolidated financial statements and related disclosures.

Note 3 — License Agreement

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

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

- Upfront, non-refundable payment of $30.0 million;
- Up to $20.0 million in shared (50%) research, development, and out-of-pocket costs incurred by HanAll, which obligation has since expired;
- Up to an aggregate of $420.0 million (after an aggregate amount of $32.5 million paid for milestone events achieved as of March 31, 2026) upon the achievement of certain regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens percentage of net sales of licensed products subject to standard offsets and reductions on a product-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 11th anniversary of the first commercial sale of such product in such country.

On August 18, 2018, RSG entered into a sublicense agreement (the "Sublicense Agreement") with ISG to sublicense this technology, as well as RSG's know how and patents necessary for the development, manufacture or commercialization of any compound or product that pertains to immunology. On December 7, 2018, RSG issued a notice to terminate the Sublicense Agreement with ISG and entered into an assignment and assumption agreement to assign to ISG all of the rights, title, interest, and future obligations under the HanAll Agreement from RSG, including all rights to IMVT-1402 and batoclimab in the Licensed Territory, for an aggregate purchase price of $37.8 million. Each party to the HanAll Agreement has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory.

During the quarter ended June 30, 2023, the Company achieved its third and fourth development and regulatory milestone events under the HanAll Agreement of $12.5 million, combined, which was paid in the quarter ended September 30, 2023 and recorded as acquired in-process research and development expenses in the accompanying consolidated statement of operations for the year ended March 31, 2024.

In January 2026, the Company completed an internal reorganization and transfer of intellectual property rights related to the Company's product candidates between two wholly-owned subsidiaries of the Company. See Note 6 - Income Taxes for additional details.

Note 4 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31,	
	2026	2025
Research and development expenses	$ 33,860	$ 32,622
Contractual costs related to batoclimab program discontinuation	42,482	—
Accrued bonuses	16,767	15,618
Legal and other professional fees	1,342	789
Other expenses	2,183	1,719
Total accrued expenses	**$ 96,634**	**$ 50,748**

Note 5 — Related Party Transactions

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

In August 2018, the Company entered into amended and restated services agreements (each a "Services Agreement" and together 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 the Company. RSI assigned its Services Agreement to RSL effective April 1, 2025. Under each Services Agreement, the Company will pay or reimburse RSL 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 under the Services Agreements, the service provider will charge the service recipient a fully loaded cost based upon employee costs plus a pre-determined mark-up, except where otherwise negotiated. Any external services cross charged through the Services Agreements will be invoiced at cost. The term of the Services Agreements will continue until terminated by the Company, RSI or RSG, as applicable, upon 90 days' written notice.

For the years ended March 31, 2026, 2025 and 2024, expenses recorded by the Company were $1.5 million, $0.8 million and $0.6 million, respectively, under the Services Agreements, which are included in the accompanying consolidated statements of operations.

RSL Information Sharing and Cooperation Agreement

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

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

RSI Subleases

In June 2020, the Company entered into two sublease agreements with RSI for two floors of office space in New York, which expired on February 27, 2024 and April 29, 2024, respectively. Rent expense under these operating leases was de minimis and $1.1 million for the years ended March 31, 2025 and 2024, respectively.

RSL Share Purchases

See Note 7 – Stockholders' Equity for a discussion of the RSL share purchases as part of the Company's underwritten offering in December 2025, private placement in January 2025 and underwritten offering and private placement in October 2023.

Note 6 — Income Taxes

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

	Years Ended March 31,		
	2026	2025	2024
(Loss) income before income taxes			
United States	$ 100,991	$ (17,730)	$ (16,180)
Switzerland	(606,288)	(395,119)	(242,518)
Bermuda	(39)	(100)	(71)
United Kingdom	(55)	—	—
Total loss before income taxes	**$ (505,391)**	**$ (412,949)**	**$ (258,769)**
Current taxes			
United States – Federal	$ —	$ 880	$ 562
United States – State	215	11	5
Total current tax expense	215	891	567
Deferred tax expense	—	—	—
Total provision for income taxes	**$ 215**	**$ 891**	**$ 567**

For the year ended March 31, 2026, the Company adopted ASU 2023-09 on a prospective basis. Accordingly, the following table is a reconciliation of the U.S. federal statutory rate to the Company's effective tax rate for the year ended March 31, 2026 in accordance with the guidance in ASU 2023-09 (amounts in thousands):

	Year ended March 31, 2026	
	Amount	Percent
U.S. federal statutory tax rate	$ (106,132)	21.00 %
State and local income taxes, net of federal income tax effect [1]	170	(0.03)
Foreign tax effects		
Switzerland		
Statutory tax rate difference	75,786	(15.00)
Intercompany reorganization	138,465	(27.40)
Deductible federal taxes	(6,852)	1.35
Change in valuation allowances	(80,199)	15.87
Other [2]	(58)	0.01
Effects of cross-border tax laws		
Foreign loss	(64,511)	12.76
Tax credits		
Research and development tax credit	(10,748)	2.13
Orphan drug credit	(3,948)	0.78
Change in valuation allowances	50,376	(9.97)
Nontaxable or nondeductible items		
Section 162(m)	8,768	(1.73)
Other adjustments	(902)	0.19
Effective tax rate	**$ 215**	**(0.04)%**

[1] The state taxes in Florida and South Carolina make up the majority of the state tax effect in this category (greater than 50%).
[2] The cantonal taxes in Swiss canton of Basel-Stadt make up the majority of the state tax effect in this category (greater than 50%).

A reconciliation of the provision for income taxes computed at the U.S. federal statutory rate of 21% for the years ended March 31, 2025 and 2024 to the provision for income taxes reflected in the consolidated statements of operations is presented below (in thousands) in accordance with the guidance prior to the prospective adoption of ASU 2023-09. As such, certain items in the effective tax rate reconciliation above may have been reclassified between categories compared to prior periods; however, such reclassifications did not have a material impact on any individual line items or the overall effective tax rate.

	Years Ended March 31,	
	2025	2024
Income tax benefit at statutory rate	$ (86,719)	$ (54,341)
Foreign rate differential	31,499	19,321
Research and development credits	(17,972)	(8,096)
Valuation allowance	74,541	46,389
Non-deductible expense	5,826	7,518
Excess tax benefits from stock-based compensation	(6,282)	(9,204)
Other	(2)	(1,020)
Total provision for income taxes	**$ 891**	**$ 567**

The Company's effective tax rate was (0.04)%, (0.22)% and (0.22)% for the years ended March 31, 2026, 2025 and 2024 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.

A summary of income taxes paid by jurisdiction, net of refunds, after the adoption of ASU 2023-09 for the year ended March 31, 2026 is as follows (in thousands):

	Year ended March 31, 2026
U.S. federal	$ 2,438
Other	(52)
Total	**$ 2,386**

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, 2026 and 2025 are as follows (in thousands):

	March 31,	
	2026	2025
Deferred tax assets		
Intangible assets	$ 3,457	$ 10,099
Net operating losses	77,731	153,370
Stock-based compensation	12,065	13,643
Capitalized research and development costs	153,532	—
Research and development credits	53,734	39,217
Accruals and reserves	11,743	3,298
Others	252	224
Total deferred tax assets	**312,514**	**219,851**
Valuation allowance	(311,961)	(218,753)
Deferred tax assets, net of valuation allowance	**$ 553**	**$ 1,098**
Deferred tax liabilities		
Others	$ (487)	$ (948)
Right-of-use assets	(15)	(41)
Depreciation	(51)	(109)
Total deferred tax liabilities	**(553)**	**(1,098)**
Total net deferred taxes	**$ —**	**$ —**

In January 2026, the Company completed an internal reorganization and transfer of intellectual property rights related to the Company's product candidates between two wholly-owned subsidiaries of the Company to align with the business operations of the Company. Ownership and rights to such intellectual property remain with the Company and its subsidiaries.

The Company recorded an income tax benefit predominantly related to the internal reorganization, reducing the provision for income taxes to $0.2 million for the year ended March 31, 2026. Further, a new deferred tax asset was created as reflected above related to capitalized research and development expenses that will be deductible in the U.S. in future periods. As of March 31, 2026, the Company has gross net operating loss carryforwards in Switzerland of $279.0 million, which decreased from $1,094.6 million as of March 31, 2025 primarily due to utilization caused by the transfer of intellectual property, and will begin to expire as of March 31, 2032. Additionally, as of March 31, 2026, the Company has gross net operating loss carryforwards in the U.S. of $195.2 million, which increased from $48.7 million as of March 31, 2025, driven by the internal reorganization and can be carried forward indefinitely with utilization limited to 80% of future taxable income. The Company has research and development and orphan drug credit carryforwards in the U.S. of $53.7 million as of March 31, 2026, which begin to expire as of March 31, 2039.

The Company assesses the realizability of its 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 records a valuation allowance as necessary. Despite the one-time partial utilization of the net operating losses within Switzerland as part of the transfer of the intellectual property, the Company remains in a cumulative loss position, which provides significant negative evidence difficult to overcome. Accordingly, the Company has recorded a valuation allowance of $312.0 million and $218.8 million for the years ended March 31, 2026 and 2025, respectively, representing the portion of the net deferred tax assets that is not expected to be realized. The amount of the net deferred tax assets considered realizable could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. The Company will continue to assess the realizability of net deferred tax assets at each balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

As of March 31, 2026, the Company does not have undistributed earnings from foreign subsidiaries. The Company regularly evaluates whether foreign earnings are expected to be indefinitely reinvested. This evaluation requires judgment about the future operating and liquidity needs of the Company. Changes in economic and business conditions, foreign or U.S. tax laws or the Company's financial situation could result in a change to the Company's position.

The Company is subject to tax and files income tax returns in the U.S. federal, state and local jurisdictions, the United Kingdom and Switzerland. The Company's tax periods for the fiscal years ended March 31, 2019 through March 31, 2026 remain open for tax examinations in most applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the consolidated results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. The Company's unrecognized tax benefit activity during the years ended March 31, 2026 and 2025 and related liabilities were not material to the Company's consolidated financial statements as of March 31, 2026 and 2025.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law in the U.S., which includes a broad range of tax reform provisions. ASC 740, "Income Taxes", requires the effects of changes in tax rates and laws on deferred tax balances to be recognized in the period in which the legislation is enacted. The impact of the OBBBA on the Company's accompanying consolidated financial statements is not material to the Company's effective tax rate.

Note 7 — Stockholders' Equity

Series A Preferred Stock

As of March 31, 2026, 10,000 shares of Series A preferred stock, par value $0.0001 per share, were outstanding and held by RSL.

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

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

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

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

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

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

Preferred Stock

As of March 31, 2026, the Company has authorized 10,010,000 shares of preferred stock, par value $0.0001 per share. The board of directors has the authority, without further action by the stockholders to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, voting, and other rights, preferences and privileges of the shares. Other than the 10,000 shares of preferred stock designated as Series A preferred stock, which are issued and outstanding, there were no issued and outstanding shares of preferred stock as of March 31, 2026.

Common Stock

As of March 31, 2026, the Company has authorized 500,000,000 shares of common stock, par value $0.0001 per share.

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

In December 2025, the Company completed an underwritten offering of 26,200,000 shares of its common stock (including 16,666,666 shares of common stock purchased by RSL on the same terms as other investors in the offering) at an offering price of $21.00 per share. The underwriter did not receive any underwriting discounts or commissions with respect to shares sold to RSL in the offering. The net proceeds to the Company were $543.7 million after deducting underwriting discounts and commissions and other offering expenses.

In January 2025, the Company entered into a share purchase agreement pursuant to which the Company issued 22,500,000 shares of the Company's common stock, par value $0.0001 per share, to certain institutional accredited investors (including 16,845,010 shares of common stock to RSL), at a price of $20.00 per share in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"). The gross proceeds to the Company were approximately $450.0 million. Pursuant to a registration rights agreement with certain of the investors, the Company subsequently filed with the SEC a prospectus supplement to its registration statement on Form S-3 (File No. 333-275419), which automatically became effective upon its filing on November 9, 2023, covering the resale of 5,654,990 shares of common stock issued in the private placement. The Company has agreed to use reasonable best efforts to keep such registration statement effective until the date the shares described above have been sold or may be resold pursuant to Rule 144 under the Securities Act without restriction.

In November 2023, the Company entered into a sales agreement with Leerink Partners LLC ("Leerink Partners"), as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of its common stock (the "ATM Shares"), subject to certain conditions as specified in the sales agreement. The Company agreed to pay Leerink Partners up to 3% of the gross proceeds from each sale of ATM Shares sold through the sale agreement. The ATM Shares would be sold at prevailing market prices at the time of the sale and, as a result, prices may vary. The ATM Shares to be sold under the sales agreement, if any, would be issued and sold pursuant to an automatic shelf registration statement on Form S-3, which the Company filed with the SEC in November 2023, along with a prospectus supplement relating to the offer and sale of up to $150.0 million of ATM Shares pursuant to the sales agreement. The Company has not issued or sold any ATM Shares pursuant to the ATM offering program.

In October 2023, the Company completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by RSL on the same terms as other investors in the offering and the full exercise of the underwriters' option to purchase 1,105,500 additional shares of common stock) at a price to the public of $38.00 per share. Concurrent with the public offering, RSL purchased 4,473,684 shares of the Company's common stock in a private placement exempt from the registration requirements of the Securities Act at the same price per share as investors in the public offering. The net proceeds to the Company were $466.7 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses.

As of March 31, 2026, the Company had 203,940,353 shares of common stock outstanding, which include the above share issuances during the year and the issuance of shares of common stock from the exercise of stock options and vesting of restricted stock units. See Note 8 – Stock-Based Compensation for additional details about stock options and restricted stock units.

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

	March 31,	
	2026	2025
Conversion of Series A preferred stock	10,000	10,000
Stock options outstanding	9,996,503	12,963,834
Restricted stock units outstanding	4,254,184	4,043,674
Capped value appreciation rights outstanding	136,574	—
Equity awards available for future grants	7,822,985	6,027,035
Total	**22,220,246**	**23,044,543**

The reserved shares underlying stock options above include 3,060 stock options that were exercised but were not settled as of March 31, 2026. The reserved shares underlying restricted stock units above include 769,110 restricted stock units that vested but were not settled as of March 31, 2026. In addition, the Company has reserved 5,000,000 shares of its common stock that may be issued under its 2023 Inducement Plan as of March 31, 2026. See Note 8 – Stock-Based Compensation for further details.

Note 8 — Stock-Based Compensation

2019 Equity Incentive Plan

In December 2019, the Company's stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") and reserved 5,500,000 shares of common stock for issuance thereunder. The number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on April 1 of each year, 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 on or prior to March 31 of such year. The maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options under the 2019 Plan is 16,500,000. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards and performance awards under the plan. Generally, each option will have an exercise price equal to the fair market value of the Company's common stock on the date of grant and a ten-year contractual term. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common stock on the date of grant and the option will have a five-year contractual term. Stock options that are forfeited, cancelled or have expired are available for future grants.

On April 1, 2025, 6,804,463 shares of common stock were added to the 2019 Plan pool in accordance with the 4.0% evergreen provision of the 2019 Plan. As of March 31, 2026, options to purchase 8,925,717 shares of common stock and 3,485,074 RSUs were outstanding under the 2019 Plan and 7,822,985 shares of common stock remained available for future grant under the 2019 Plan.

2018 Equity Incentive Plan

As of the effective date of the 2019 Plan, no further stock awards have been or will be made under the 2018 Equity Incentive Plan (the "2018 Plan"). As of March 31, 2026, options to purchase 1,067,726 shares of common stock were outstanding under the 2018 Plan.

2023 Inducement Plan

On February 1, 2023, the Company's board of directors approved the adoption of the 2023 Inducement Plan (the "Inducement Plan"), which is to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company (or following a bona fide period of non-employment) as a material inducement to such individuals' entry into employment with the Company, pursuant to Nasdaq Listing Rule 5635(c)(4). The Company has reserved 5,000,000 shares of its common stock that may be issued under the Inducement Plan. The terms and conditions of the Inducement Plan are substantially similar to those of the 2019 Plan. As of March 31, 2026, no awards were granted or outstanding under the Inducement Plan.

Stock Option Activity

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

	Number of Stock Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance – March 31, 2025	12,963,834	$ 12.00	6.25	$ 88,960
Granted	4,473,253	15.92		
Exercised	(6,138,562)	8.48		
Forfeited	(1,206,473)	16.68		
Expired	(98,609)	25.57		
Balance – March 31, 2026	**9,993,443**	**$ 15.22**	**6.10**	**$ 104,098**
Exercisable – March 31, 2026	**4,876,213**	**$ 12.68**	**4.79**	**$ 63,386**

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, 2026. The intrinsic value of stock options exercised during the years ended March 31, 2026, 2025 and 2024 was $69.9 million, $12.2 million and $22.1 million, respectively. The stock options granted during the years ended March 31, 2026, 2025 and 2024 had a weighted-average fair value of $11.19 per share, $21.51 per share and $14.10 per share, respectively, at the grant date. The total grant-date fair value of stock options vested during the years ended March 31, 2026, 2025 and 2024 was $20.7 million, $24.9 million and $21.6 million, respectively. The Company estimated the fair value of each option on the date of grant using the Black-Scholes option pricing model applying the weighted-average assumptions in the following table:

	Years Ended March 31,		
	2026	2025	2024
Risk-free interest rate	4.00%	4.33%	3.60%
Expected term, in years	6.08	6.11	6.11
Expected volatility	78.10%	82.08%	94.26%
Expected dividend yield	—%	—%	—%

Restricted Stock Unit Awards

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

	Number of RSUs	Weighted- Average Grant Date Fair Value
Nonvested as of March 31, 2025	3,239,901	$ 21.70
Issued	2,821,133	15.81
Vested	(1,458,595)	19.99
Forfeited	(1,117,365)	18.48
Nonvested as of March 31, 2026	**3,485,074**	**$ 18.67**

The RSUs granted during the years ended March 31, 2026, 2025 and 2024 had a weighted-average fair value of $15.81 per share, $28.97 per share and $17.15 per share, respectively, at the grant date. The total grant-date fair value of RSUs vested during the years ended March 31, 2026, 2025 and 2024 was $29.2 million, $19.5 million and $13.5 million, respectively.

Performance Restricted Stock Units

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

	Number of PSUs	Weighted- Average Grant Date Fair Value
Nonvested as of March 31, 2025	—	$ —
Issued	820,000	15.23
Forfeited	(430,000)	15.23
Nonvested as of March 31, 2026	**390,000**	**$ 15.23**

During the year ended March 31, 2026, the Company granted 820,000 PSUs, which were valued at $12.5 million on the date of grant. The vesting of these PSUs requires that certain performance conditions be achieved during the performance period. A performance condition required as of March 31, 2026 was not met, resulting in the forfeiture of 430,000 PSUs. The remaining PSUs were determined to be improbable of vesting and therefore no expense was recorded for the year ended March 31, 2026.

Stock-based Compensation Expense

For the years ended March 31, 2026, 2025 and 2024, stock-based compensation expense under the Company's equity incentive plans was as follows (in thousands):

	Years Ended March 31,		
	2026	2025	2024
Research and development expenses	$ 29,527	$ 27,014	$ 20,409
General and administrative expenses	25,365	22,449	20,604
Total stock-based compensation	**$ 54,892**	**$ 49,463**	**$ 41,013**

As of March 31, 2026, total unrecognized compensation expense related to nonvested stock options and RSUs was $43.8 million and $44.6 million, respectively, which is expected to be recognized over the remaining weighted-average service period of 2.60 years and 2.54 years, respectively.

Stock-based Compensation Allocated to the Company by RSL

In relation to RSL RSUs issued by RSL to employees of the Company, stock-based compensation expense was $0.8 million for the year ended March 31, 2026. These RSUs are vesting over a period of four years. For the years ended March 31, 2025 and 2024, stock-based compensation expense recorded by the Company related to RSL RSUs was de minimis and $0.1 million, respectively. As of March 31, 2026, the amount of unrecognized compensation expense related to unvested RSL RSUs was $1.6 million.

The RSL common share awards are valued at fair value on the date of grant and stock-based compensation expense is recognized and allocated to the Company over the required service period.

Note 9 — Segment Information

The Company operates in a single operating segment and has one reportable segment, which includes all activities related to the discovery, development and manufacturing of its product candidates. The determination of a single segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its chief executive officer. The CODM, in alignment with the Company's strategic goals, uses consolidated net loss to monitor budget to actual results and cash forecast models for assessing performance and making operating decisions. The measurement of segment assets is reported on the consolidated balance sheet as total assets.

The Company's significant segment expenses are as follows (in thousands):

	Years Ended March 31,		
	2026	2025	2024
Therapeutic area-specific research and development:			
Endocrine diseases	$ 90,359	$ 63,073	$ 33,205
Neurological diseases	82,515	93,224	41,060
Rheumatology diseases	48,813	23,897	—
Dermatology diseases	20,264	15,633	—
Other clinical and nonclinical	3,367	9,327	39,811
Other unallocated research and development	43,856	44,264	24,562
Contractual costs related to batoclimab program discontinuation	38,952	—	—
Personnel-related research and development [1]	128,534	111,499	74,290
Acquired in-process research and development	—	—	12,500
Personnel-related general and administrative [2]	48,730	41,095	34,684
Other general and administrative [3]	27,512	36,140	22,597
Interest income, net	(25,330)	(24,732)	(24,948)
Other segment items [4]	(1,966)	420	1,575
Net loss	**$ 505,606**	**$ 413,840**	**$ 259,336**

[1] Includes stock-based compensation expense of $29,712, $27,014 and $20,409 for the years ended March 31, 2026, 2025 and 2024, respectively
[2] Includes stock-based compensation expense of $26,012, $22,473 and $20,707 for the years ended March 31, 2026, 2025 and 2024, respectively
[3] Other general and administrative expenses primarily include legal and other professional fees, information technology costs and market research costs
[4] Other segment items include other (income) expense, net and provision for income taxes

Note 10 — Commitments and Contingencies

Indemnification Agreements

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. The Company also indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance.

Litigation

The Company may be subject to various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable. As of March 31, 2026, the Company was not party to any material legal proceedings and thus no contingent liabilities were recorded.

Commitments

See Note 4 - Accrued Expenses for accumulated non-cancelable contractual costs accrued as a result of the discontinuation of batoclimab, of which $39.0 million was recognized as research and development expenses during the year ended March 31, 2026.

As of March 31, 2026, the Company did not have any other ongoing material contractual obligations for which cash flows were fixed and determinable. In the normal course of business, the Company enters into agreements with CROs for clinical trials and with vendors for nonclinical studies, manufacturing and other services and products for operating purposes, which agreements are generally cancellable by the Company at any time, subject to payment of remaining obligations under binding purchase orders and, in certain cases, nominal early-termination fees. These commitments are not deemed significant. There are certain contracts wherein the Company has a minimum purchase commitment, however, most of it is due and payable within one year.

Contingencies

The extent of the impact of geopolitical tensions, changes in inflation and interest rates, changes in international trade policies and tariffs and any resulting economic slowdown or recession on the Company’s future operational and financial performance will depend on certain developments, including the potential impact on the Company’s clinical trial plans and timelines, such as the enrollment and activation of additional clinical trial sites, and the results of the Company’s clinical trials, all of which are uncertain and cannot be predicted. At this point, the extent to which these events may impact the Company’s future financial condition or results of operations is uncertain.

Note 11 — Subsequent Event

The Company enters into agreements with vendors in the ordinary course of business that include unconditional purchase obligations for manufacturing and other services. In April 2026, the Company entered into an agreement that includes provisions for minimum obligations for the contract manufacturing of IMVT-1402 drug substance. As of May 20, 2026, the minimum commitment was approximately $22.8 million, of which $4.2 million and $18.6 million is expected to be paid during the fiscal years ending March 31, 2027 and 2028, respectively. The agreement includes a variable component whereby service prices may be adjusted based on related commitments for raw materials and other costs, and annual inflationary changes in an applicable price index.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2026, 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, 2026 at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting.

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined under Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

Our management has assessed the effectiveness of our internal control over financial reporting as of March 31, 2026. In making this assessment, management used the criteria set forth in the Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of March 31, 2026, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of March 31, 2026 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Immunovant, Inc.'s internal control over financial reporting as of March 31, 2026, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Immunovant, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of March 31, 2026, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of March 31, 2026 and 2025, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended March 31, 2026, and the related notes and our report dated May 20, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Ernst & Young LLP

Iselin, New Jersey

May 20, 2026

Item 9B. Other Information

During the three months ended March 31, 2026, none of our directors or Section 16 reporting officers adopted, modified or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of the SEC's Regulation S-K) with respect to the trading of Immunovant common stock.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

We will file a definitive proxy statement for our 2026 Annual Meeting of Stockholders ("2026 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year, or March 31, 2026. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2026 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 2026 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Meetings of the Board and its Committees" and "Executive Officers" and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that is applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.immunovant.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to the principal executive officer, principal financial officer and principal accounting officer or controller or persons performing similar functions, we will promptly disclose the nature of the amendment or waiver on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item will be contained in our 2026 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 2026 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plans at March 31, 2026" 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 2026 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 2026 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a) Documents filed as part of this report

(1) All financial statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report or the notes thereto or is not applicable or required.

(3) Exhibits

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
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	Description of Securities.	10-K	001-38906	4.3	June 29, 2020
10.1	UK Sub-Plan to the Immunovant, Inc. 2019 Equity Incentive Plan	10-Q	001-38906	10.1	February 3, 2023
10.2	Form of Stock Option Grant Notice and Agreement for the UK Sub-Plan	10-Q	001-38906	10.2	February 3, 2023
10.3	Form of Restricted Stock Unit Grant Notice and Agreement for the UK Sub-Plan	10-Q	001-38906	10.3	February 3, 2023
10.4	Immunovant, Inc. 2023 Inducement Plan	10-Q	001-38906	10.4	February 3, 2023
10.5	Form of Stock Option Grant Notice and Option Agreement for the Immunovant, Inc. 2023 Inducement Plan	10-Q	001-38906	10.5	February 3, 2023
10.6	Form of Restricted Stock Unit Grant Notice and Award Agreement for the Immunovant, Inc. 2023 Inducement Plan	10-Q	001-38906	10.6	February 3, 2023
10.7	Amended and Restated Registration Rights Agreement, dated September 29, 2019, by and among Health Sciences Acquisitions Corporation and the Investors party thereto.	8-K	001-38906	10.1	December 20, 2019
10.8	Restricted Stock Agreement, dated September 29, 2019, by and between Health Sciences Acquisitions Corporation and Health Sciences Holdings, LLC.	8-K	001-38906	10.2	December 20, 2019
10.9†	2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3	June 29, 2020
10.10.1†	Forms of Option Grant Notices and Option Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3.1	June 29, 2020
10.10.2†	Forms of Restricted Stock Unit Grant Notices and Award Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3.2	June 29, 2020
10.11†	2018 Equity Incentive Plan of Immunovant Sciences Ltd., and forms of award agreements thereunder.	8-K	001-38906	10.4	December 20, 2019
10.12†	Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan.	S-4	333-256165	10.25	May 14, 2021
10.13†	Form of Indemnification Agreement.	8-K	001-38906	10.5	December 20, 2019

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
10.14††	License Agreement, dated December 19, 2017, by and between Roivant Sciences GmbH and HanAll BioPharma Co., Ltd.	8-K	001-38906	10.6	December 20, 2019
10.15	Assignment and Assumption Agreement, dated as of December 7, 2018, by and between Immunovant Sciences GmbH and Roivant Sciences GmbH, relating to the License Agreement by and between Roivant Sciences GmbH and HanAll BioPharma Co., Ltd.	8-K	001-38906	10.7	December 20, 2019
10.16	Services Agreement, effective as of August 20, 2018, by and between Roivant Sciences, Inc., Immunovant Sciences GmbH, IMVT Corporation (formerly Immunovant, Inc.) and Immunovant Sciences Ltd.	8-K	001-38906	10.8	December 20, 2019
10.17	Services Agreement, effective as of August 20, 2018, by and between Roivant Sciences GmbH and Immunovant Sciences GmbH.	8-K	001-38906	10.9	December 20, 2019
10.18	Amended and Restated Information Sharing and Cooperation Agreement, effective as of December 28, 2018, by and between Immunovant Sciences Ltd. and Roivant Sciences Ltd.	8-K	001-38906	10.10	December 20, 2019
10.19†	Employment Agreement with Eric Venker, dated as of April 21, 2025.	10-Q	001-38906	10.4	August 11, 2025
10.20†	Employment Agreement with Tiago Girao, dated as of April 21, 2025.	10-K	001-38906	10.19	May 29, 2025
10.21†	Employment Agreement with Jay Stout, dated as of April 11, 2023.	10-K	001-38906	10.24	May 22, 2023
10.22†	Employment Agreement with Michael Geffner, dated as of January 9, 2024.	10-Q	001-38906	10.1	February 12, 2024
10.23†	Separation Agreement and General Release with Michael Geffner, dated as of November 20, 2025.	10-Q	001-38906	10.1	February 6, 2026
10.24†	Employment Agreement with Melanie Gloria, dated as of November 5, 2024.	10-Q	001-38906	10.1	November 7, 2024
10.25†	Employment Agreement with Christopher Van Tuyl, dated as of November 27, 2024.	10-Q	001-38906	10.1	February 6, 2025
10.26†	Employment Agreement with Peter Salzmann, dated as of May 30, 2019.	8-K	001-38906	10.11	December 20, 2019
10.27†	Separation Agreement and General Release with Peter Salzmann, dated as of April 20, 2025.	10-K	001-38906	10.25	May 29, 2025
10.28†	Separation Agreement and General Release with Renee Barnett, dated as of May 9, 2025.	10-Q	001-38906	10.2	August 11, 2025
10.29	Sales Agreement, by and between Immunovant, Inc. and Leerink Partners LLC, dated November 9, 2023.	S-3ASR	333-275419	1.2	November 9, 2023
10.30	Registration Rights Agreement, by and between the Company and certain of the Purchasers, dated January 13, 2025.	8-K	001-38906	10.2	January 13, 2025
19.1	Immunovant, Inc. Insider Trading Policy				
21.1	List of Subsidiaries.	10-K	001-38906	21.1	June 8, 2022
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)				

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
31.1	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1#	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2#	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1	Immunovant Inc. Incentive Compensation Recoupment Policy	10-K	001-38906	97.1	May 29, 2024
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents				
104	Cover Page Interactive Data (embedded within the Inline XBRL document)				

_____

+ The annexes, schedules and certain exhibits to the Share Exchange Agreement have been omitted pursuant to Item 601 of Regulation S-K.

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

†† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type that Immunovant, Inc. treats as private or confidential.

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Date: May 20, 2026

IMMUNOVANT, INC.

By: /s/ Eric Venker
Eric Venker, M.D., Pharm. D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Eric Venker, M.D., Pharm. D. and Tiago Girao, and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

SIGNATURE	TITLE	DATE
/s/ Eric Venker Eric Venker, M.D., Pharm. D.	Chief Executive Officer and Director (*Principal Executive Officer*)	May 20, 2026
/s/ Tiago Girao Tiago Girao	Chief Financial Officer *(Principal Financial and Accounting Officer)*	May 20, 2026
/s/ Frank M. Torti Frank M. Torti, M.D.	Executive Chairperson of the Board of Directors	May 20, 2026
/s/ Jacob Bauer Jacob Bauer	Director	May 20, 2026
/s/ Andrew Fromkin Andrew Fromkin	Director	May 20, 2026
/s/ Douglas Hughes Douglas Hughes	Director	May 20, 2026
/s/ Atul Pande Atul Pande, M.D.	Director	May 20, 2026
/s/ Robert Susman Robert Susman	Director	May 20, 2026

Exhibit 19.1

IMMUNOVANT, INC.

AMENDED AND RESTATED INSIDER TRADING POLICY

1. Introduction

This Insider Trading Policy (the "***Policy***") determines acceptable transactions in the securities of certain publicly traded companies by the directors, executive officers, and employees of Immunovant, Inc. and its consolidated subsidiaries (collectively, "***Immunovant***" or the "***Company***").

As Immunovant is a controlled affiliate of Roivant Sciences Ltd. ("***Roivant***"), this Policy also applies to transactions involving the securities of Roivant or one or more of the publicly traded subsidiaries of Roivant other than Immunovant (each, a "***Roivant Group Company***" and, collectively, the "***Roivant Group Companies***"), in conjunction with the insider trading policy of such Roivant Group Company.

During the course of your directorship, holding executive office, or employment with Immunovant or a Roivant Group Company, you may receive material information that is not yet publicly available about Immunovant, Roivant Group Companies, or other publicly traded companies with which Immunovant has business dealings ("***inside information***"). Inside information can include confidential information received from third parties in the course of such third parties exploring business opportunities with Immunovant. Because of your access to inside information, you may be in a position to profit financially by buying or selling, or in some other way dealing, in the securities of Immunovant, a Roivant Group Company, or another publicly traded company, or to disclose such information to a third party who does so profit (a "***tippee***").

All Company personnel are required to comply with the provisions of this Policy. Company personnel who intend to trade in the securities of a Roivant Group Company (including Roivant) are also required to comply with the applicable provisions of the insider trading policy of such Roivant Group Company, including with respect to any applicable blackout periods, as described below.

If you have any questions about this Policy, or whether a particular action is permissible under this Policy, you should not hesitate to contact Immunovant's Chief Legal Officer or another member of the Immunovant legal department in advance of taking that particular action.

2. Insider Trading Policy

A. Securities Transactions

It is always illegal to, and it is a violation of this Policy for you to, buy or sell securities of a publicly traded company while in possession of inside information about such company. It is also illegal and a violation of this Policy for you to inappropriately communicate or "tip" such information to others who do not have a legitimate business need for acquiring such information. You can be held liable both for your own transactions and for transactions effected by a tippee, or even a tippee of a tippee.

Furthermore, it is important that the **appearance** of insider trading in securities be avoided. The only exception is that transactions directly with Immunovant, e.g., option exercises for cash under the equity incentive plans of the Immunovant, generally are permitted. However, the subsequent sale (including the sale of shares in a cashless exercise program) or other disposition of such shares is fully subject to the restrictions set forth in this Policy. For purposes of this Policy, "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of Immunovant's or a Roivant Group Company's common stock in the public market, but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants and

other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities, including, but not limited to, engaging in short sales, transactions in put or call options and hedging transactions.

B. Inside Information

As a practical matter, it is sometimes difficult to determine whether you possess inside information. The key to determining whether nonpublic information you possess about a public company is inside information is whether dissemination of the information would likely affect the market price of the company's stock (either up or down) or would likely be considered important, or "material," by investors who are considering trading in that company's stock. Certainly, if the information makes **you** want to trade, it would probably have the same effect on others. Remember, both positive and negative information can be material. If you possess inside information about a company, you may not trade in such company's stock, advise anyone else to do so, or communicate the information to anyone else (other than a Non-Covered Person (defined below) in a manner consistent with applicable securities laws, rules and regulations) until you know that the information has been publicly disseminated. In some circumstances, you may have to forgo a proposed transaction in a company's securities even if you planned to execute the transaction prior to learning of the inside information and even though you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting.

Although by no means an all-inclusive list, information about the following topics may be considered inside information until it is publicly disseminated:

- financial results or forecasts;
- results of clinical trials or pre-clinical studies;
- communications with government agencies;
- strategic plans;
- discovery and development of new product candidates;
- acquisitions or dispositions of assets, divisions, companies, etc.;
- licensing transactions;
- negotiations to enter into certain transactions with third parties;
- certain business development activities with third parties;
- pending public or private sales of debt or equity securities;
- declaration of stock splits, dividends or changes in dividend policy;
- major contract awards or cancellations;
- top management or control changes;
- possible tender offers or proxy fights;
- significant write-offs;
- significant litigation;
- impending bankruptcy;
- gain or loss of significant partners, customers or suppliers;
- pricing changes or discount policies;

- partner or collaborator relationships; and
- notice of issuance of patents.

For information to be considered publicly disseminated, it must be widely disclosed through a press release or filing with the Securities and Exchange Commission or otherwise publicly available, and a sufficient amount of time must have passed to allow the information to be fully disclosed. Generally speaking, information will be considered publicly disseminated after **one (1) full trading day** has elapsed since the date of public disclosure of the information in a national news medium. For example, if an announcement of inside information concerning a third-party company, of which you were aware, was made *prior* to trading on Wednesday, then you may execute a transaction in the securities of that company on Thursday.

3. Trading by Covered Insiders

Due to the size of Immunovant, all directors, executive officers, and employees of Immunovant are likely to possess inside information regarding Immunovant at one time or another. Therefore, all directors, executive officers and employees of Immunovant (each a "***Covered Insider***" and, collectively, the "***Covered Insiders***"), along with any Specified Person (as defined below), are subject to the requirements of this Policy.

Generally, other than a Non-Covered Person (defined below), a "***Specified Person***" is any (a) immediate family member of a Covered Insider, (b) individual who shares the same address as, or is financially dependent on, any Covered Insider, (c) individual, whether or not a family member, whose trades are subject to the direction of a Covered Insider, and (d) entity for which trading activities are controlled by or influenced by any Covered Insider, including any controlled corporations, partnerships or trusts. For purposes of this Policy, Specified Persons are subject to the same restrictions as those of the Covered Insider, and transactions by Specified Persons are treated for the purposes of this Policy as if they were for the account of the Covered Insider.

For purposes of this Policy, a "***Non-Covered Person***" is any entity (i) of which the Covered Insider is an employee, member or partner, (ii) that engages in the management of investment in securities for investment funds in the ordinary course of its business or is a managed fund of such person, and (iii) that has confirmed to Immunovant in writing that it has established its own policies and procedures for compliance with insider trading restrictions under applicable securities laws. For the avoidance of doubt, a Non-Covered Person is not considered a Covered Insider subject to this Policy, and it is not a breach of this Policy for a Covered Person to recommend investments or be involved in the investment decision making of a Non-Covered Person in accordance with applicable securities laws, rules and regulations.

4. Blackout Periods

All Covered Insiders and Specified Persons are prohibited from trading in Immunovant's securities during blackout periods.

A. Quarterly Blackout Periods

Trading in securities of Immunovant or Roivant is prohibited during the period beginning at the close of trading on the final business day of each fiscal quarter and ending at the close of trading on the first (1st) full trading day following the date Immunovant's financial results for such fiscal quarter are publicly disclosed. During these periods, Covered Insiders generally possess or are presumed to possess material non-public information about Immunovant's financial results.

All Covered Insiders are also prohibited from trading in securities of any Roivant Group Company (including Roivant) during any blackout period applicable to such Roivant Group Company. Covered Insiders are encouraged to contact Immunovant's Chief Legal Officer or another member of the Immunovant legal department to confirm the status of any blackout period prior to trading in any securities of a Roivant Group Company.

B. Other Blackout Periods

From time to time, other types of material non-public information regarding Immunovant (such as negotiation of mergers or acquisitions, or clinical, manufacturing or commercial developments) may be pending and not be publicly disclosed. While such material non-public information is pending, Immunovant may impose special blackout periods during which Covered Insiders are prohibited from trading in Immunovant's securities. If Immunovant imposes a special blackout period, it will notify the Covered Insiders affected.

C. Exceptions

1. **Option Exercises + RSU Net Settlement**. Covered Insiders may, without restriction to any particular period, (i) exercise for cash stock options granted under the Company's equity incentive plan and (ii) net settle restricted stock units ("***RSUs***") and have the Company withhold common stock to satisfy tax withholding obligations when RSUs settle. However, the subsequent sale of the shares (including sales of shares in a cashless exercise) acquired upon the exercise of options is subject to all provisions of this Policy.
2. **10b5-1 Automatic Trading Programs**. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), any person may establish a trading plan under which a broker is instructed to buy and sell Immunovant securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of Immunovant securities pursuant to that Trading Plan are not subject to this Policy. To be properly established, a person's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Immunovant at a time when they were unaware of any material nonpublic information relating to Immunovant and when they were not otherwise subject to a trading blackout period. Please see the requirements set forth in the current Immunovant, Rule 10b5-1 trading plan guidelines (if any) for further information.

D. Hedging and Derivatives

Covered Insiders are prohibited from engaging in any derivative transactions (including transactions involving options, puts, calls, prepaid variable forward contracts, equity swaps, collars or other derivatives) that are designed to hedge against or speculate on any change in the market value of the Company's or any Roivant Group Company's equity securities. Covered Insiders are also prohibited from short selling of the Company's or any Roivant Group Company's securities. These prohibitions apply at all times, even during an open trading window.

E. Short-Swing Trading/Control Stock/Section 16 Reports

Executive officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care not to violate the prohibition on short-swing trading (Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5) and any notices of sale required by Rule 144.

5. Trading Window

Covered Insiders are permitted to trade in the securities of Immunovant or Roivant Group Companies when no blackout period is in effect. Generally, this means that Covered Insiders can trade during the period beginning at the close of trading on the first (1st) full trading day following the date Immunovant's financial results for such fiscal quarter are publicly disclosed and ending at the close of trading on the final business day of each fiscal quarter. However, even during this trading window, a Covered Insider who is in possession of any material non-public information should not trade in securities of Immunovant or any Roivant Group Company until the information has been made publicly available or is no longer material. Immunovant may close its trading window if a special blackout period as described above is imposed and will re-open the trading window once the special blackout period has ended.

6. Pre-clearance of Securities Transactions

(a) Because certain Covered Insiders are likely to obtain material non-public information on a regular basis, Immunovant requires all such persons to refrain from trading, even during a trading window as described above, without first pre-clearing all transactions in securities of Immunovant or Roivant. Accordingly, the "**Pre-Clearance Group**" consists of (i) directors and executive officers of Immunovant, their assistants and associated Specified Persons, (ii) such Immunovant personnel designated by the Chief Legal Officer and/or Chief Financial Officer as having access to material financial information, and (iii) such other persons as may be designated from time to time and informed of such status by the Chief Legal Officer. **All members of the Pre-Clearance Group must obtain pre-clearance for trades as set forth below.**

(b) Subject to the exemption in subsection (d) below, no Covered Insider within the Pre-Clearance Group may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any security of Immunovant or Roivant at any time without first obtaining prior approval from the Chief Legal Officer, or in the absence of the Chief Legal Officer, the Chief Financial Officer (the "***Clearing Officer***"), or his or her designee. These procedures also apply to transactions by Specified Persons associated with such Covered Insider, including such person's spouse, other persons living in such person's household and minor children and to transactions by entities over which such person exercises control.

(c) The Clearing Officer or his or her designee will record the date each request is received and the time each request is approved or disapproved. The Clearing Officer will generally approve or disapprove a request within two (2) business days. Unless revoked, an approved request will remain valid until the close of trading **two (2) business days** following the date of approval. If the transaction does not occur during the two-day period, pre-clearance of the transaction must be re-requested. Note that at any time, the Clearing Officer may decline to pre-clear a requested trade, even during a trading window. The Clearing Officer is not obligated to provide an explanation for the limitation on trading.

(d) Pre-clearance is not required for purchases and sales of securities under a Trading Plan in accordance with Rule 10b5-1; *provided, that* such Trading Plan has been approved by the Clearing Officer (or his or her designee) prior to the adoption, amendment or modification thereof.

7. Duration of Policy's Applicability

This Policy continues to apply to your transactions in the securities of Immunovant and the Roivant Group Companies or the stock of other public companies engaged in business transactions with Immunovant even after your directorship, holding office or employment with Immunovant has terminated. Namely, if you are in possession of inside information when your relationship with Immunovant concludes, you are still subject to the

restrictions contained in this Policy until one full trading day has elapsed following the date the information is otherwise publicly disseminated.

8. Penalties

Anyone who effects transactions in the securities of Immunovant, the Roivant Group Companies, or the stock of other public companies engaged in business transactions with Immunovant (or provides information to enable others to do so) on the basis of inside information is subject to both civil liability and criminal penalties, as well as disciplinary action by Immunovant, including termination of employment or other service relationship. A Covered Insider who has questions about this policy should contact the Chief Legal Officer of Immunovant.

9. Certification

All Covered Insiders shall certify his or her understanding of, and intent to comply with, the procedures set forth in this policy at such times as may be requested by the Chief Legal Officer of Immunovant.

Adopted by the Board of Directors: December 18, 2019
Amended and Restated: February 10, 2026

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements of Immunovant, Inc.:

(1) Registration Statement (Form S-8 No. 333-236665) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan and the Immunovant Sciences Ltd. 2018 Equity Incentive Plan,
(2) Registration Statement (Form S-8 No. 333-239537) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan,
(3) Registration Statement (Form S-3 No. 333-251865),
(4) Registration Statement (Form S-8 No. 333-262087) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan,
(5) Registration Statement (Form S-8 No. 333-265477) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan,
(6) Registration Statement (Form S-8 No. 333-269546) pertaining to the Immunovant, Inc. 2023 Inducement Plan,
(7) Registration Statement (Form S-8 No. 333-271138) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan,
(8) Registration Statement (Form S-3 No. 333-275419),
(9) Registration Statement (Form S-8 No. 333-278686) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan, and
(10) Registration Statement (Form S-8 No. 333-286848) pertaining to the Immunovant, Inc. 2019 Equity Incentive Plan;

of our reports dated May 20, 2026, with respect to the consolidated financial statements of Immunovant, Inc. and the effectiveness of internal control over financial reporting of Immunovant, Inc. included in this Annual Report
(Form 10-K) of Immunovant, Inc. for the year ended March 31, 2026.

/s/ Ernst & Young LLP

Iselin, New Jersey
May 20, 2026

Exhibit 31.1

CERTIFICATION

I, Eric Venker, M.D., Pharm. D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Immunovant, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 20, 2026

/s/ ERIC VENKER, M.D., PHARM. D.

Eric Venker, M.D., Pharm. D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Tiago Girao, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immunovant, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 20, 2026

/s/ TIAGO GIRAO

Tiago Girao
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Eric Venker, M.D., Pharm. D., Chief Executive Officer of Immunovant, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2026, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 20, 2026

/s/ ERIC VENKER, M.D., PHARM D.

Eric Venker, M.D., Pharm. D.
Chief Executive Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Tiago Girao, Chief Financial Officer of Immunovant, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2026, to which this Certification is attached as Exhibit 32.2 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 20, 2026

/s/ TIAGO GIRAO
Tiago Girao
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.