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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

Commission File Number 001-38906

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

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

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

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

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 1, 2024, there were 146,784,639 shares of the Registrant's common stock, $0.0001 par value per share, outstanding.

IMMUNOVANT, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024

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Where You Can Find More Information

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.

The information contained on the website referenced in this Quarterly Report on Form 10-Q is not incorporated by reference into this filing, and the website address is provided only as an inactive textual reference.

SUMMARY RISK FACTORS

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

- Our business is currently dependent on the successful and timely development, regulatory approval and commercialization of our product candidates.
- Our product candidates, or anti-FcRn product candidates or products developed by others, may cause adverse events or undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.
- Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
- The results of our nonclinical 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.
- Roivant Sciences Ltd. owns a significant percentage of shares of our common stock and may exert significant control over matters subject to stockholder approval.
- Our business, operations, clinical development plans, timelines and supply chain could be adversely affected by the effects of health epidemics and pandemics on manufacturing, clinical trials and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, contract research organizations, suppliers, shippers and others.
- Our business could be adversely affected by economic downturns, changes in inflation and interest rates, natural disasters, political crises, geopolitical events, such as the crises in Ukraine and the Middle East, or other macroeconomic conditions, which may in the future negatively impact our business and financial performance.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- Our failure to maintain or continuously improve our quality management program could have an adverse effect upon our business, subject us to regulatory actions and cause a loss of patient confidence in us or our products, among other negative consequences.
- We rely on third parties to conduct, supervise and monitor our clinical trials and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements or our quality management program fails to detect such events in a timely manner, it may harm our business.

- We may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- We have expanded our organization and plan to continue to do so and we may experience difficulties in managing this growth, which could disrupt our operations.
- Our third-party manufacturers may encounter difficulties in production or our quality management program may fail to detect quality issues at our third-party manufacturers which may delay or prevent our ability to obtain marketing approval or commercialize 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.
- We rely on the license agreement with HanAll Biopharma Co., Ltd., or the HanAll Agreement, to provide us rights to the core intellectual property relating to IMVT-1402 and batoclimab. Any termination or loss of significant rights under the HanAll Agreement would adversely affect our development or commercialization of IMVT-1402 and batoclimab.
- We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune disease indications. Our operating results will suffer if we fail to compete effectively.
- International expansion of our business exposes us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the U.S.
- We are subject to stringent and changing privacy, data protection, and information security laws, contractual obligations, self-regulatory schemes, government regulation and standards related to data privacy and security. Further, if our information technology systems or those of our affiliates, service providers or other relevant third parties are compromised now or in the future, this could result in a material adverse effect on our business.
- If securities or industry analysts do not publish research or reports about our business or publish negative reports about our business, our share price and trading volume could decline and has declined in the past upon downgrades of our common stock.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

IMMUNOVANT, INC.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share data)

	September 30, 2024	March 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 472,941	$ 635,365
Accounts receivable	1,876	5,337
Prepaid expenses and other current assets	32,555	25,068
Total current assets	507,372	665,770
Operating lease right-of-use assets	45	133
Other assets	7,619	—
Property and equipment, net	671	462
Total assets	**$ 515,707**	**$ 666,365**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 20,727	$ 7,155
Accrued expenses	45,879	41,315
Current portion of operating lease liabilities	47	138
Total current liabilities	66,653	48,608
Total liabilities	66,653	48,608
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Series A preferred stock, par value $0.0001 per share, 10,000 shares authorized, issued and outstanding at September 30, 2024 and March 31, 2024	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2024 and March 31, 2024	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 146,565,049 shares issued and outstanding at September 30, 2024 and 500,000,000 shares authorized, 145,582,999 shares issued and outstanding at March 31, 2024	14	14
Additional paid-in capital	1,469,082	1,441,518
Accumulated other comprehensive income	1,910	1,908
Accumulated deficit	(1,021,952)	(825,683)
Total stockholders' equity	449,054	617,757
Total liabilities and stockholders' equity	**$ 515,707**	**$ 666,365**

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

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 97,272	$ 47,959	$ 172,745	$ 98,534
Acquired in-process research and development	—	—	—	12,500
General and administrative	18,471	13,841	37,279	29,243
Total operating expenses	115,743	61,800	210,024	140,277
Interest income	(6,073)	(3,572)	(13,254)	(7,637)
Other income, net	(629)	(20)	(657)	(484)
Loss before provision for income taxes	(109,041)	(58,208)	(196,113)	(132,156)
Provision for income taxes	78	454	156	443
Net loss	**$ (109,119)**	**$ (58,662)**	**$ (196,269)**	**$ (132,599)**
Net loss per common share – basic and diluted	$ (0.74)	$ (0.45)	$ (1.34)	$ (1.01)
Weighted-average common shares outstanding – basic and diluted	146,468,991	131,155,642	146,313,696	130,872,717

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

IMMUNOVANT, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited, in thousands)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (109,119)	$ (58,662)	$ (196,269)	$ (132,599)
Other comprehensive income:				
Foreign currency translation adjustments	90	69	2	339
Total other comprehensive income	90	69	2	339
Comprehensive loss	**$ (109,029)**	**$ (58,593)**	**$ (196,267)**	**$ (132,260)**

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

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

	Series A preferred stock		Common stock					
	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at March 31, 2024	**10,000**	**$ —**	**145,582,999**	**$ 14**	**$ 1,441,518**	**$ 1,908**	**$ (825,683)**	**$ 617,757**
Stock options exercised and restricted stock units vested and settled	—	—	612,674	—	686	—	—	686
Capital contribution – stock-based compensation	—	—	—	—	12	—	—	12
Stock-based compensation	—	—	—	—	13,443	—	—	13,443
Foreign currency translation adjustments	—	—	—	—	—	(88)	—	(88)
Net loss	—	—	—	—	—	—	(87,150)	(87,150)
Balance at June 30, 2024	**10,000**	**$ —**	**146,195,673**	**$ 14**	**$ 1,455,659**	**$ 1,820**	**$ (912,833)**	**$ 544,660**
Stock options exercised and restricted stock units vested and settled	—	—	369,376	—	730	—	—	730
Capital contribution – stock-based compensation	—	—	—	—	8	—	—	8
Stock-based compensation	—	—	—	—	12,685	—	—	12,685
Foreign currency translation adjustments	—	—	—	—	—	90	—	90
Net loss	—	—	—	—	—	—	(109,119)	(109,119)
Balance at September 30, 2024	**10,000**	**$ —**	**146,565,049**	**$ 14**	**$ 1,469,082**	**$ 1,910**	**$ (1,021,952)**	**$ 449,054**

	Series A preferred stock		Common stock					
	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at March 31, 2023	**10,000**	**$ —**	**130,329,863**	**$ 13**	**$ 927,976**	**$ 852**	**$ (566,347)**	**$ 362,494**
Stock options exercised and restricted stock units vested and settled	—	—	235,566	—	890	—	—	890
Capital contribution – stock-based compensation	—	—	—	—	35	—	—	35
Stock-based compensation	—	—	—	—	10,653	—	—	10,653
Foreign currency translation adjustments	—	—	—	—	—	(270)	—	(270)
Net loss	—	—	—	—	—	—	(73,937)	(73,937)
Balance at June 30, 2023	**10,000**	**$ —**	**130,565,429**	**$ 13**	**$ 939,554**	**$ 582**	**$ (640,284)**	**$ 299,865**
Stock options exercised and restricted stock units vested and settled	—	—	876,595	—	148	—	—	148
Capital contribution – stock-based compensation	—	—	—	—	28	—	—	28
Stock-based compensation	—	—	—	—	10,501	—	—	10,501
Foreign currency translation adjustments	—	—	—	—	—	(69)	—	(69)
Net loss	—	—	—	—	—	—	(58,662)	(58,662)
Balance at September 30, 2023	**10,000**	**$ —**	**131,442,024**	**$ 13**	**$ 950,231**	**$ 513**	**$ (698,946)**	**$ 251,811**

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

IMMUNOVANT, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	Six Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (196,269)	$ (132,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	26,148	21,217
Depreciation on property and equipment	169	109
Non-cash lease expense	88	583
Changes in operating assets and liabilities:		
Accounts receivable	3,344	(703)
Prepaid expenses and other current assets	(6,541)	7,240
Other assets	(8,071)	—
Accounts payable	13,248	6,096
Accrued expenses	3,130	(8,767)
Operating lease liabilities	(92)	(606)
Net cash used in operating activities	**(164,846)**	**(107,430)**
Cash flows from investing activities		
Purchase of property and equipment	(378)	(79)
Net cash used in investing activities	**(378)**	**(79)**
Cash flows from financing activities		
Proceeds from stock options exercised	1,416	1,038
Net cash provided by financing activities	**1,416**	**1,038**
Effect of exchange rate changes on cash and cash equivalents	**1,384**	**(133)**
Net change in cash and cash equivalents	(162,424)	(106,604)
Cash and cash equivalents – beginning of period	635,365	376,532
Cash and cash equivalents – end of period	**$ 472,941**	**$ 269,928**
Supplemental disclosure of cash paid:		
Income taxes	**$ 301**	**$ —**

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

IMMUNOVANT, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1 — Description of Business and Liquidity

[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's innovative product pipeline includes its product candidates, IMVT-1402 and batoclimab, formerly referred to as IMVT-1401, both of which are novel, fully human, monoclonal antibodies that target the neonatal fragment crystallizable receptor ("FcRn"). Designed to be optimized as simple, subcutaneous injections with dosing that the Company believes can be tailored based on disease stage and severity, IMVT-1402 and batoclimab have 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 has determined that it hasone operating and reporting segment.

[B] Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of September 30, 2024, the Company's cash and cash equivalents totaled $472.9 million and its accumulated deficit was $1,022.0 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, batoclimab or any future product candidate. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates. The Company currently expects that its existing cash and cash equivalents as of September 30, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date these unaudited condensed consolidated financial statements are issued.

Note 2 — Summary of Significant Accounting Policies

[A] Basis of Presentation

The Company's fiscal year ends on March 31 and its first three fiscal quarters end on June 30, September 30, and December 31, respectively. The accompanying condensed consolidated financial statements are unaudited. The unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and follow the requirements of the U.S. Securities and Exchange Commission ("SEC") for interim financial reporting. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. The unaudited condensed 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. Certain amounts in the consolidated financial statements of the prior year have been reclassified to conform to current year presentation. 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").

In the opinion of management, the unaudited condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair statement of results for the interim periods. The results for the three and six months ended September 30, 2024 are not necessarily indicative of those expected for the year ending March 31, 2025 or for any future period. The condensed consolidated balance sheet as of March 31, 2024 included herein was derived from the audited consolidated financial statements as of that date. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the SEC on May 29, 2024.

[B] Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based compensation, litigation accruals, clinical trial accruals, operating leases, research and development costs and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Additionally, the Company assessed the impact of macroeconomic and geopolitical factors on its operations and financial results as of September 30, 2024 and through the issuance of these unaudited condensed consolidated financial statements. 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 September 30, 2024, 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. As of September 30, 2024 and March 31, 2024, cash and cash equivalents included $431.9 million and $607.7 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] Research and Development Expenses

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

The Company participates in cost-sharing arrangements with third parties whereas the third parties have agreed to share a portion of the costs incurred by the Company, related to batoclimab drug manufacturing and clinical trials. The Company records the third parties' share of the costs as a reduction of research and development expenses and an increase to accounts receivable in the accompanying unaudited condensed 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.

[G] Acquired In-Process Research and Development Expenses

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

The Company evaluates in-licensed agreements for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as acquired in-process research and development expenses in its unaudited condensed 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.

[H] Stock-based Compensation

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

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate, expected dividend yield and the fair value of the Company's common stock. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. In prior fiscal years, because the Company did not have sufficient trading history to rely on the volatility of its common stock, volatility was estimated by taking the average historical price volatility for comparable publicly traded peer companies. Beginning on April 1, 2024, the Company determined that its common stock had sufficient trading activity to utilize company-specific trading data within the assumption of volatility of the underlying shares. The expected share price volatility for the Company's common stock is estimated using a weighted blend of the Company's historical price volatility and the average historical price volatility for comparable publicly traded peer companies. 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.

[I] Net Loss per Common Share

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

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

	Six Months Ended September 30,	
	2024	2023
Preferred stock as converted	10,000	10,000
Stock options	13,596,262	13,372,356
Restricted stock units	3,650,581	4,036,663
Total	**17,256,843**	**17,419,019**

[J] Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," which updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. This ASU is applicable to the Company's Annual Report on Form 10-K for the fiscal year ending March 31, 2025, and subsequent interim periods, with early adoption permitted. These amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which updates income tax disclosures related to the rate reconciliation and disaggregation of income taxes paid by jurisdiction. The amendments are effective for fiscal years beginning after December 15, 2024 and is applicable to the Company's fiscal year beginning April 1, 2025, with early adoption permitted. The amendments should be applied prospectively, however retrospective application is permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the SEC did not, or are not expected to, have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

Note 3 — Material Agreements

License Agreement

On December 19, 2017, Roivant Sciences GmbH ("RSG"), a wholly owned subsidiary of Roivant Sciences Ltd. ("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 United States of America (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 September 30, 2024) 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 reduction, on a product-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 11th anniversary of the first commercial sale of such product in such country.

On August 18, 2018, RSG entered into a sublicense agreement (the "Sublicense Agreement") with Immunovant Sciences GmbH ("ISG"), a wholly-owned subsidiary of the Company, to sublicense this technology, as well as RSG's know-how and patents necessary for the development, manufacture or commercialization of any compound or product that pertains to immunology. On December 7, 2018, RSG issued a notice to terminate the Sublicense Agreement with ISG and entered into an assignment and assumption agreement to assign to ISG all the rights, title, interest, and future obligations under the HanAll Agreement from RSG, including all rights to IMVT-1402 and batoclimab in the Licensed Territory, for an aggregate purchase price of $37.8 million. Each party 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 unaudited condensed consolidated statement of operations for the six months ended September 30, 2023.

Product Service Agreement and Master Services Agreement

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

The PSA will continue until the later of December 31, 2029 or the completion of the services thereunder, unless the PSA is terminated earlier. Either party may terminate the PSA on account of (i) the other party's material breach of the PSA that is not cured within a specified period after the termination notice, (ii) the other party's insolvency or bankruptcy, or (iii) certain force majeure events. As of September 30, 2024, the remaining minimum purchase commitment related to this agreement was estimated to be approximately $43.6 million.

Note 4 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2024	March 31, 2024
Research and development expenses	$ 37,462	$ 24,634
Accrued bonuses	7,064	14,744
Legal and other professional fees	299	465
Other expenses	1,054	1,472
Total accrued expenses	**$ 45,879**	**$ 41,315**

Note 5 — Related Party Transactions

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

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

For the three and six months ended September 30, 2024, the Company incurred $0.3 million and $0.4 million, respectively, under the Services Agreements, which is included in the accompanying unaudited condensed consolidated statements of operations. For the three and six months ended September 30, 2023, the Company did not incur expenses under the Services Agreements.

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. There was no rent expense under these operating leases for the three months ended September 30, 2024 and rent expense under these operating leases was de minimis for the six months ended September 30, 2024. For the three and six months ended September 30, 2023, the Company incurred $0.3 million and $0.6 million, respectively, in rent expense under these operating leases.

Note 6 — Income Taxes

The Company's effective tax rates were (0.07)% and (0.78)% for the three months ended September 30, 2024 and 2023, respectively, and (0.08)% and (0.34)% for the six months ended September 30, 2024 and 2023, respectively. The Company's effective rate is primarily driven by its jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

The Company assesses the realizability of its 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.

Note 7 — Stockholders' Equity

Series A Preferred Stock

As of September 30, 2024, 10,000 shares of Series A preferred stock, par value $0.0001 per share, were outstanding and held by RSL.

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. 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 September 30, 2024, the Company has authorized 10,010,000 shares of preferred stock, par value $0.0001 per share. Other than the 10,000 shares of preferred stock designated as Series A preferred stock, there were no issued and outstanding shares of preferred stock as of September 30, 2024.

Common Stock

As of September 30, 2024, the Company has authorized 500,000,000 shares of common stock, par value $0.0001 per share and has 146,565,049 shares of common stock issued and outstanding.

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

	September 30, 2024	March 31, 2024
Conversion of Series A preferred stock	10,000	10,000
Stock options outstanding	13,596,262	13,050,172
Restricted stock units outstanding	4,436,477	4,099,279
Equity awards available for future grants	6,048,348	2,090,367
Total	**24,091,087**	**19,249,818**

The reserved shares underlying restricted stock units above include 785,896 restricted stock units that vested but were not settled as of September 30, 2024. 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 September 30, 2024. 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 maximum number of shares of common stock that may be issued pursuant to the exercise of incentive options under the 2019 Plan is 16,500,000. The 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. On April 1, 2024, 5,823,319 shares of common stock were added to the 2019 Plan pool in accordance with the evergreen provision of the 2019 Plan. As of September 30, 2024, options to purchase 10,988,489 shares of common stock and 3,650,581 restricted stock units ("RSUs") were outstanding under the 2019 Plan and 6,048,348 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 September 30, 2024, options to purchase 2,607,773 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 September 30, 2024, 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, 2024	13,026,329	$ 9.85	7.51	$ 293,920
Granted	1,242,430	30.44		
Exercised	(150,025)	8.65		
Forfeited	(522,472)	14.61		
Balance - September 30, 2024	**13,596,262**	**$ 11.56**	**6.88**	**$ 235,080**
Exercisable - September 30, 2024	**8,975,814**	**$ 8.76**	**6.06**	**$ 177,257**

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:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	3.59% - 4.16%	4.10% - 4.62%	3.59% - 4.71%	3.45% - 4.62%
Expected term, in years	6.11	6.11	6.11	6.11
Expected volatility	80.03% - 80.75%	97.68% - 97.81%	80.03% - 83.31%	93.66% - 98.15%
Expected dividend yield	—%	—%	—%	—%

Restricted Stock Unit Awards

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

	Number of RSUs	Weighted- Average Grant Date Fair Value
Nonvested as of March 31, 2024	3,466,057	$ 12.32
Issued	1,544,038	30.04
Vested	(960,856)	11.99
Forfeited	(398,658)	16.90
Nonvested as of September 30, 2024	**3,650,581**	**$ 19.40**

Stock-based Compensation Expense

For the three and six months ended September 30, 2024 and 2023, stock-based compensation expense under the Company's equity incentive plans was as follows (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	$ 6,756	$ 5,182	$ 13,941	$ 10,060
General and administrative expenses	5,929	5,319	12,187	11,094
Total stock-based compensation	**$ 12,685**	**$ 10,501**	**$ 26,128**	**$ 21,154**

As of September 30, 2024, total unrecognized compensation expense related to nonvested stock options and RSUs was $13.8 million and $62.8 million, respectively, which is expected to be recognized over the remaining weighted-average service period of 2.33 years and 2.60 years, respectively.

Stock-based Compensation Allocated to the Company by RSL

In relation to the RSL common share awards and options issued by RSL to employees of Roivant and the Company, the Company did not have any stock-based compensation expense for the three and six months ended September 30, 2024 and 2023 in the accompanying unaudited condensed consolidated statements of operations.

RSL RSUs

The Company's Chief Executive Officer was granted 73,155 RSUs of RSL in January 2021, which are vesting over a period of four years. For the three and six months ended September 30, 2024 and 2023, stock-based compensation recorded by the Company related to these RSUs was de minimis. As of September 30, 2024, the amount of unrecognized compensation expense related to unvested RSL RSUs was de minimis.

Note 9 — Commitments and Contingencies

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 September 30, 2024, the Company was not party to any material legal proceedings and thus no contingent liabilities were recorded.

In February 2021, a putative securities class action complaint was filed against the Company and certain of its current and former officers in the U.S. District Court for the Eastern District of New York alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Following appointment of lead plaintiff and extensive briefing by the parties, including multiple amendments to the complaint and motions to dismiss, on March 29, 2024, the court dismissed the operative complaint with prejudice. On April 5, 2024, the Court entered judgment in favor of defendants. Plaintiffs did not appeal the Court's judgment, so the litigation is now concluded. The Company has not recorded a liability related to this lawsuit.

Commitments

During the year ended March 31, 2022, ISG entered into the PSA with Samsung to manufacture a certain quantity of batoclimab drug substance for, among other things, commercial sale, if approved. As of September 30, 2024, in connection with this agreement, the Company has a remaining minimum obligation to Samsung of approximately $43.6 million, of which $3.0 million, $12.6 million, $14.0 million and $14.0 million is expected to be paid during the remainder of the fiscal year ending March 31, 2025, and for the fiscal years ending March 31, 2026, 2027, and 2029, respectively. During the three and six months ended September 30, 2024, the Company recorded $0.1 million and $0.2 million, respectively, of research and development expenses related to the PSA. During the three and six months ended September 30, 2023, the Company recorded $0.6 million and $1.3 million, respectively, of research and development expenses related to the PSA. The Company made cash payments of $2.6 million related to the PSA during the six months ended September 30, 2024 and recorded $1.9 million in accrued expenses in the accompanying unaudited condensed consolidated balance sheet as of September 30, 2024.

As of September 30, 2024, 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 and global slowdown of economic activity, changes in inflation and interest rates, and a potential recession in the U.S. on the Company's future operational and financial performance will depend on certain developments, including the potential impact on the Company's clinical trial plans and timelines, such as the enrollment, activation and initiation 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our (1) unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report"), and (2) audited consolidated financial statements and the related notes thereto and management's discussion and analysis of financial condition and results of operations for the fiscal year ended March 31, 2024, included in our Annual Report on Form 10-K ("Annual Report"), filed with the Securities and Exchange Commission (the "SEC") on May 29, 2024. Unless the context requires otherwise, references in this Quarterly Report to "Immunovant," the "Company," "we," "us," and "our" refer to Immunovant, Inc. and its wholly owned subsidiaries.

Forward-Looking Statements

This Quarterly Report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "forecast," "goal," "hope," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements.

Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of this Quarterly Report and in our other filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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 Quarterly 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. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a clinical-stage immunology company pursuing a broad anti-FcRn strategy based on the potential best-in-class profile of our lead asset, IMVT-1402, and informed by the breadth of the class, in which 23 indications have been publicly announced for study by multiple companies to date. We expect to initiate programs evaluating IMVT-1402 in several therapeutic areas, including rheumatology, endocrinology and neurology. To address the unmet needs of people with autoantibody-driven diseases, we are committed to initiating a broad set of late-stage programs for IMVT-1402, including first-in-class indications such as Graves' disease ("GD"), classic autoantibody indications such as myasthenia gravis ("MG") and other indications with positive in-class data such as chronic inflammatory demyelinating polyneuropathy ("CIDP") and rheumatoid arthritis ("RA"). We expect to leverage disease state insights, clinical trial data observed to date within the anti-FcRn class, and operational experience from past and ongoing batoclimab studies and trials to inform and accelerate the development of IMVT-1402.

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

The physiologic function of FcRn is to prevent the degradation of immunoglobulin G ("IgG") antibodies. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases. Inhibition of FcRn, such as through the use of an anti-FcRn antibody, has been shown to reduce levels of total IgG and pathogenic IgG antibodies. We believe our completed clinical trials and other clinical trials assessing anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results, suggesting that FcRn is a therapeutically important and validated pharmacologic target to reduce levels of disease-causing IgG antibodies. Thus, we are developing IMVT-1402 and batoclimab in autoimmune diseases for which there is robust evidence that pathogenic IgG antibodies drive disease manifestation and for which we believe that reduction of IgG antibodies should lead to clinical benefit.

Batoclimab, our initial product candidate, is dosed subcutaneously using a small gauge needle in small volumes (e.g., 2 mL), and has generated therapeutically relevant pharmacodynamic activity. We believe these attributes will drive patient preference and market adoption. In clinical trials conducted to date, batoclimab has been observed to reduce 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.

Likewise, IMVT-1402, our lead product candidate, has also been observed to reduce IgG antibody levels in a Phase 1 clinical trial conducted in healthy adults, similar to that observed in our original Phase 1 clinical trial of batoclimab. Importantly, although FcRn also plays a role in maintaining serum albumin levels which in turn correlate inversely with low-density lipoprotein ("LDL") cholesterol levels, no or minimal reduction in albumin and no or minimal increases in LDL cholesterol levels were observed in study participants administered either 300 mg or 600 mg of IMVT-1402 subcutaneously once weekly for four weeks. Across both dose regimens, the changes in albumin and LDL cholesterol were similar to those observed with placebo administration. This is a key attribute for IMVT-1402, which we believe could potentially allow its use as a treatment of chronic conditions requiring maintenance doses that achieve high degrees of IgG suppression.

We believe that FcRn inhibition has broad therapeutic and commercial potential to address IgG-mediated autoimmune diseases in a number of therapeutic areas, including but not limited to, neurology, endocrinology, hematology, rheumatology, and dermatology. Based on third-party patient prevalence estimates, for the 23 indications that have been publicly announced by multiple companies for clinical development with anti-FcRn assets, we estimate the total potential opportunity for our FcRn franchise to be greater than two million patients in the U.S. and Europe. Our estimates in Europe include all European Union ("E.U.") countries, Norway, Lichtenstein, Iceland, (together with the E.U. countries, the "EEA"), the United Kingdom ("U.K."), and Switzerland.

Our goal is to fully optimize the IMVT-1402 clinical development program consistent with its potential best-in-class profile. Our strategic priority is to build a class-leading portfolio of indications in several therapeutic areas by leveraging data derived from studies with batoclimab and from studies with other FcRn inhibitors, both approved and in development. We are on track to initiate four to five potentially registrational programs for IMVT-1402 in several therapeutic areas, including rheumatology, endocrinology and neurology, by March 31, 2025, and exceeded the goal of having three Initial New Drug ("IND") applications for IMVT-1402 cleared by the end of calendar year 2024, with five IND applications now active for IMVT-1402. Inclusive of these programs, by March 31, 2026, we plan to have initiated clinical trials of IMVT-1402 in a total of ten indications. The current development program for batoclimab remains important, in particular for accelerating and optimizing the registrational development program of IMVT-1402. In addition, we expect to achieve financial efficiencies in our IMVT-1402 development program by taking advantage of batoclimab data and by applying learning from publicly disclosed in-class competitor data and trial designs.

As a result of our rational design and current outlook on potential opportunities, we believe our product candidates, if developed and approved for commercial sale, would be differentiated from currently available treatments for advanced IgG-mediated autoimmune diseases. To date, these product candidates have demonstrated potential best-in-class IgG reduction and are being developed for delivery using a simple, self-administered subcutaneous injection.

Recent Developments in Our Clinical Programs

IMVT-1402

In the quarter ended June 30, 2023, the FDA cleared our IND application for IMVT-1402 and we initiated a Phase 1 clinical trial in healthy adults in New Zealand after approval of the Clinical Trial Application ("CTA") by the regulatory authority, MEDSAFE.

Based on trial results announced to date and the strength of its potential best-in-class profile, we plan to pursue studies with IMVT-1402 in rheumatology, endocrinology, neurology and other therapeutic areas, with a focus on indications representing first-in-class opportunities, classic autoantibody diseases, and diseases where IgG autoantibodies are believed to play a role. In selecting indications for development, we plan to leverage data from our batoclimab development program and also take advantage of publicly disclosed in-class competitor data, which can be used to establish proof-of-concept as well as provide insights into potentially more informative study designs.

Endocrine Diseases

IMVT-1402 as a Potential Treatment for Graves' Disease

Data from our Phase 2 proof of concept trial evaluating batoclimab in GD demonstrate the potential of FcRn inhibition for the treatment of GD by modifying the underlying disease pathology, which is driven by thyroid-stimulating hormone receptor autoantibodies ("TRAb"). In addition, the data represent strong evidence that deeper IgG reduction correlates with better clinical outcomes in GD.

Current Treatment Paradigm

The treatment of GD has seen minimal innovation in treatment options over the past 70-plus years. Anti-thyroid drugs ("ATDs"), as the only existing pharmacological therapy, do not address the underlying disease pathology characterized by high levels of TRAb. A conservative analysis of Inovalon claims data estimates that the prevalence and incidence of GD patients is approximately 880,000 and 65,000 in the U.S. Further, market-sizing analyses by various methods suggest that 25-30% of GD patients are relapsed, uncontrolled on or intolerant to ATDs, representing a potentially significant unmet medical need.

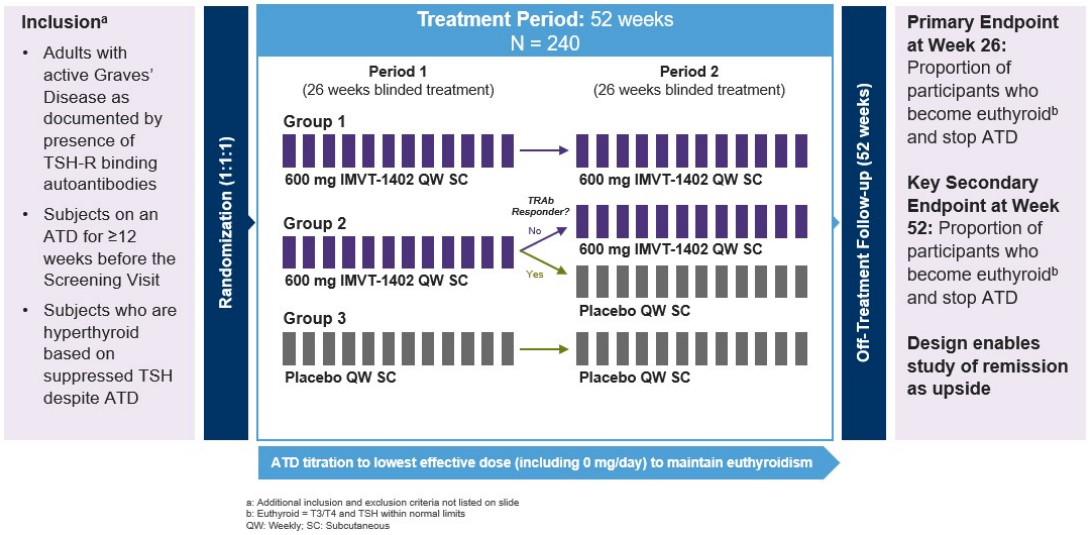
GD Pivotal Study

In September 2024 we announced receipt of IND clearance from the FDA for IMVT-1402 in GD. Leveraging the data from the batoclimab proof-of-concept trial, we expect to initiate a pivotal trial by December 31, 2024 to evaluate IMVT-1402 in Graves' patients who are hyperthyroid despite treatment with ATDs.

The IMVT-1402 pivotal study is a randomized, placebo-controlled, 52-week trial in Graves' disease patients who are hyperthyroid (as evidenced by TRAb levels) despite treatment with an ATD for 12 or more weeks prior to beginning the study. The study will enroll approximately 240 participants randomized (1:1:1) to one of two blinded treatment groups each receiving IMVT-1402, 600 mg weekly by subcutaneous injection ("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 group 2 IMVT-1402 treatment group 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 will evaluate 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.

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

GD Pivotal Trial Design



Rheumatology Diseases

IMVT-1402 as a Potential Treatment for 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. RA is the most common systemic autoimmune disease. The exact cause of RA is not completely known but is associated with a variety of genetic, hormonal and environmental factors. RA can occur at any age, but it is more commonly diagnosed in middle age and women are more likely to be affected than men. RA affects 18 million persons globally and 1.5 million persons in the United States. Several autoantibodies have been identified in RA. Among these are rheumatoid factor ("RF") and anti-citrullinated protein antibodies ("ACPA"). These RA-specific autoantibodies are found in 70-80% of RA patients and amplify inflammation via immune complex formation. Autoantibodies are associated with severe disease and poor outcomes on current available therapies. An estimated 5% to 20% of RA patients are characterized as having difficult-to-treat ("D2T") RA due to a failure to respond to two or more biologic or targeted synthetic disease modifying anti-rheumatic drugs ("DMARDs").

Current Treatment Paradigm

Currently available treatments used to help control joint inflammation include a variety of conventional oral, targeted synthetic and biologic DMARDs, most of which reduce cytokines. For D2T RA patients, who remain symptomatic despite multiple lines of treatment, there remains a significant unmet need.

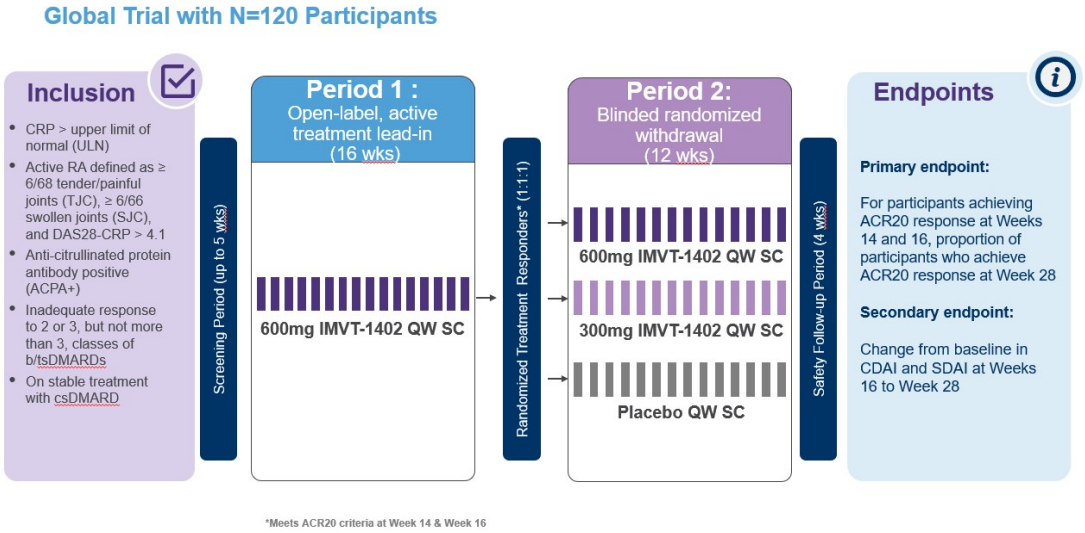
Because of the role of FcRn in preventing degradation of IgG autoantibodies, such as ACPAs, FcRn inhibition is an attractive mechanism as a potential treatment for ACPA-positive RA. Recent in-class anti-FcRn data from a Phase 2a placebo-controlled, proof-of-concept trial evaluating nipocalimab in patients with RA demonstrated that both higher baseline ACPA levels and deeper ACPA reduction correlated with better clinical improvement with nipocalimab treatment.

RA Pivotal Study

Having received FDA clearance of the IND for IMVT-1402 in RA, we plan to initiate a potentially registrational trial evaluating our lead asset IMVT-1402 in D2T RA by March 31, 2025. The trial is expected to build on in-class learning in terms of its target population (enriched for above-normal ACPA levels) and study design (open-label lead-in followed by randomized withdrawal). The trial is expected to enroll approximately 120 participants into an initial 16-week open-label, active treatment period, followed by a blinded, randomized withdrawal period of 12 weeks. To ensure the enrollment of patients with active D2T RA, the trial inclusion criteria require elevated ACPA levels and prior inadequate response to 2 or 3 (but no more than 3) biologic or target synthetic DMARDs. The study will leverage IMVT-1402's higher dose (600 mg) during the open-label induction phase of the trial with the intent of maximizing reduction in ACPA levels. For participants achieving a response at weeks 14 and 16 per the American College of Rheumatology ("ACR") response criteria ACR20, the primary endpoint will assess the proportion of such participants who maintain the ACR20 response at week 28.

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

RA Pivotal Study Design



Neurological Diseases

IMVT-1402 as a Potential Treatment for Myasthenia Gravis

We may transition our registrational development programs for MG from batoclimab to IMVT-1402, with a final decision for this program contingent on top-line data from the batoclimab study in this indication. We expect to report top-line data from the batoclimab MG study by March 31, 2025 with potential registrational development for MG expected to transition from batoclimab to IMVT-1402 in the same timeframe.

IMVT-1402 as a Potential Treatment for Chronic Inflammatory Demyelinating Polyneuropathy

We may transition our registrational development program for CIDP from batoclimab to IMVT-1402 and the pivotal study with IMVT-1402 in CIDP may be optimized based on unblinded batoclimab CIDP data available by March 31, 2025.

Batoclimab

Endocrine Diseases

In September 2024, we announced additional data from our proof-of-concept Phase 2 clinical trial in uncontrolled GD, which enrolled patients who remained hyperthyroid despite ATD therapy. Participants in the trial received 12 weeks of high dose batoclimab, 680 mg weekly SC followed by 12 weeks of lower dose batoclimab, 340 mg weekly SC. At the end of the first 12 weeks, participants experienced a mean IgG reduction of 77% leading to a 76% response rate (defined as T3 and T4 falling below the upper limit of normal ("ULN") without increasing the ATD dose). Also, by the end of 12 weeks of higher dose batoclimab, 56% of subjects achieved an ATD-Free Response (defined as T3 and T4 falling below the ULN and the patient simultaneously tapering completely off their ATD). Despite benefiting from a lower starting IgG level after 12 weeks of 680 mg therapy, during weeks 13 to 24, the lower 340 mg dose of batoclimab resulted in mean IgG reduction of 65% (vs. 77% on 680 mg dose) with a correspondingly lower responder rate of 68%. In addition, a lower ATD-Free Response rate of 36% was also observed in the second 12 weeks. Finally, patients who achieved 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 (60% vs. 23%). Batoclimab was generally well tolerated with no new safety signals observed.

In November 2024, additional incremental data observed in the study for certain thyroidal and extrathyroidal manifestations of GD were presented at the American Thyroid Association 2024 Annual Meeting. These data show that a 60% response rate was achieved by week 2, demonstrating the rapidity of response to batoclimab 680 mg dosed weekly. Meaningful improvements in proptosis and lid aperture were also observed at both week 12 and week 24. Pronounced improvements in multiple Thyroid-Related Patient-Reported Outcomes (ThyPRO-39) measurement scales were also observed, with ATD-Free Responders reporting greater improvements than other participants. This clinical trial is ongoing.

In the quarter ended December 31, 2022, we initiated our Phase 3 clinical program to evaluate batoclimab as a treatment for TED. Over the course of the program to date, we observed increasing competition for patients with TED to participate in clinical trials. We completed a robust review of the inclusion and exclusion criteria of our Phase 3 batoclimab clinical trials in TED to determine if modifications could be made to improve patient enrollment without a resulting negative impact to the potential clinical trial results. In conjunction with input from key opinion leaders, we determined that no such modifications should be made, and we are therefore continuing enrollment in the study with the inclusion and exclusion criteria as originally designed to maximize effect size on proptosis response in TED. As a result, we expect top-line results to be available in the second half of calendar year 2025, along with a decision on whether to advance batoclimab to registration in TED or pursue IMVT-1402 in this indication.

Neurological Diseases

In the quarter ended December 31, 2022, we initiated a pivotal Phase 2b trial of batoclimab as a treatment for CIDP. Enrollment is completed for patients to be included in the period 1 top-line results, which are expected by March 31, 2025. We believe data from this batoclimab trial, combined with learning from other trials in CIDP, can be used to optimize the IMVT-1402 trial design in active CIDP patients.

In the quarter ended June 30, 2022, we initiated our Phase 3 pivotal trial of batoclimab as a treatment for MG. Enrollment in this pivotal trial has now completed and we expect top-line data to be available by March 31, 2025. Further potential registrational development with IMVT-1402 is expected to begin in the same timeframe, with a final decision to be made based on results from the current batoclimab trial.

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, a potential recession in the U.S., recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and the Russia-Ukraine war and conflict in the Middle East, 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 II, Item 1A in this Quarterly Report.

Our Key Agreements

License Agreement with HanAll ("HanAll Agreement")

For a description of our transactions under the HanAll Agreement, refer to "*Note 3 – Material Agreements*" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

Product Service Agreement and Master Services Agreement

For a description of our transactions under the Product Service Agreement and Master Services Agreement with Samsung Biologics Co., Ltd., refer to "*Note 3 – Material Agreements*" and "*Note 9 – Commitments and Contingencies*" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

Related Party Transactions

For a description of our transactions under agreements with related parties, refer to "*Note 5 – Related Party Transactions*" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

Financial Operations Overview

Revenue

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

Research and Development Expenses

We have been primarily engaged in preparing for and conducting clinical trials. Research and development expenses include 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, including under our agreement with Samsung, to the extent they can be allocated to a specific therapeutic area.

Unallocated costs include:

- personnel-related expenses for research and development personnel, which includes employee-related expenses such as salaries, benefits and other staff-related costs;
- stock-based compensation expenses for research and development personnel;
- costs allocated to us under our services agreements with Roivant Sciences Inc. ("RSI") and Roivant Sciences GmbH ("RSG") (the "Services Agreements"); and
- other expenses, which include the cost of consultants who assist with 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 as we continue our Phase 3 trial of batoclimab as a treatment for MG, our Phase 3 clinical program to evaluate batoclimab for the treatment of TED, a pivotal Phase 2b trial of batoclimab as a treatment for CIDP and a proof-of-concept Phase 2 clinical trial of batoclimab as a treatment for GD. With respect to our IMVT-1402 development activities, our Phase 1 clinical trial of IMVT-1402 in New Zealand remains open and we anticipate initiating pivotal trials of IMVT-1402 in GD by December 31, 2024 and RA by March 31, 2025. Our research and development expenses are expected to further increase as we seek to execute our plan to initiate an additional two to three potentially registrational programs for IMVT-1402 in other indications by March 31, 2025 and ultimately initiate trials of IMVT-1402 in a total of ten indications (inclusive of those programs to be initiated in fiscal 2025) by March 31, 2026. Our research and development expenses are also expected to continue to increase over the next several years as we hire personnel and our compensation costs increase, increase manufacturing of IMVT-1402 and batoclimab drug substance and drug product and prepare to seek regulatory approval for our product candidates. It is not possible to determine with certainty the duration and completion costs of any clinical trial we may conduct.

The duration, costs and timing of clinical trials of IMVT-1402, batoclimab, 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 and interest rates, a potential recession in the U.S., recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and the Russia-Ukraine war and the conflict in the Middle East;
- 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 salaries and related benefits, stock-based compensation for general and administrative personnel, legal and accounting fees, consulting services, costs allocated under the Services Agreements and other operating costs relating to corporate matters and daily operations.

We anticipate that our general and administrative expenses will continue to 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, increased costs related to the hiring of additional personnel and fees to outside consultants for professional services. In addition, if either IMVT-1402 or batoclimab obtains regulatory approval, we expect that we would incur significant additional expenses associated with market research activities and building commercial teams.

Results of Operations for the Three Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 97,272	$ 47,959	$ 49,313
General and administrative	18,471	13,841	4,630
Total operating expenses	115,743	61,800	53,943
Interest income	(6,073)	(3,572)	(2,501)
Other income, net	(629)	(20)	(609)
Loss before provision (benefit) for income taxes	(109,041)	(58,208)	(50,833)
Provision (benefit) for income taxes	78	454	(376)
Net loss	**$ (109,119)**	**$ (58,662)**	**$ (50,457)**

Research and Development Expenses for the Three Months Ended September 30, 2024 and 2023

The following table summarizes the period-over-period changes in research and development expenses for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Change
	2024	2023*	$
Therapeutic area-specific costs:			
Neurological diseases	$ 29,614	$ 5,133	$ 24,481
Endocrine diseases	14,887	8,431	6,456
Rheumatology diseases	7,219	—	7,219
Other clinical and nonclinical	7,903	11,875	(3,972)
Total therapeutic area-specific costs	59,623	25,439	34,184
Unallocated costs:			
Personnel-related expenses including stock-based compensation	26,319	17,048	9,271
Other	11,330	5,472	5,858
Total research and development expenses	**$ 97,272**	**$ 47,959**	**$ 49,313**

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

For the three months ended September 30, 2024, research and development expenses increased $49.3 million as compared with the prior-year period.

For the three months ended September 30, 2024, therapeutic area-specific research and development costs, including contract manufacturing costs for drug substance, increased $34.2 million as compared with the prior-year period. Research and development costs related to neurological diseases, which include MG and CIDP, increased $24.5 million. This increase was primarily due to preparation for potential future clinical trials of IMVT-1402 in neurological diseases and higher overall clinical trial costs related to our batoclimab Phase 3 clinical trial. Research and development costs related to endocrine diseases, which include TED and GD, increased $6.5 million. This increase was primarily due to preparation for potential future clinical trials of IMVT-1402 in endocrine diseases and, to a lesser extent, higher overall clinical trial costs related to our batoclimab Phase 3 clinical program. Research and development costs related to rheumatology diseases of $7.2 million in the current-year period reflected preparation for potential future clinical trials of IMVT-1402. Research and development costs related to other clinical and nonclinical activities decreased $4.0 million, reflecting lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies, partially offset by overall costs in preparation for future IMVT-1402 clinical programs.

For the three months ended September 30, 2024, unallocated research and development costs increased $15.1 million as compared with the prior-year period. This increase reflected higher personnel-related expenses of $9.3 million, driven by higher headcount and enhancement of our capabilities to support our strategic objectives as we progress our clinical activities in existing and new therapeutic areas. In addition, other expenses increased $5.9 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.

General and Administrative Expenses for the Three Months Ended September 30, 2024 and 2023

For the three months ended September 30, 2024, general and administrative expenses increased $4.6 million as compared with the prior-year period, primarily reflecting higher personnel-related expenses, legal and other professional fees, and information technology costs.

Interest Income for the Three Months Ended September 30, 2024 and 2023

For the three months ended September 30, 2024, interest income increased $2.5 million as compared with the prior-year period, primarily reflecting interest earned on higher money market fund balances as a result of proceeds from our October 2023 underwritten public offering and concurrent private placement.

Results of Operations for the Six Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the six months ended September 30, 2024 and 2023 (in thousands):

	Six Months Ended September 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 172,745	$ 98,534	$ 74,211
Acquired in-process research and development	—	12,500	(12,500)
General and administrative	37,279	29,243	8,036
Total operating expenses	210,024	140,277	69,747
Interest income	(13,254)	(7,637)	(5,617)
Other income, net	(657)	(484)	(173)
Loss before provision (benefit) for income taxes	(196,113)	(132,156)	(63,957)
Provision (benefit) for income taxes	156	443	(287)
Net loss	**$ (196,269)**	**$ (132,599)**	**$ (63,670)**

Research and Development Expenses for the Six Months Ended September 30, 2024 and 2023

The following table summarizes the period-over-period changes in research and development expenses for the six months ended September 30, 2024 and 2023 (in thousands):

	Six Months Ended September 30,		Change
	2024	2023*	$
Batoclimab - Program-specific costs:			
Neurology diseases	$ 47,956	$ 16,376	$ 31,580
Endocrine diseases	30,937	14,750	16,187
Rheumatology diseases	7,219	—	7,219
Other clinical and nonclinical	14,304	21,705	(7,401)
Total therapeutic area-specific costs	100,416	52,831	47,585
Unallocated costs:			
Personnel-related expenses including stock-based compensation	50,839	34,006	16,833
Other	21,490	11,697	9,793
Total research and development expenses	**$ 172,745**	**$ 98,534**	**$ 74,211**

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

For the six months ended September 30, 2024, research and development expenses increased $74.2 million as compared with the prior-year period.

For the six months ended September 30, 2024, therapeutic area-specific research and development costs, including contract manufacturing costs for drug substance, increased $47.6 million as compared with the prior-year period. Research and development costs related to neurological diseases, which include MG and CIDP, increased $31.6 million. This increase was primarily due to preparation for potential future clinical trials of IMVT-1402 in neurological diseases and higher overall clinical trial costs related to our batoclimab Phase 3 clinical trial. Research and development costs related to endocrine diseases, which include TED and GD, increased $16.2 million. This increase was primarily due to preparation for potential future clinical trials 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 rheumatology diseases of $7.2 million in the current-year period reflected preparation for potential future clinical trials of IMVT-1402. Research and development costs related to other clinical and nonclinical activities decreased $7.4 million, reflecting lower overall costs related to our IMVT-1402 Phase 1 trial and nonclinical studies, partially offset by overall costs in preparation for future IMVT-1402 clinical programs.

For the six months ended September 30, 2024, unallocated research and development costs increased $26.6 million as compared with the prior-year period. This increase reflected higher personnel-related expenses of $16.8 million, driven by higher headcount and enhancement of our capabilities to support our strategic objectives as we progress our clinical activities in existing and new therapeutic areas. In addition, other expenses increased $9.8 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 for the Six Months Ended September 30, 2024 and 2023

There were no acquired in-process research and development expenses for the six months ended September 30, 2024. During the six months ended September 30, 2023, acquired in-process research and development expenses were $12.5 million related to the achievement of development and regulatory milestones for batoclimab as specified in the HanAll Agreement.

General and Administrative Expenses for the Six Months Ended September 30, 2024 and 2023

For the six months ended September 30, 2024, general and administrative expenses increased $8.0 million as compared with the prior-year period, primarily reflecting higher personnel-related expenses, legal and other professional fees, and information technology costs.

Interest Income for the Six Months Ended September 30, 2024 and 2023

For the six months ended September 30, 2024, interest income increased $5.6 million as compared with the prior-year period, primarily reflecting interest earned on higher money market fund balances as a result of proceeds from our October 2023 underwritten public offering and concurrent private placement.

Liquidity and Capital Resources

Sources of Liquidity

We had cash and cash equivalents of $472.9 million and $635.4 million as of September 30, 2024 and March 31, 2024, respectively. For the three months ended September 30, 2024 and 2023, we had net losses of $109.1 million and $58.7 million, respectively and for the six months ended September 30, 2024 and 2023, we had net losses of $196.3 million and $132.6 million, respectively. We expect to continue to incur significant expenses and increasing operating losses at least for the next several years. We have never generated any revenue and we do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for batoclimab, IMVT-1402 or any future product candidate.

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

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

On November 9, 2023, we entered into 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 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 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.

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 six months ended September 30, 2024 and 2023 (in thousands):

	Six Months Ended September 30,	
	2024	2023
Net cash used in operating activities	$ (164,846)	$ (107,430)
Net cash used in investing activities	(378)	(79)
Net cash provided by financing activities	1,416	1,038

Operating Activities

For the six months ended September 30, 2024, $164.8 million of cash was used in operating activities, primarily reflecting a net loss from operations for the period of $196.3 million, partially offset by non-cash charges of $26.4 million and a net change in operating assets and liabilities of $5.0 million. The non-cash charges consisted mainly of stock-based compensation of $26.1 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 of $13.2 million, primarily related to clinical trial and contract manufacturing costs and a decrease in accounts receivable of $3.3 million, reflecting the collection of amounts owed to us under research and development cost-sharing arrangements with a third party. In addition, accrued expenses increased $3.1 million, primarily reflecting the timing of payments and services related to contract manufacturing and our ongoing clinical trials, partially offset by payments related to employee incentive compensation. These changes were partially offset by an increase in other assets of $8.1 million as a result of prepaid expenses related to planned contract manufacturing activities, as well as higher prepaid expenses and other current assets of $6.5 million, driven primarily by the timing of payments and services performed related to our ongoing and planned clinical trials.

For the six months ended September 30, 2023, $107.4 million of cash was used in operating activities, primarily reflecting a net loss from operations for the year of $132.6 million, partially offset by non-cash charges of $21.9 million and a net change in operating assets and liabilities of $3.3 million. The non-cash charges consisted mainly of stock-based compensation of $21.2 million, reflecting the higher headcount and incentive equity awards as compared with the prior year. The change in operating assets and liabilities reflected $7.2 million of lower prepaid expenses and other current assets, driven primarily by the timing of payments and services performed related to our ongoing clinical trials. Changes in accounts payable reflected an increase of $6.1 million driven by the timing and level of payments related to contract manufacturing and research and development costs related to our clinical trials. These changes were partially offset by a decrease in accrued expenses of $8.8 million, primarily reflecting payments for contract manufacturing costs.

Investing Activities

For the six months ended September 30, 2024 and 2023, cash used in investing activities was related to the purchase of property and equipment.

Financing Activities

For the six months ended September 30, 2024 and 2023, cash provided by financing activities consisted 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 and nonclinical 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 or batoclimab manufacturing, HanAll milestone payments and our expenditures on other research and development activities.

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

Our short-term and long-term material cash requirements as of September 30, 2024 primarily consisted of those related to our clinical trials and clinical development activities, which we expect to fund primarily with our existing cash balance. Our most significant cash requirements are described below:

Product Service Agreement and Master Services Agreement

During the year ended March 31, 2022, we entered into an agreement with Samsung to manufacture a certain quantity of batoclimab drug substance for, among other things, commercial sale, if approved. As of September 30, 2024, in connection with this agreement, we have a remaining minimum obligation to Samsung of approximately $43.6 million, of which $3.0 million, $12.6 million, $14.0 million and $14.0 million is expected to be paid during the remainder of the fiscal year ending March 31, 2025, and for the fiscal years ending March 31, 2026, 2027 and 2029, respectively. See "*Note 3 - Material Agreements*" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report for additional details.

HanAll Agreement

Potential future payments due under the HanAll Agreement are contingent upon future events. As ofSeptember 30, 2024, 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 September 30, 2024) upon the achievement of certain regulatory and sales milestone events. During the quarter ended June 30, 2023, we achieved our third and fourth development and regulatory milestones under the HanAll Agreement and made a $12.5 million milestone payment in the quarter ended September 30, 2023 in accordance with the terms of the agreement.

Outlook

We currently expect that our existing cash and cash equivalents as of September 30, 2024 of $472.9 million will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of the filing of this Quarterly Report and in the long term beyond the next 12 months.

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

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

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

Our primary use of cash is to fund our clinical trials, 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 or batoclimab. We anticipate that we will continue to incur net losses for the foreseeable future.

Critical Accounting Estimates

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

We define our critical accounting estimates as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the three and six months ended September 30, 2024, there were no material changes to our critical accounting estimates from those disclosed in the audited consolidated financial statements for the year ended March 31, 2024 included in our Annual Report.

Recent Accounting Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our unaudited condensed consolidated financial statements, refer to "*Note 2 – Summary of Significant Accounting Policies*" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of September 30, 2024, we had cash and cash equivalents of $472.9 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 liquidity.

Foreign Currency Exchange Rate Risk

Our employees and our operations are currently primarily located in the United States 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. We believe an immediate hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our liquidity or our 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 results of operations as of September 30, 2024.

Item 4. 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 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 September 30, 2024, the end of the period covered by this Quarterly Report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2024 at the reasonable assurance level.

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 September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we 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, refer to "*Note 9 – Commitments and Contingencies*" in our unaudited condensed consolidated financial statements in Part I, Item I of this Quarterly Report.

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

Risks Related to Development, Regulatory Approval and Commercialization

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

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 IMVT-1402. 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. Delays or failures in the clinical trials for our product candidates, such as the voluntary pause of our batoclimab clinical trials announced in February 2021 and resulting inconclusive study results, have and could in the future significantly impact and harm our business. See "Risks Related to Development, Regulatory Approval and Commercialization – Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes."

We cannot be certain that 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. In addition, we have not yet demonstrated our ability to complete later-stage or pivotal clinical trials for our product candidates. We have not submitted a BLA for 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:

- we may not be able to demonstrate that our product candidates are safe and effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant foreign regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant foreign regulatory authorities for marketing approval;
- the FDA or other relevant foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our clinical trials;

- the CROs that we retain to conduct clinical trials may take actions outside of our control or otherwise commit errors or breaches of protocols that materially adversely impact our clinical trials and ability to obtain market approvals;
- the FDA or other relevant foreign regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of our product candidates outweigh 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 FDA or other relevant foreign regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant foreign regulatory authorities may require development of a Risk Evaluation and Mitigation Strategy ("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.

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

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

If unacceptable AEs or side effects arise in the development of our or others' anti-FcRn product candidates, we, other reviewing entities, clinical trial sites or regulatory authorities could suspend, vary or terminate our clinical trials or the regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. If an unacceptable frequency or severity of AEs or new safety signals are reported in our or others' anti-FcRn clinical trials 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. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

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

Furthermore, it is possible we will not be able to agree upon sufficient risk mitigation with all regulatory authorities and that our development of our product candidates will not continue in certain countries or for certain indications. Even if we are able to continue clinical development of our product candidates with such risk mitigations, any future approval and marketing would suffer from the risks of potential AEs or side effects and potential impact of mitigating measures, including, among others, limited indication, monitoring, a 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.

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 initiating four to five potentially registrational programs for IMVT-1402 over the course of our fiscal year ending March 31, 2025, and we plan to initiate trials of IMVT-1402 in ten indications (inclusive of the four to five programs initiated in fiscal 2025) by March 31, 2026. We cannot provide any assurance that we will submit a BLA for regulatory approval for our product candidates within our projected timeframes or whether any such application will be accepted for review or ultimately approved by the relevant regulatory authorities. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other foreign regulatory authorities may not agree with our proposed analysis plans or trial design for any clinical trials for our product candidates; during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of a BLA or similar foreign marketing authorization application. The FDA or a foreign regulatory authority may also find that the benefits of our product candidates in any of our target indications do not outweigh their risks, including in the case of batoclimab, the risks associated with elevated lipid levels and lower albumin levels, in a manner sufficient to grant regulatory approval. The clinical trial process is also time-consuming and costly and is dependent upon collaboration with many CROs and clinical trial sites.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation delaying the next stage of clinical development or submission of a BLA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit negative safety signals in later stage clinical trials that they did not exhibit in nonclinical or earlier-stage clinical trials. A number of companies in the 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 and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

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

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

- inappropriate unblinding of trial results.

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

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

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

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

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

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

We may encounter delays or difficulties in enrolling or be unable to enroll a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate or be stopped, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials evaluating batoclimab for MG, TED, CIDP and GD due to existing alternative treatments available, including teprotumumab for the treatment of TED, IVIg, plasma exchange and steroids for CIDP and anti-thyroid drugs for GD, or 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. Similar difficulties may occur in our development programs for IMVT-1402.

Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, 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, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents and our ability to successfully complete prerequisite studies before enrolling certain patient populations. Our product candidates are focused in part on addressing rare autoimmune indications, and we have focused our initial development efforts 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, and could be faced with limited patient pools if we pursue these and certain other indications for IMVT-1402.

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

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

The results of our nonclinical 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 nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior nonclinical testing and clinical trials. In addition, preclinical testing may not adequately uncover drug side effects. In particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our Phase 1 and Phase 2 clinical trials of batoclimab or in the Phase 1 trial of IMVT-1402 will be observed in any future clinical trials or that such reductions in IgG antibodies will result in clinical benefit that is sufficient to demonstrate that the efficacy endpoints of the study are met. Likewise, positive results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and lack statistical significance, which further limits the reliability of such data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after positive results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings observed while clinical trials were underway and safety or efficacy observations in clinical trials.

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

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

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

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

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

Our product candidates are novel therapeutic antibodies and their potential therapeutic benefits are unproven. While IMVT-1402 has demonstrated in a Phase 1 healthy volunteer study clinically meaningful reductions in IgG with a clean safety profile, and batoclimab has shown meaningful reductions in IgG antibody levels in clinical trials conducted to date, IMVT-1402 and/or batoclimab may not demonstrate in patients any or all of the pharmacologic or clinical benefits we believe they may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for our product candidates in large-scale, pivotal clinical trials or in obtaining marketing approval thereafter for any indication. Results from our early-stage clinical trials are not necessarily predictive of the results of our current or planned clinical trials. If results from early clinical trials cannot be replicated, or if the increase in total cholesterol and LDL levels or total albumin reductions observed in our Phase 2 clinical trial of batoclimab cannot be managed, we may be unable to successfully develop, obtain regulatory approval for and commercialize batoclimab for the treatment of any of the indications for which it is being evaluated or any other autoimmune indication. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize our product candidates, raise capital, expand our business or continue our operations.

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

Batoclimab, IMVT-1402 and any future product candidate that we may develop, as well as the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution are subject to comprehensive regulation by the FDA and other regulatory 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.

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

We have in-licensed the rights to 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, TED and RA. 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 expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases, including multiple agents in the same class as IMVT-1402 and batoclimab. We are aware of several FcRn inhibitors that are in clinical development. These include efgartigimod (argenx SE), nipocalimab (Johnson & Johnson) and rozanolixizumab (UCB). In June 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 December 2021. In June 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 February 2024, Johnson & Johnson reported positive top-line results for nipocalimab from a Phase 3 pivotal study in gMG. In June 2024, the FDA expanded the label for VYVGART Hytrulo to include the treatment of CIDP. Viridian Therapeutics is developing a portfolio of engineered FcRn inhibitors, including VRDN-006 and VRDN-008, that are currently in preclinical 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 gMG 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 October 2024, Amgen announced positive data in patients who are positive for anti-AChR antibodies for UPLIZNA® (inebilizumab), a CD19-targeted humanized monoclonal antibody, currently in Phase 3 development for the treatment of gMG.

For patients with TED, the first line of treatment is generally immunosuppressive therapy, including high doses of corticosteroids. Rituximab (Roche), a monoclonal antibody that binds to an antigen specific to antibody-producing B cells, and tocilizumab (Roche), an anti-IL-6R monoclonal antibody, may also be used as off-label treatment options for TED and other IgG-mediated autoimmune diseases. In January 2020, the FDA approved Horizon Therapeutics' TEPEZZA® (teprotumumab), an anti-insulin like growth factor 1 receptor ("IGF-1R") antibody, for the treatment of TED. In September 2024, Viridian Therapeutics reported positive top-line results for veligrotug (VRDN-001), an IGF-1R antibody, from a Phase 3 pivotal study in TED. It is also advancing VRDN-003, a second anti-IGF-1R therapy, in Phase 3 development in TED.

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. On October 6, 2023, Amgen completed its previously announced acquisition of Horizon Therapeutics for approximately $27.8 billion, expanding its rare disease pipeline. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

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

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

- develop and commercialize therapies in our target indications that are superior to other products in the market;
- demonstrate through our clinical trials that IMVT-1402, batoclimab, 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, batoclimab, or any future product candidates;
- obtain required regulatory approvals, including approvals to market IMVT-1402, batoclimab, 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, batoclimab, 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 pre-filled syringe or autoinjector presentations of batoclimab or IMVT-1402 because it would be subject to regulation as a combination product.

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

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

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

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

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

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

- monitoring and assuring regulatory compliance for clinical trials, manufacturing and testing of good practice (“GxP”) products;
- monitoring and providing oversight of all GxP suppliers (e.g., contract development manufacturing organizations and CROs);
- establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain and distribution operations; and
- cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality.

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

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

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

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

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for the manufacturing processes, 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 batoclimab, IMVT-1402, or any future product candidate. For example, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, a number of changes to the regulatory framework governing medicinal products in the European Economic Area ("EEA") may occur. These include a possible decrease in data and market exclusivity for our product candidates 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 at any given price level of our product candidates;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of our product candidate, if approved, together with other medications.

Market acceptance of new products for the treatment of the indications we pursue with our product candidates, including MG, CIDP, GD, TED and RA, may also be affected by the perception that existing available 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 batoclimab, IMVT-1402, or any future product candidate, if approved, will achieve broad market acceptance among physicians, patients and third-party payors. The failure of any such product candidate that receives regulatory approval or clearance to achieve market acceptance or commercial success would adversely affect our business and results of operations.

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

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

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

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

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

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

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

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

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

We have been granted orphan drug designation for batoclimab for the treatment of MG, and may seek orphan drug 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 plan to seek orphan drug designation from the FDA our product candidates where there is a medically plausible basis for their use, as well as with respect to other product candidates we may develop. We may also seek orphan drug designations for our product candidates for the treatment of other indications in European countries, where available.

Although we intend to 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 batoclimab for the treatment of MG does not mean we will be able to obtain such designation for any other indications. Even if we were to obtain orphan drug designation for IMVT-1402 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.

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

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

- different post-approval regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection of intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- workforce uncertainty, economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign tax, reimbursement, pricing and insurance regimes;
- any foreign partners or collaborators not fulfilling their respective regulatory reporting requirements and any foreign regulatory authorities taking actions with respect to such failures, which would be reportable to the FDA;
- any foreign partners or collaborators not informing us of any new post-marketing safety signals in a timely manner;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- potential noncompliance with the Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), the United Kingdom Bribery Act 2010 (the “U.K. Bribery Act”) or similar antibribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

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

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

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

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

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

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

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for price negotiation in 2025. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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

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

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

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

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

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

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

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

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

Risks Related to Our Business, Financial Position and Capital Requirements

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

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. For example, restrictions imposed by healthcare facilities during the COVID-19 pandemic impacted clinical site activation and patient enrollment due to limited access, capacity and staffing shortages, resulting in a backlog of patient enrollment and delayed site initiations across the industry. Our inability to successfully recruit and retain patients and principal investigators and site staff could adversely impact our clinical trial operations.

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

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 $109.1 million and $58.7 million for the three months ended September 30, 2024 and 2023, respectively, and $196.3 million and $132.6 million for the six months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $1,022.0 million.

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

We expect our research and development expenses in connection with our development programs for our product candidates to continue to be significant. For example, we expect our research and development expenses to significantly increase as we seek to execute our plan to initiate four to five potentially registrational programs for IMVT-1402 by March 31, 2025 and initiate trials of IMVT-1402 in ten indications (inclusive of the four to five programs initiated in fiscal 2025) by March 31, 2026. In addition, if we obtain regulatory approval for batoclimab or IMVT-1402, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses had and will continue to have an adverse effect on our results of operations, financial position and working capital.

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

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

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of and obtain the necessary regulatory approvals for 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 batoclimab, IMVT-1402, or any future product candidate, we do not know when or if we will generate product revenue.

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

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

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

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

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

- the process by which we identify and decide to acquire product candidates or technologies, including through the business development support we receive from RSL and its subsidiaries pursuant to the Services Agreements, may not be successful;
- potential product candidates may, upon further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;

- potential product candidates may not be effective in treating their targeted diseases; or
- the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs or higher than expected acquisition or integration costs.

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

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

We will require additional capital to fund our operations. If we fail to obtain necessary financing, we may not be able to complete the development and commercialization of 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 plan to initiate four to five potentially registrational programs for IMVT-1402 by March 31, 2025 and initiate trials of IMVT-1402 in ten indications (inclusive of the four to five programs initiated in fiscal 2025) by March 31, 2026. Our expenditures may also include costs associated with the HanAll Agreement, including payments in connection with the achievement of certain regulatory milestones 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 batoclimab or 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, the ongoing military conflict between Russia and Ukraine and in the Middle East, changes in inflation and interest rates, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and other factors. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

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

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

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

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

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

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

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

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

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 September 30, 2024), certain of which will occur prior to commercialization of batoclimab or IMVT-1402. Accordingly, we will be required to make such payments prior to the time at which we are able to generate any revenue, if any, from commercial sales of batoclimab or IMVT-1402. Following commercialization, we may be required to make significant further payments upon the achievement of sales milestones and make tiered royalty payments in connection with the commercial sale of batoclimab and/or IMVT-1402, if approved. There can be no assurance that we will have the funds necessary to make such payments or be able to raise such funds when needed on terms acceptable to us or at all. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

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

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, including our plan to initiate clinical trials of IMVT-1402 in ten indications by March 31, 2026, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategies.

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

We have expanded our organization and plan to continue to do so and we may experience difficulties in managing this growth, which could disrupt our operations.

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

We may have difficulties identifying, hiring, integrating and retaining new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors, including training additional qualified personnel. For example, our development plans for IMVT-1402 call for four to five potentially registrational programs to be initiated by March 31, 2025 and trials in a total of ten indications started by March 31, 2026. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of batoclimab, IMVT-1402 and any future product candidate. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize batoclimab, IMVT-1402 or any future product candidate and compete effectively will partly depend on our ability to effectively manage any future growth.

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

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

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

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

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

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

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

- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, the U.K. Bribery Act and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

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

We are subject to stringent and changing privacy, data protection, and information security laws, contractual obligations, self-regulatory schemes, government regulation and standards related to data privacy and security. The actual or perceived failure by us, our CROs or vendors 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 to 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.

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

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). In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights 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 ("CPRA") (collectively, "CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. 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. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

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 ("E.U. GDPR") and the United Kingdom's GDPR ("U.K. 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 E.U. GDPR, 17.5 million pounds sterling under the U.K. 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 U.K. (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 (U.K.) 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 U.K. to the United States in compliance with law, such as the EEA and U.K.'s standard contractual clauses, the U.K.'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 U.K. 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 U.K. 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.

In addition to data privacy and security laws, 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 regarding our data privacy and security practices. If these policies are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

We are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications and frameworks ("Privacy Policies"), and contractual obligations to third parties related to privacy, data protection, information security and Processing ("Data Protection Obligations").

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

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

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

We may in the future receive inquiries or be subject to investigations, proceedings or actions by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect on our 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 those of our affiliates, service providers or other relevant third parties are 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 collect, Process and store proprietary, confidential and sensitive information, including personal information (including health information), intellectual property, trade secrets and proprietary business information owned or controlled by ourselves or other parties ("Sensitive Information").

We may use third-party service providers and subprocessors to help us operate our business and engage in Processing on our behalf, such as RSL and its affiliates, our CROs and other contractors. We may also share Sensitive Information with our affiliates or other third parties in conjunction with our business. If we, our service providers, affiliates or other relevant third parties have experienced, or in the future experience, 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 upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which 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), 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 computer assets, adware 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 become more common and 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 incident 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 upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) 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 may 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 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. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. In addition, security researchers and other individuals have and will continue to actively search for and exploit actual and potential vulnerabilities in our (or our third parties') information technology and communications. 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.

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 acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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

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

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

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

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

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, changes in inflation and interest rates, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and uncertainty about economic stability. For example, 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. Similarly, the ongoing military conflict between Russia and Ukraine and the Israel/Hamas conflict in the Middle East 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 to produce clinical supplies and commercial supplies of our product candidates. For example, in November 2021, we entered into an agreement with Samsung Biologics Co., Ltd. to manufacture and supply us with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. Additional third-party vendors may be difficult to identify for our product candidate process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. Any significant delay in the supply of batoclimab, IMVT-1402 or the raw material components thereof, or in placebo controls for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of batoclimab, IMVT-1402 or any future product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for batoclimab, IMVT-1402 or any future product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of such product candidate. In addition, 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 batoclimab, IMVT-1402 or any future product candidate must be approved by the FDA and comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit our BLA to the FDA or comparable applications to foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidate. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market batoclimab, IMVT-1402 or any future product candidate, if approved. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

In the U.S., the Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. New biologics, such as 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.

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

If we are unable to obtain and maintain patent protection for 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 patent applications in the U.S. and abroad in the Licensed Territory related to our current and future drug development programs and product candidates, successfully defending our intellectual property rights against third-party challenges and successfully enforcing our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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

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

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

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

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

Publications of discoveries in scientific literature often lag behind the actual discoveries and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not until a patent issues. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect 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, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices, both in the U.S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Moreover, patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Without patent protection for 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.

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

For biologics subject to approval by the FDA via a BLA, such as 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.

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 to the same extent as federal laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in certain jurisdictions. Competitors may exploit our inventions in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

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

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property rights in the U.S. and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. Depending upon the timing, duration and specifics of FDA marketing approval of batoclimab or other product candidates that we may identify, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA premarket regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries, including the E.U. 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 our product candidates, from HanAll. We are heavily dependent on the HanAll Agreement for the development, manufacture and commercialization of our product candidates. If, for any reason, our licenses under the HanAll Agreement are terminated or we otherwise lose those rights, it could adversely affect our business. The HanAll Agreement imposes and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and HanAll, as the licensor, may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or having to negotiate new or reinstated licenses on less favorable terms or enable a competitor to gain access to the licensed technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our product candidates, 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

General Risks Related to an Investment in Our Securities

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

As of November 1, 2024, RSL beneficially owned approximately 54.4% of the voting power of our outstanding shares of common stock. Therefore, we are controlled by RSL and RSL has the ability to substantially influence us and exert significant control through this ownership position. It is possible RSL may be able to control elections of directors, the issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL is publicly traded and its interests may not always coincide with our corporate interests or the interests of other stockholders and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. There may be changes to the management or ownership of RSL, or to RSL's business model, that could impact RSL's interests in a way that may not coincide with our corporate interests or the interests of other stockholders. Any such changes may diminish or eliminate entirely any benefits we expect to derive from our membership in the Roivant family of companies. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

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

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

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

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

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

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

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

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

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

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, in February 2021, a securities class action complaint was filed against us, certain of our officers and a board member of HSAC 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. See Part I, Item 3. Legal Proceedings for more information.

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

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

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

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

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

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

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

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

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002 (the "Sarbanes Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. We also expect that compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act ("Section 404") and increased disclosure requirements will substantially increase our legal and financial compliance costs. Our management and other personnel will need to continue to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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 to the capital markets.

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

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

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

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

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

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views for instance with respect to, among other things, the manner in which the 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 U.K. and Switzerland), the U.S., Bermuda and other jurisdictions as well as being affected by certain international tax developments, including certain changes currently proposed by the Organization for Economic Co-operation and Development ("OECD") and their action plan on Base Erosion and Profit Shifting ("BEPS"), as well as other initiatives led by the OECD and the European Commission. For example, the OECD is leading work on proposals, commonly referred to as "BEPS 2.0", which, 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 U.K., Switzerland and Bermuda) have enacted, or are in the process of enacting, core elements of the Pillar Two rules. Based on our current understanding of the minimum revenue thresholds, we are currently outside the scope of both the Pillar One and Pillar Two rules but could fall within their scope in the future, which could increase our tax obligations and require us to incur additional material 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, or NOLs, generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs is generally limited to 80% of taxable income. In addition, our research and development credit carryforwards in the U.S. will begin to expire in 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 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Insider Trading Arrangements

During the three months ended September 30, 2024, none of our directors or Section 16 reporting officersadopted, 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).

Appointment of Chief Operating Officer

On November 4, 2024, our board of directors appointed Melanie Gloria, BSN, to serve as our Chief Operating Officer, effective November 18, 2024 (the "Start Date").

Ms. Gloria, age 47, served as Chief Operating Officer of Acelyrin, Inc. (Nasdaq: SLRN) from November 2021 to October 2024. From June 2018 to November 2021, she was the Senior Vice President Development Operations – ClinOps, Compliance & Standards, Regulatory, Safety & PV at Horizon Therapeutics Public Limited Company. From August 2014 through July 2018, Ms. Gloria served as Senior Director of Clinical Program Development at AbbVie Inc. From November 2009 to August 2014, she was Associate Director of Clinical Program Development for Abbott Laboratories. Ms. Gloria received a B.S. in nursing from the University of Illinois, Chicago.

In connection with her appointment, we entered into an executive employment agreement with Ms. Gloria that will govern the terms of her employment with us. The employment agreement provides that Ms. Gloria will receive an initial annual base salary of $481,000 and will be eligible to receive an annual performance bonus with an initial target bonus percentage equal to 45% of her base salary. Pursuant to the employment agreement, and effective as of the Start Date, our board of directors granted Ms. Gloria (i) an option (the "Option") to purchase 137,446 shares of our Common Stock at an exercise price per share equal to the closing price of the Common Stock on The Nasdaq Global Select Market on the Start Date, and (ii) 109,956 restricted stock units ("RSUs"). The Option and the RSUs were granted pursuant to our 2019 Equity Incentive Plan. Each of the Option and the RSUs will vest as follows: 25% of the award will vest on the one-year anniversary of the grant date and the remainder of the award will vest in 12 substantially equal installments on a quarterly basis over 3 years thereafter, subject, in each case, to Ms. Gloria's continuous service with our company.

Pursuant to the employment agreement, in the event Ms. Gloria is terminated by us without "Cause" or she resigns for "Good Reason" (as such terms are defined in the employment agreement), then subject to Ms. Gloria signing a general release of claims in accordance with the employment agreement, Ms. Gloria will be entitled to: (i) an amount equal to nine (9) months of her then current base salary, and (ii) nine (9) months of COBRA coverage, with such aggregate amount payable in equal installments over the nine-month period following the date of her termination in accordance with customary payroll practices.

In the event Ms. Gloria is terminated by us without "Cause" or she terminates her employment for "Good Reason," in each case within 12 months following a "Change in Control" (as such terms are defined in the employment agreement), then subject to Ms. Gloria signing a general release of claims in accordance with the employment agreement, she will be entitled to: (i) the sum of her then current base salary and target annual performance bonus (with such bonus calculated at forty percent (40%) of the then current base salary) for the year in which the termination takes place, (ii) twelve (12) months of COBRA coverage, with such aggregate amount payable in equal installments over the twelve-month period following the date of her termination in accordance with customary payroll practices, and (iii) immediate acceleration in full of any and all time-vested equity awards.
Ms. Gloria will also enter into an indemnity agreement with us in the form previously filed as Exhibit 10.5 to our Current Report on Form 8-K, originally filed with the SEC on December 20, 2019.

There are no family relationships between Ms. Gloria and any of our directors or executive officers. Ms. Gloria is not a party to any transaction that would require disclosure under Item 404(a) of Regulation S-K promulgated under the Securities Act of 1933, as amended, and there is no arrangement or understanding between either Ms. Gloria and any other person pursuant to which she was appointed as Chief Operating Officer.

The foregoing summary of the employment agreement with Ms. Gloria does not purport to be complete and is qualified in its entirety by reference to the full text of the employment agreement, a copy of which is filed with this Quarterly Report on Form 10-Q as Exhibit 10.1 and incorporated herein by reference.

Item 6. Exhibits

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1+	Share Exchange Agreement, dated September 29, 2019, by and among Immunovant Sciences Ltd., the stockholders of Immunovant Sciences Ltd., Roivant Sciences Ltd., and Health Sciences Acquisitions Corporation.	8-K	001-38906	2.1	October 2, 2019
3.1	Amended and Restated Certificate of Incorporation of Immunovant, Inc.	8-K	001-38906	3.1	December 20, 2019
3.2	Amended and Restated Bylaws of Immunovant, Inc.	8-K	001-38906	3.2	December 20, 2019
10.1†*	Employment Agreement with Melanie Gloria, dated as of November 5, 2024.				
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 Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
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)				

* Filed herewith.
+ 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.
# 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 Quarterly Report on Form 10-Q 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.

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.

Immunovant, Inc.

Date: November 7, 2024

By: /s/ Peter Salzmann, M.D.
Peter Salzmann, M.D.
Chief Executive Officer

By: /s/ Eva Renee Barnett
Eva Renee Barnett
Chief Financial Officer

Exhibit 10.1

EMPLOYMENT AGREEMENT

This Employment Agreement (this "**Agreement**") is entered into as of November 5, 2024, by and between Melanie Gloria (the "**Executive**") and **IMVT Corporation** (the "**Company**").

RECITALS

A. The Company desires the association and services of the Executive and the Executive's skills, abilities, background and knowledge, and is willing to engage the Executive's services on the terms and conditions set forth in this Agreement.

B. The Executive desires to be in the employ of the Company and is willing to accept such employment on the terms and conditions set forth in this Agreement.

C. This Agreement supersedes any and all prior and contemporaneous oral or written employment agreements or arrangements between the Executive and the Company or any predecessor thereof.

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position; Duties. Subject to the terms and conditions of this Agreement, the Executive will hold the position of Chief Operating Officer of the Company and of Immunovant, Inc. (the "**Parent**"). The Executive will report to the Chief Executive Officer of the Company and Parent (the "**CEO**"). The Executive will devote the Executive's full business energies, interest, abilities and productive time to the proper and efficient performance of the Executive's duties under this Agreement.

1.2 Location of Employment. The Executive's principal place of employment will be remote/work from home. The Executive understands that the Executive's duties also will require periodic business travel.

1.3 Start Date. The Executive's employment with the Company will commence on or about November 18, 2024 (the "**Start Date**").

1.4 Exclusive Employment; Agreement Not to Compete. Except with the prior written consent of the CEO, the Executive will not, during the Executive's employment with the Company, undertake or engage in any other employment, occupation or business enterprise that requires more than a de minimis amount of time or attention. It is understood and agreed that the Executive and the CEO have discussed the Executive's activities described on **Exhibit A** attached hereto and that the Executive may continue to engage in such activities during the term of this Agreement, so long as such activities are not adverse or antagonistic to the Company, its business, or prospects, financial or otherwise, or in any way in competition with the business of the Company. During the Executive's employment, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by the Executive to be adverse or antagonistic to the Company, its business, or prospects, financial or otherwise, or in any company, person, or entity that is, directly or indirectly, in competition with the business of the Company. Ownership by the Executive in professionally managed funds over which the Executive does not have control or discretion in investment decisions, or, an investment of less than two

percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed on a national securities exchange or publicly traded on a national securities exchange or in the over-the-counter market will not constitute a breach of this Section.

2. COMPENSATION AND BENEFITS.

2.1 Salary. The Company will pay the Executive a base salary at the annualized rate equal to US$481,000.00 (the " **Base Salary**"), less payroll deductions and all required withholdings, payable in regular periodic payments in accordance with the Company's normal payroll practices. The Base Salary will be prorated for any partial year of employment based on a 365-day year. The Base Salary will be subject to periodic review and may be adjusted from time to time at the discretion of the board of directors of the Company (the "**Board**").

2.2 Annual Performance Bonus. Each fiscal year, the Executive will be eligible to earn an annual discretionary cash bonus (the " **Annual Performance Bonus**") with a target bonus opportunity equal to forty-five percent (45%) of the Executive's Base Salary, which could increase for outperformance of Company goals, based on the board of directors of the Parent (the "**Parent Board**") (and/or a committee thereof) assessment of the Executive's individual performance and overall Company performance. To earn and receive the Annual Performance Bonus, the Executive must remain employed by the Company through and including the date on which the Annual Performance Bonus is paid, except as set forth in **Section 5.3** herein. The Annual Performance Bonus, if any, will be paid no later than thirty (30) days following the end of the Company's fiscal year (March 31st), or by April 30th. The Annual Performance Bonus payable, if any, will be prorated for the initial year of employment (based on a three hundred sixty-five (365)-day year) and will be prorated if the Company's review or assessment of the Executive's performance covers a period that is less than a full fiscal year.

2.3 Equity Incentive Grant (Options). Subject to the terms of the 2019 Equity Incentive Plan (the " **Plan**") of Parent and approval of the grant by the Parent Board, the Executive will be granted an award of an option to purchase 137,446 common shares of the Parent (the "**Option Award**"). The Option Award is intended to be a material inducement for the Executive to enter into employment with the Company. The Option Award will be granted on or about the Start Date, with an exercise price equal to the fair market value of Parent's common shares on such date of grant, as set forth in the Plan. The Option Award will be governed by the Plan and other documents issued in connection with the grant and will incorporate the terms set forth in this **Section 2.3** and **Sections 5.2** and **5.3** below.

The Option Award will vest over a period of four (4) years, with twenty-five percent (25%) of the Option Award vesting on the one-year anniversary of the Start Date and the balance of the Option Award vesting in a series of twelve (12) successive equal quarterly installments measured from the first anniversary of the Start Date, provided Executive is employed by the Company on each vesting date, except as set forth in **Section 5.3** herein.

2.4 Equity Incentive Grant (RSUs). Subject to the terms of the Plan and approval of the grant by the Parent Board, the Executive will be granted restricted stock units for 109,956 shares of common shares of the Parent (the "**RSU Grant**") pursuant to the Plan. The RSU Grant is intended to be a material inducement for the Executive to enter into employment with the Company. The RSU Grant will be made on or about the Start Date and will be subject to a 4-year vesting period, with twenty-five percent (25%) of the RSU Grant vesting on the one (1) year anniversary of the Start Date and the balance of the RSU Grant vesting in a series of twelve (12) successive equal quarterly installments thereafter, provided Executive is employed by the Company on each such vesting date, except as set forth in **Section 5.3**

herein. In all cases, the RSU Grant will be subject to the terms and conditions contained in the Plan and the applicable equity incentive agreement, which will incorporate the terms set forth in this **Section 2.4** and **Section 5.3** below) (the "**RSU Equity Incentive Agreement**") between Executive and the Parent. In the event of a conflict between the terms of this Agreement and the terms of the RSU Equity Incentive Agreement, except in connection with the vesting schedule and acceleration rights set forth in **Section 5.3**, the terms of the RSU Equity Incentive Agreement will prevail.

The Executive may be eligible to receive additional discretionary annual equity incentive grants in amounts and on terms and conditions determined by the Parent Board in its sole discretion.

2.5 Benefits and Insurance. The Executive will, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company executives (including, but not limited to, being named as an officer for purposes of the Company's Directors & Officers insurance policy). The Company reserves the right in its sole discretion to modify, add or eliminate benefits at any time. All benefits will be subject to the terms and conditions of the applicable plan documents, which may be amended or terminated at any time. The Executive will be entitled to vacation each year, in addition to sick leave and observed holidays in accordance with the policies and practices of the Company. Vacation may be taken at such times and intervals as the Executive will determine, subject to the business needs of the Company.

2.6 Expense Reimbursements. The Company will reimburse the Executive for all reasonable and documented business expenses that the Executive incurs in conducting the Executive's duties hereunder, pursuant to the Company's usual expense reimbursement policies.

3. AT-WILL EMPLOYMENT.

The Executive's employment relationship with the Company is, and will at all times remain, at-will. This means that either the Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without Cause (as defined below) or advance notice, subject to the payment obligations set forth in **Sections 5.2** or **5.3**.

4. PROPRIETARY INFORMATION OBLIGATIONS.

As a condition of employment, the Executive agrees to execute and abide by the Company's Employee Non-Disclosure, Invention Assignment and Restrictive Covenant Agreement ("**NDIA**").

5. TERMINATION OF EMPLOYMENT.

5.1 Termination Generally. Upon termination of Executive's employment for any reason, the Company will pay the Executive any earned but unpaid Base Salary and unused vacation accrued (if applicable) through the date of termination, at the rates then in effect, less standard deductions and withholdings. The Company will thereafter have no further obligations to the Executive, except as set forth in this **Section 5** or otherwise as required by law.

5.2 Termination Without Cause or Resignation for Good Reason. If (i) the Company terminates Executive's employment without Cause or the Executive resigns for Good Reason, (ii) the Executive furnishes to the Company an executed waiver and release of claims in the form specified by the Company (the "**Release**"), and (iii) the Executive allows the Release to become effective in accordance with its terms no later than the release deadline (which date may not be later than sixty (60) days following the date of Executive's "separation from service" within the meaning of Section 409A (as

defined below)) (the "**Release Date**"), then the Executive will receive an aggregate amount equal to: (a) nine (9) months of the Executive's then current Base Salary; and (b) nine (9) months of COBRA coverage, with such aggregate amount payable in equal installments over the nine-month period following the date of the Executive's termination in accordance with customary payroll practices, but no less frequently than monthly. Such payments will commence within the next payroll cycle following the Release Date and will be subject to required withholding.

5.3 Termination Without Cause Or Resignation For Good Reason Within Twelve Months Following Change In Control. If (i) the Company terminates the Executive's employment without Cause or the Executive resigns for Good Reason within twelve (12) months following a Change in Control (as defined in the Plan), (ii) the Executive allows the Release to become effective in accordance with its terms no later than the Release Date, then the Executive will receive an aggregate amount equal to: (a) the sum of the Executive's then-current Base Salary (without regard to any reduction that gave rise to Good Reason) and target Annual Performance Bonus (such Annual Performance Bonus to be calculated at forty percent (40%) of the then current Base Salary) for the year in which the termination takes place; and (b) twelve (12) months of COBRA coverage, with such aggregate amount payable in equal installments over the twelve (12) month period following the date of the Executive's termination in accordance with customary payroll practices, but no less frequently than monthly; and (c) any and all time-vested equity awards will immediately vest in full. Such payments will commence within the next payroll cycle following the Release Date and will be subject to required withholding.

5.4 Definitions. For purposes of this Agreement, the following terms will have the following meanings:

(a) "***Cause***" will mean the occurrence of any of the following, the Executive's: (i) arrest for, arraignment on, conviction of, or plea of no contest to, any felony or any crime involving moral turpitude or dishonesty; (ii) participation in a fraud against the Company; (iii) willful and material breach of the Executive's duties and obligations under this Agreement or any other agreement between the Executive and the Company or its affiliates that has not been cured (if curable) within thirty (30) days after receiving written notice from the Board of such breach; (iv) engagement in misconduct that causes or is reasonably likely to cause material damage to the Company's property or reputation; (v) material failure to comply with the Company's Code of Conduct or other material policies; or (vi) violation of any law, rule or regulation (collectively, "**Law**") relating in any way to the business or activities of the Company or its subsidiaries or affiliates, or other Law that is violated during the course of the Executive's performance of services hereunder that results in the Executive's arrest, censure, or regulatory suspension or disqualification, including, without limitation, the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities (provided that Executive may rely on the advice of counsel).

(b) "***Good Reason***" will mean the occurrence of any of the following events without the Executive's consent: (i) a material reduction of the Executive's Base Salary as initially set forth herein or as the same may be increased from time to time, provided, however, that if such reduction occurs in connection with a Company-wide decrease in executive officer team compensation, such reduction will not constitute Good Reason provided that it is a reduction of a proportionally like amount or percentage affecting the entire executive team not to exceed ten percent (10%); or (ii) material reduction in the Executive's authority, duties or responsibilities, as compared to the Executive's authority, duties or responsibilities immediately prior to such reduction; *provided*, *however*, any resignation by the Executive will only be deemed for Good Reason pursuant to this definition if: (1) the Executive gives the Company written notice of the Executive's intent to terminate for Good Reason within ninety (90) days following

the first occurrence of the condition(s) that the Executive believes constitute(s) Good Reason, which notice will describe such condition(s); (2) the Company fails to remedy such condition(s) within ninety (90) days following receipt of the written notice (the "**Cure Period**"); and (3) the Executive voluntarily resigns from employment with the Company within thirty (30) days following the end of the Cure Period.

5.5 Effect of Termination. The Executive agrees that should the Executive's employment terminate for any reason, the Executive will be deemed to have resigned from any and all positions with the Company and the Parent.

5.6 Section 409A Compliance.

(a) It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"), provided under Treasury Regulations Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), the Executive's right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) will be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder will at all times be considered a separate and distinct payment. A termination of employment will not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "resignation," "termination," "termination of employment" or like terms will mean separation from service. In no event may Executive, directly or indirectly, designate the calendar year of a payment. Notwithstanding any provision of this Agreement to the contrary, in no event will the timing of the Executive's execution of the Release, directly or indirectly, result in the Executive designating the calendar year of payment of any amounts of deferred compensation subject to Section 409A, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment will be made in the later taxable year. The Company makes no representation or warranty and will have no liability to the Executive or any other person if any compensation under this Agreement constitutes deferred compensation subject to Code Section 409A but does not satisfy an exemption from, or the conditions of, Code Section 409A.

(b) Notwithstanding any provision to the contrary in this Agreement, if the Executive is deemed by the Company at the time of a separation from service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i), and if any payments or benefits that the Executive becomes entitled to under this Agreement on account of such separation from service are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments or benefits is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments will not be provided prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of separation from service, (ii) the date of the Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first (1st) business day following the expiration of such period, all payments deferred pursuant to this paragraph will be paid in a lump sum, and any remaining payments due will be paid as otherwise provided herein. No interest will be due on any amounts so deferred.

(c) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits will not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year will not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, and (iii) such payments will be made on or before the last day of the Executive's taxable year following the taxable year in which the expense was incurred.

6. ARBITRATION.

Except as otherwise set forth below in connection with equitable remedies, any dispute, claim or controversy arising out of or relating to this Agreement or the Executive's employment with the Company and/or related to the Parent (collectively, "**Disputes**"), including, without limitation, any dispute, claim or controversy concerning the validity, enforceability, breach or termination of this Agreement, if not resolved by the parties, will be finally settled by arbitration in accordance with the then-prevailing Employment Arbitration Rules and Procedures of JAMS, as modified herein ("**Rules**"). The requirement to arbitrate covers all Disputes (other than disputes which by statute are not arbitrable) including, but not limited to, claims, demands or actions under the Age Discrimination in Employment Act (including Older Workers Benefit Protection Act); Americans with Disabilities Act; Civil Rights Act of 1866; Civil Rights Act of 1991; Employee Retirement Income Security Act of 1974; Equal Pay Act; Family and Medical Leave Act of 1993; Title VII of the Civil Rights Act of 1964; Fair Labor Standards Act; Fair Employment and Housing Act; and any other law, ordinance or regulation regarding discrimination or harassment or any terms or conditions of employment. There will be one arbitrator who will be jointly selected by the parties. If the parties have not jointly agreed upon an arbitrator within twenty (20) calendar days of respondent's receipt of claimant's notice of intention to arbitrate, either party may request JAMS to furnish the parties with a list of names from which the parties will jointly select an arbitrator. If the parties have not agreed upon an arbitrator within ten (10) calendar days of the transmittal date of such list, then each party will have an additional five (5) calendar days in which to strike any names objected to, number the remaining names in order of preference, and return the list to JAMS, which will then select an arbitrator in accordance with the Rules. The place of arbitration will be New York, NY. By agreeing to arbitration, the parties hereto do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, including, without limitation, with respect to the NDIA. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16. Judgment upon the award of the arbitrator may be entered in any court of competent jurisdiction. The arbitrator will: (a) have authority to compel discovery which will be narrowly tailored to efficiently resolve the disputed issues in the proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company will pay all administrative fees of JAMS in excess of four hundred thirty-five dollars ($435) (a typical filing fee in court) and all arbitrator's fees and expenses. Each party will bear its or his/her own costs and expenses (including attorney's fees) in any such arbitration; provided that the arbitrator will have the power to award costs and attorney's fees in the arbitrator's discretion to the prevailing party (the party receiving substantially the relief sought) upon an application by the prevailing party. In the event any portion of this arbitration provision is found unenforceable by a court of competent jurisdiction, such portion will become null and void leaving the remainder of this arbitration provision in full force and effect. The parties agree that all information regarding the arbitration, including any settlement thereof, will not be disclosed by the parties hereto, except as otherwise required by applicable law.

7. GENERAL PROVISIONS.

7.1 Representations and Warranties.

(a) The Executive represents and warrants that the Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that the Executive's execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity. The Executive represents and warrants that the Executive is not subject to any confidentiality or non-competition agreement or any other similar type of restriction that could restrict in any way the Executive's hiring by the Company and the performance of the Executive's expected job duties with the Company.

(b) The Company and its affiliates do not wish to incorporate any unlicensed or unauthorized material, or otherwise use such material in any way in connection with, its and their respective products and services. Therefore, the Executive hereby represents, warrants and covenants that the Executive has not and will not disclose to the Company or its affiliates, use in their business, or cause them to use, any information or material which is a trade secret, or confidential or proprietary information, of a third party, including, but not limited to, any former employer, competitor or client, unless the Company or its affiliates have a right to receive and use such information or material.

(c) The Executive represents and warrants that the Executive is not debarred and has not received notice of any action or threat with respect to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities. The Executive understands and agrees that this Agreement is contingent on the Executive's submission of satisfactory proof of identity and legal authorization to work in the United States, as well as verification of auditor independence.

7.2 Advertising Waiver. The Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning business of the Company in which the Executive's name and/or pictures of the Executive appear. The Executive hereby waives and releases any claim or right the Executive may otherwise have arising out of such use, publication or distribution.

7.3 Miscellaneous.

(a) This Agreement, along with the NDIA, the Indemnification Agreement and any applicable equity awards that have been granted, constitutes the complete, final and exclusive embodiment of the entire agreement between the Executive and the Company regarding its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations.

(b) This Agreement may not be modified or amended except in a writing signed by both the Executive and a duly authorized officer of the Company or a member of the Board.

(c) This Agreement will bind the heirs, personal representatives, successors and assigns of both the Executive and the Company, and inure to the benefit of both the Executive and the Company, and to the Executive's and the Company's heirs, successors and assigns, as applicable, except that the duties and responsibilities of the Executive are of a personal nature and will not be assignable or delegable in whole or in part by the Executive. The Company may assign its rights, together with its

obligations hereunder, in connection with any merger, consolidation, or transfer or other disposition of all or substantially all of its assets, and such rights and obligations will inure to, and be binding upon, any successor to the Company or any successor to all or substantially all of the assets of the Company, which successor will expressly assume such obligations.

(d) If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable.

(e) This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the state in which the Executive resides as applied to contracts made and to be performed entirely within such state.

(f) Any ambiguity in this Agreement will not be construed against either party as the drafter. Any waiver of a breach of this Agreement will be in writing and will not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.

[*SIGNATURE PAGE FOLLOWS*]

In Witness Whereof, the parties have executed this Agreement as of the day and year first written above.

IMVT Corporation

By: /s/ Pete Salzmann

Name: Pete Salzmann

Title: Chief Executive Officer

Accepted and agreed:

/s/ Melania Gloria

Melanie Gloria

Acknowledged and Agreed: IMMUNOVANT, INC.

By: /s/ Pete Salzmann

Name: Pete Salzmann

Title: Chief Executive Officer

EXHIBIT A

PERMITTED ACTIVITIES

None

Exhibit 31.1

CERTIFICATION

I, Peter Salzmann, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 7, 2024

/s/ Peter Salzmann, M.D.
Peter Salzmann, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Eva Renee Barnett, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 7, 2024

/s/ Eva Renee Barnett
Eva Renee Barnett
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), Peter Salzmann, M.D., Chief Executive Officer of Immunovant, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2024

/s/ Peter Salzmann, M.D.
Peter Salzmann, M.D.
Chief Executive Officer

This certification accompanies the Form 10-Q 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-Q), 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), Eva Renee Barnett, Chief Financial Officer of Immunovant, Inc. (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2024

/s/ Eva Renee Barnett
Eva Renee Barnett
Chief Financial Officer

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.