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 December 31, 2021

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**	
(Address of principal executive offices)	**10018** **(Zip Code)**

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

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

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

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 February 1, 2022, there were 116,395,727 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 DECEMBER 31, 2021

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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 candidate, 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 1.A 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 success relies upon a sole product candidate, batoclimab, formerly referred to as IMVT-1401 or RVT-1401. In February 2021, we paused all clinical development of batoclimab after elevated lipid levels were observed in some patients dosed with the drug. In December 2021, we announced that we recently achieved alignment with the U.S. Food and Drug Administration's Division of Neurology 1 to move forward with batoclimab in patients suffering from Myasthenia Gravis. Unless we can continue to determine a dosing regimen, target patient population, safety monitoring and risk management for batoclimab in autoimmune diseases for which the risks of lipid elevations and albumin reductions can be mitigated, we will not be able to show adequate benefit to risk ratio and will not be able to continue clinical development or seek or obtain marketing authorization in any jurisdiction.

- Batoclimab has caused and may cause adverse events or have other properties that could delay or prevent its regulatory approval, cause us to further suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

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

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

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

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

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

- 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 and timelines and supply chain could be adversely affected by the effects of health epidemics and pandemics, including the ongoing global Novel Coronavirus Disease 2019 ("COVID-19") pandemic, on the manufacturing, clinical trials and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, contract research organizations, suppliers, shippers and others.

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

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

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

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

- We plan to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.
- Our third-party manufacturers may encounter difficulties in production or our quality management program may fail to detect quality issues at our third-party manufacturers which may delay or prevent our ability to obtain marketing approval or commercialize our product candidate if approved.
- We have a limited operating history and have never generated any product revenue.
- We will require additional capital to fund our operations and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of batoclimab.
- 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 our license agreement with HanAll Biopharma Co., Ltd. (the "HanAll Agreement") to provide us rights to the core intellectual property relating to batoclimab. Any termination or loss of significant rights under the HanAll Agreement would adversely affect our development and commercialization of batoclimab.
- The HanAll Agreement obligates us to make certain milestone payments, some of which may be triggered prior to our potential commercialization of batoclimab.
- We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune disease indications, and our operating results will suffer if we fail to compete effectively.
- We are subject to stringent and changing privacy, data security, and information security laws, contractual obligations, self-regulatory schemes, government regulation and standards related to data privacy and security. Further, if our security measures are compromised now or in the future, or the security, confidentiality, integrity or availability of our information technology, software, services, communications or data is compromised, limited or fails, this could result in a material adverse effect on our business.
- If securities or industry analysts do not publish research or reports about our business or publish negative reports about our business, our share price and trading volume could decline and has declined in the past upon downgrades of our common stock.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	December 31, 2021	March 31, 2021
Assets		
Current assets:		
Cash	$ 527,003	$ 400,146
Prepaid expenses and other current assets	13,477	8,860
Total current assets	540,480	409,006
Operating lease right-of-use assets	2,452	3,282
Property and equipment, net	250	201
Total assets	**$ 543,182**	**$ 412,489**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,827	$ 2,432
Accrued expenses	31,448	15,160
Current portion of operating lease liabilities	1,079	1,179
Total current liabilities	36,354	18,771
Operating lease liabilities, net of current portion, and other noncurrent liabilities	1,680	2,238
Total liabilities	38,034	21,009
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 December 31, 2021 and March 31, 2021	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2021 and March 31, 2021	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 115,109,833 shares issued and outstanding at December 31, 2021 and 500,000,000 shares authorized, 97,971,243 shares issued and outstanding at March 31, 2021	12	10
Additional paid-in capital	812,933	590,425
Accumulated other comprehensive income (loss)	419	(298)
Accumulated deficit	(308,216)	(198,657)
Total stockholders' equity	505,148	391,480
Total liabilities and stockholders' equity	**$ 543,182**	**$ 412,489**

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 December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 29,756	$ 21,091	$ 69,822	$ 49,989
General and administrative	11,515	10,549	38,984	29,211
Total operating expenses	41,271	31,640	108,806	79,200
Other expense	114	503	825	352
Loss before benefit for income taxes	(41,385)	(32,143)	(109,631)	(79,552)
Benefit for income taxes	—	(367)	(72)	(279)
Net loss	**$ (41,385)**	**$ (31,776)**	**$ (109,559)**	**$ (79,273)**
Net loss per common share – basic and diluted	$ (0.36)	$ (0.32)	$ (1.02)	$ (0.94)
Weighted-average common shares outstanding – basic and diluted	115,025,191	97,920,460	107,447,745	84,413,511

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 December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Net loss	$ (41,385)	$ (31,776)	$ (109,559)	$ (79,273)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(23)	689	717	483
Total other comprehensive income (loss)	(23)	689	717	483
Comprehensive loss	**$ (41,408)**	**$ (31,087)**	**$ (108,842)**	**$ (78,790)**

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		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at March 31, 2021	**10,000**	**$ —**	**97,971,243**	**$ 10**	**$ 590,425**	**$ (298)**	**$ (198,657)**	**$ 391,480**
Restricted stock units vested and settled	—	—	6,352	—	—	—	—	—
Capital contribution – stock-based compensation	—	—	—	—	41	—	—	41
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	91	—	—	91
Stock-based compensation	—	—	—	—	3,820	—	—	3,820
Foreign currency translation adjustments	—	—	—	—	—	571	—	571
Net loss	—	—	—	—	—	—	(30,471)	(30,471)
Balance at June 30, 2021	**10,000**	**$ —**	**97,977,595**	**$ 10**	**$ 594,377**	**$ 273**	**$ (229,128)**	**$ 365,532**
Issuance of common stock upon investment by Roivant Sciences Ltd.	—	—	17,021,276	2	199,998	—	—	200,000
Capital contribution – stock-based compensation	—	—	—	—	692	—	—	692
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	38	—	—	38
Stock-based compensation	—	—	—	—	7,669	—	—	7,669
Foreign currency translation adjustments	—	—	—	—	—	169	—	169
Net loss	—	—	—	—	—	—	(37,703)	(37,703)
Balance at September 30, 2021	**10,000**	**$ —**	**114,998,871**	**$ 12**	**$ 802,774**	**$ 442**	**$ (266,831)**	**$ 536,397**
Restricted stock units vested and settled	—	—	110,962	—	—	—	—	—
Capital contribution – stock-based compensation	—	—	—	—	205	—	—	205
Stock-based compensation	—	—	—	—	9,954	—	—	9,954
Foreign currency translation adjustments	—	—	—	—	—	(23)	—	(23)
Net loss	—	—	—	—	—	—	(41,385)	(41,385)
Balance at December 31, 2021	**10,000**	**$ —**	**115,109,833**	**$ 12**	**$ 812,933**	**$ 419**	**$ (308,216)**	**$ 505,148**

	Series A preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at March 31, 2020	**10,000**	**$ —**	**54,655,376**	**$ 5**	**$ 185,306**	**$ (16)**	**$ (91,226)**	**$ 94,069**
Issuance of common stock upon underwritten public offering	—	—	9,613,365	1	130,427	—	—	130,428
Issuance of common stock upon achievement of earnout shares milestone	—	—	10,000,000	1	(1)	—	—	—
Vesting of sponsor restricted shares	—	—	900,000	—	—	—	—	—
Issuance of common stock upon warrant redemption	—	—	5,719,145	1	65,751	—	—	65,752
Stock options exercised	—	—	23,841	—	63	—	—	63
Capital contribution – stock-based compensation	—	—	—	—	63	—	—	63
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	164	—	—	164
Stock-based compensation	—	—	—	—	3,918	—	—	3,918
Foreign currency translation adjustments	—	—	—	—	—	26	—	26
Net loss	—	—	—	—	—	—	(26,708)	(26,708)
Balance at June 30, 2020	**10,000**	**$ —**	**80,911,727**	**$ 8**	**$ 385,691**	**$ 10**	**$ (117,934)**	**$ 267,775**
Issuance of common stock upon underwritten public offering	—	—	6,060,606	1	188,118	—	—	188,119
Issuance of common stock upon achievement of earnout shares milestone	—	—	10,000,000	1	(1)	—	—	—
Vesting of sponsor restricted shares	—	—	900,000	—	—	—	—	—
Stock options exercised	—	—	18,372	—	119	—	—	119
Capital contribution – stock-based compensation	—	—	—	—	54	—	—	54
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	53	—	—	53
Stock-based compensation	—	—	—	—	3,307	—	—	3,307
Foreign currency translation adjustments	—	—	—	—	—	(232)	—	(232)
Net loss	—	—	—	—	—	—	(20,789)	(20,789)
Balance at September 30, 2020	**10,000**	**$ —**	**97,890,705**	**$ 10**	**$ 577,341**	**$ (222)**	**$ (138,723)**	**$ 438,406**
Stock options exercised and vesting of restricted stock units	—	—	80,538	—	725	—	—	725
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	116	—	—	116
Stock-based compensation	—	—	—	—	5,992	—	—	5,992
Foreign currency translation adjustments	—	—	—	—	—	689	—	689
Net loss	—	—	—	—	—	—	(31,776)	(31,776)
Balance at December 31, 2020	**10,000**	**$ —**	**97,971,243**	**$ 10**	**$ 584,174**	**$ 467**	**$ (170,499)**	**$ 414,152**

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)

	Nine Months Ended December 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (109,559)	$ (79,273)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	22,381	13,334
Depreciation on property and equipment	87	43
Non-cash lease expense	831	714
Other non-cash items	—	483
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,809)	1,051
Accounts payable	1,383	914
Accrued expenses	16,188	2,590
Operating lease and other noncurrent liabilities	(658)	(687)
Net cash used in operating activities	**(73,156)**	**(60,831)**
Cash flows from investing activities		
Purchase of property and equipment	(136)	(115)
Net cash used in investing activities	**(136)**	**(115)**
Cash flows from financing activities		
Capital contributions	129	333
Proceeds from investment by Roivant Sciences Ltd.	200,000	—
Proceeds from issuance of common stock upon underwritten public offering	—	319,783
Proceeds from issuance of common stock upon warrant redemption	—	65,752
Proceeds from stock options exercised	—	907
Payment of deferred offering costs	—	(1,236)
Repayment of note payable to Roivant Sciences Ltd.	—	(3,190)
Net cash provided by financing activities	**200,129**	**382,349**
Effect of exchange rate changes on cash	**20**	—
Net change in cash	126,857	321,403
Cash – beginning of period	400,146	100,571
Cash – end of period	**$ 527,003**	**$ 421,974**

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 biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases. The Company is developing a novel, fully human monoclonal antibody, batoclimab, formerly referred to as IMVT-1401 or RVT-1401, that selectively binds to and inhibits the neonatal fragment crystallizable receptor. The Company intends to develop batoclimab for indications in which there is robust evidence that pathogenic immunoglobulin G antibodies drive disease manifestation and for which reduction of these antibodies should lead to clinical benefit for patients with autoimmune diseases.

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

Reverse Recapitalization

On December 18, 2019, Health Sciences Acquisitions Corporation ("HSAC") completed the acquisition of Immunovant Sciences Ltd. ("ISL") pursuant to the share exchange agreement dated as of September 29, 2019 (the "Share Exchange Agreement"), by and among HSAC, ISL, the stockholders of ISL (the "Sellers"), and Roivant Sciences Ltd. ("RSL"), as representative of the Sellers (the "Business Combination"). As of immediately prior to the closing of the Business Combination, the Sellers owned 100% of the issued and outstanding common shares of ISL ("ISL Shares"). At the closing of the Business Combination, HSAC acquired 100% of the issued and outstanding ISL Shares, in exchange for 42,080,376 shares of HSAC's common stock issued to the Sellers and10,000 shares of HSAC Series A preferred stock issued to RSL. Upon the closing of the Business Combination, ISL became a wholly owned subsidiary of HSAC and HSAC was renamed "Immunovant, Inc."

[B] Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2021, the Company's cash totaled $27.0 million and its accumulated deficit was $308.2 million.

The Company has not generated any revenues to date and does not anticipate generating any revenues unless and until it successfully completes development and obtains regulatory approval for batoclimab 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 candidate. The Company currently expects that its existing cash as of December 31, 2021 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. 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 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. 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 nine months ended December 31, 2021 are not necessarily indicative of those expected for the year ending March 31, 2022 or for any future period. The condensed consolidated balance sheet as of March 31, 2021 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 June 1, 2021.

[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 that the COVID-19 pandemic has had on its operations and financial results as of December 31, 2021 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 the COVID-19 pandemic may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

[C] Risks and Uncertainties

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

[D] Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash. As of December 31, 2021, the cash 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 with an accredited financial institution and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses on its cash.

[E] Research and Development Expense

Research and development costs with no alternative future use are expensed as incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of product sales over the remaining useful life of the asset. Research and development expenses primarily consist of employee-related costs, milestone payments under the HanAll Agreement 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 the amounts actually incurred.

[F] 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.

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

[G] 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:

	Nine Months Ended December 31,	
	2021	**2020**
Preferred stock as converted	10,000	10,000
Options	6,703,576	5,757,732
Restricted stock units	3,536,809	214,980
Total	**10,250,385**	**5,982,712**

[H] Recent Accounting Pronouncements

Recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the 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 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, 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;
- Up to an aggregate of $442.5 million (after a $10.0 million milestone payment in August 2019) upon the achievement of certain development, regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens on net product sales subject to reduction on a product-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 11th anniversary of the first commercial sale of such product in such country.

As of December 31, 2021, $0.3 million was payable to HanAll for research and development costs incurred and reported to the Company pursuant to the HanAll Agreement.

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 batoclimab from RSG in the Licensed Territory, for an aggregate purchase price of $37.8 million.

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

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

As of December 31, 2021, the minimum purchase commitment related to this agreement is estimated to be approximately $36.0 million.

Note 4 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2021	March 31, 2021
Research and development expenses	$ 28,038	$ 10,147
Accrued bonuses	2,513	3,138
Legal and other professional fees	310	1,196
Other expenses	587	679
Total accrued expenses	**$ 31,448**	**$ 15,160**

Note 5 — Related Party Transactions

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

In addition to the agreements discussed in Note 3, in August 2018, the Company entered into 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 during its formative period. Under each Services Agreement, the Company will pay or reimburse RSI or RSG, as applicable, for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI or RSG employees, RSI or RSG, as applicable, will charge back the employee compensation expense plus a pre-determined mark-up. RSI and RSG also provided such services prior to the formalization of the Services Agreements, and such costs have been recognized by the Company in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost. The term of the Services Agreements will continue until terminated by the Company, RSI or RSG, as applicable, upon 90 days' written notice.

For the three and nine months ended December 31, 2021, the Company was charged $0.4 million and $1.3 million, respectively, by RSI, RSG and RSL, of which $0.2 million and $1.1 million, respectively, were treated as capital contributions and $0.2 million and $0.2 million, respectively, were treated as amounts due to RSL in accrued expenses in the accompanying unaudited condensed consolidated financial statements.

For the three and nine months ended December 31, 2020, the Company was charged $0.2 million and $0.7 million, respectively, by RSI, RSG and RSL, of which $0.1 million and $0.4 million, respectively, were treated as capital contributions and $0.1 million and $0.3 million, respectively, were treated as amounts due to RSL in accrued expenses in the accompanying unaudited condensed consolidated financial statements.

RSL Promissory Note

In July 2019, the Company entered into an interest-free promissory note payable to RSL in the amount of $2.9 million (the "July Promissory Note"). The July Promissory Note had a 180-day term and was payable on demand upon the expiration of the term. In May 2020, the Company paid and settled the July Promissory Note.

RSL Information Sharing and Cooperation Agreement

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

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

RSI Subleases

In June 2020, the Company entered into two sublease agreements with RSI for two floors of the building the Company currently occupies as its headquarters in New York. The subleases will expire on February 27, 2024 and April 29, 2024, respectively, and have scheduled rent increases each year. During the three months ended December 31, 2021 and 2020, the Company incurred $0.3 million and $0.2 million, respectively, in rent expense under these operating leases. During the nine months ended December 31, 2021 and 2020, the Company incurred $0.9 million and $0.7 million, respectively, in rent expense under these operating leases.

RSL Share Purchase Agreement

On August 2, 2021, the Company and RSL entered into a share purchase agreement pursuant to which the Company issued17,021,276 shares of the Company's common stock, par value $0.0001 per share, to RSL at a per share price of $11.75 and received aggregate net proceeds of $200.0 million. Prior to the share issuance, the Company and RSL explored alternative potential transactions whereby the Company incurred additional costs, including $5.0 million in financial advisory fees, which are included in general and administrative expenses in the accompanying unaudited condensed consolidated financial statements for the nine months ended December 31, 2021.

Note 6 — Income Taxes

The Company's effective tax rates were 0% and 0.07% for the three and nine months ended December 31, 2021, respectively, and1.14% and 0.35% for the three and nine months ended December 31, 2020, 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

In connection with the closing of the Business Combination, the Company designated and issued 10,000 shares of Series A preferred stock, par value $0.0001 per share, to RSL, all of which shares are outstanding as of December 31, 2021.

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

In connection with the closing of the Business Combination, the Company authorized 10,010,000 shares of preferred stock, par value $0.0001 per share. 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 December 31, 2021.

Common Stock

In connection with the closing of the Business Combination, the Company authorized 500,000,000 shares of common stock, par value $0.0001 per share. As of December 31, 2021, the Company has 115,109,833 shares of common stock issued and outstanding.

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

	December 31, 2021	March 31, 2021
Conversion of Series A preferred stock	10,000	10,000
Options outstanding	6,703,576	7,988,999
Restricted stock units outstanding	3,696,838	1,095,676
Equity awards available for future grants	4,002,861	1,781,043
Total	**14,413,275**	**10,875,718**

The reserved shares underlying restricted stock units above include 160,029 restricted stock units that vested but were not settled as of December 31, 2021.

Note 8 — Stock-Based Compensation

2019 Equity Incentive Plan

In December 2019, in connection with the Business Combination, the Company's stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") and reserved 5,500,000 shares of common stock for issuance thereunder. The 2019 Plan became effective immediately upon the closing of the Business Combination. The 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. Each year on April 1, the number of common shares reserved for issuance increased automatically by 4.0% of the total number of shares of common stock outstanding on the last day of the preceding month. On April 1, 2021, 3,918,849 shares of common stock were added to the 2019 Plan pool in accordance with the evergreen provision of the 2019 Plan. As of December 31, 2021, options to purchase 3,756,402 shares of common stock and 3,696,838 restricted stock units ("RSUs") were outstanding under the 2019 Plan and 4,002,861 shares of common stock remained available for future grant under the 2019 Plan.

Stock Option Repricing

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

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

2018 Equity Incentive Plan

Pursuant to the Share Exchange Agreement, upon the closing of the Business Combination, all vested and unvested outstanding options to purchase common shares of ISL under its 2018 Equity Incentive Plan (the "2018 Plan") were automatically assumed by the Company and converted into options to purchase 4,408,287 shares of the Company's common stock with no changes to the terms of the awards. As of the effective date of the 2019 Plan, no further stock awards have been or will be made under 2018 Plan. As of December 31, 2021, 2,947,174 stock options were outstanding under the 2018 Plan.

Stock Option Activity

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

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance - March 31, 2021	7,988,999	$ 16.97	9.04	$ 25,958
Granted	1,369,823	9.33		
Forfeited	(2,510,089)	23.45		
Expired	(145,157)	18.37		
Balance - December 31, 2021	**6,703,576**	**$ 8.79**	**8.49**	**$ 1,638**
Exercisable - December 31, 2021	**2,613,059**	**$ 8.70**	**7.74**	**$ 1,074**

The weighted-average exercise price, remaining contractual term and aggregate intrinsic value as of December 31, 2021 reflect the impact of the stock option repricing discussed above. The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable stock options and the fair value of the Company's common stock as of December 31, 2021. There were no stock options exercised during the nine months ended December 31, 2021. The stock options granted during the nine months ended December 31, 2021 had a weighted-average grant date fair value per share of $6.75.

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 December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Risk-free interest rate	1.17% - 1.36%	0.38% - 0.56%	0.80% - 1.36%	0.30% - 0.56%
Expected term, in years	6.11	6.08 - 6.11	6.03 - 6.11	5.56 - 6.11
Expected volatility	86.74% - 87.78%	83.40% - 83.80%	82.92% - 91.15%	78.16% - 84.05%
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, 2021	1,095,676	$ 20.43
Issued	3,212,767	7.53
Vested	(277,343)	17.44
Forfeited	(494,291)	18.58
Nonvested as of December 31, 2021	3,536,809	$ 9.21

Stock-based Compensation Expense

For the three and nine months ended December 31, 2021 and 2020, stock-based compensation expense under the Company's equity incentive plans was as follows (in thousands):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Research and development expenses	$ 4,797	$ 2,549	$ 8,602	$ 3,919
General and administrative expenses	5,157	3,443	12,841	9,298
Total stock-based compensation	**$ 9,954**	**$ 5,992**	**$ 21,443**	**$ 13,217**

As of December 31, 2021, total unrecognized compensation expense related to non-vested stock options and RSUs was $6.8 million and $24.1 million, respectively, which is expected to be recognized over the remaining weighted-average service period of 2.66 years and 1.62 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 RSL, RSI, RSG and the Company, stock-based compensation expense of $0.1 million and $0 was recorded for the three months ended December 31, 2021 and 2020, respectively, and $0.4 million and $0.1 million for the nine months ended December 31, 2021 and 2020, respectively, in the accompanying unaudited condensed consolidated statements of operations.

RSL RSUs

The Company's Chief Executive Officer was granted 25,000 RSUs of RSL in January 2021. These RSUs have a requisite service period of eight years. These RSUs will vest upon the achievement of both a time-based service requirement and RSL liquidity event requirement on or before the grant expiration date.

In September 2021, as a result of the closing of RSL's business combination with Montes Archimedes Acquisition Corp. and the subsequent public listing of RSL's common shares, the liquidity event of these RSL RSUs was achieved. Accordingly, the Company commenced recognition of stock-based compensation expense for the RSL RSUs in September 2021. For the three and nine months ended December 31, 2021, the Company recorded $0.1 million and $0.5 million, respectively, of stock-based compensation expense related to these RSUs. As of December 31, 2021, there was $0.5 million of unrecognized compensation expense related to unvested RSL RSUs. The Company will recognize this stock-based compensation expense over the remaining requisite service period.

Note 9 — Commitments and Contingencies

Litigation

The Company is involved in various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable.

In February 2021, a putative securities class action complaint was filed against the Company and certain of its current and former officers in the U.S. District Court for the Eastern District of New York on behalf of a class consisting of those who acquired the Company's securities from October 2, 2019 and February 1, 2021. The complaint alleges that the Company and certain of its officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by making false and misleading statements regarding the safety of batoclimab and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys' fees. On December 29, 2021, the U.S. District Court appointed a lead plaintiff. On February 1, 2022, the lead plaintiff filed an amended complaint adding the Company's directors and underwriters as defendants, and asserting additional claims under Section 11, 12(a)(2), and 15 of the Securities Act of 1933. Pending court approval of the parties' stipulation, defendants are not required to respond to this amended complaint. The deadline for lead plaintiff to file the operative amended complaint is March 15, 2022. The Company expects defendants, including the Company, to file a motion to dismiss that amended complaint. The Company intends to vigorously defend the case and has not recorded a liability related to this lawsuit because, at this time, the Company is unable to reasonably estimate possible losses or determine whether an unfavorable outcome is either probable or remote.

Commitments

During the three months ended December 31, 2021, ISG entered into an agreement with Samsung to manufacture a certain quantity of batoclimab drug substance for, among other things, commercial sale, if approved. In connection with this agreement, the Company has a minimum obligation to Samsung of approximately $36.0 million, of which is $17.7 million is expected to be paid during the fiscal year ending March 31, 2023 and $18.3 million is expected to be paid during the fiscal year ending March 31, 2026. See Note 3 - Material Agreements for additional details.

As of December 31, 2021, 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

In March 2020, COVID-19 was declared a pandemic by the World Health Organization. The COVID-19 pandemic continues to and is disrupting supply chains and affecting production and sales across a range of industries. Currently, the Company has not suffered significant adverse consequences as a result of the COVID-19 pandemic, though it did slow enrollment of its clinical trials prior to the Company's voluntary pause of clinical dosing in February 2021. The extent of the impact of COVID-19 on the Company's future operational and financial performance will depend on certain developments, including the duration and spread of the pandemic, including its variants, impact on employees and vendors, and impact on clinical trial sites and patients, all of which are uncertain and cannot be predicted. At this point, the extent to which COVID-19 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, 2021, included in our Annual Report on Form 10-K ("Annual Report"), filed with the Securities and Exchange Commission (the "SEC") on June 1, 2021. 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.

Prior to December 18, 2019, we were known as Health Sciences Acquisitions Corporation ("HSAC"). On December 18, 2019, we completed the Business Combination (as defined in "Note 1 – Description of Business and Liquidity" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report) with Immunovant Sciences Ltd. ("ISL"), a private company. For accounting purposes, HSAC was deemed to be the acquired entity.

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 biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, batoclimab, formerly referred to as IMVT-1401 or RVT-1401, that selectively binds to and inhibits the neonatal fragment crystallizable receptor ("FcRn"). Batoclimab is the product of a multi-step, multi-year research program conducted by HanAll Biopharma Co., Ltd. ("HanAll"), to design a highly potent anti-FcRn antibody optimized for subcutaneous delivery. Our product candidate has been dosed in small volumes (e.g., 2 mL) and with a 27-gauge needle, while still generating therapeutically relevant pharmacodynamic activity, important attributes that we believe will drive patient preference and market adoption. In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce immunoglobulin G ("IgG") antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in these disease areas. We are developing batoclimab in autoimmune diseases for which there is robust evidence that pathogenic IgG antibodies drive disease manifestation and for which reduction of IgG antibodies should lead to clinical benefit.

We are developing batoclimab as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule as discussed below. As a result of our rational design and current outlook on potential opportunities, we believe that batoclimab, if developed and approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases. Examples of indications for which trials for anti-FcRn assets have been announced are: Myasthenia Gravis ("MG"), Warm Autoimmune Hemolytic Anemia ("WAIHA"), Thyroid Eye Disease ("TED", formerly referred to as Graves' Ophthalmopathy, or "GO"), Idiopathic Thrombocytopenic Purpura, Pemphigus Vulgaris, Chronic Inflammatory Demyelinating Polyneuropathy, Bullous Pemphigoid, Pemphigus Foliaceus, Myositis, Autoimmune Encephalitis (LGI1+), Myelin Oligodendrocyte Glycoprotein Antibody Disorders, moderate-to-severe Primary Sjögrens Syndrome, Lupus Nephritis, Systemic Lupus Erythematosus, refractory Rheumatoid Arthritis, Hemolytic Disease of the Fetus and Newborn and moderate-to-severe Cutaneous Lupus Erythematosus. In 2021, we estimate these diseases had an aggregate prevalence of approximately 1,200,000 patients in the United States and 1,530,000 patients in Europe. To the extent we choose to develop batoclimab as a potential treatment for certain of these rare diseases, we plan to seek orphan drug designation in the United States and Europe, where applicable. Such designations would primarily provide financial and exclusivity incentives intended to make the development of orphan drugs financially viable. In July 2021, we were granted orphan drug designation by the U.S. Food and Drug Administration ("FDA") for batoclimab for the potential treatment of MG and we plan to seek orphan drug designation from the FDA for batoclimab for the treatment of WAIHA and TED and potentially in other orphan indications in which there is a medically plausible basis for its use, and we may seek orphan drug designation for batoclimab in Europe.

We are developing batoclimab as a fixed-dose subcutaneous injection, and have focused our initial development efforts on the treatment of MG, WAIHA and TED. We are also pursuing a number of other indications. MG is an autoimmune disease associated with muscle weakness. WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of red blood cells. TED is an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes, which can be sight-threatening.

As previously disclosed in our Annual Report, in February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and low-density lipoprotein ("LDL") levels observed in some trial subjects treated with batoclimab. No major adverse cardiovascular events have been reported to date in batoclimab clinical trials. In order to better characterize the observed lipid findings, we conducted from February 2021 through May 2021 a program-wide data review with input from external scientific and medical experts.

Utilizing pharmacokinetic ("PK") and pharmacodynamic ("PD") data obtained from our Phase 1 and Phase 2 studies, we are selecting dosing regimens for batoclimab which optimize reductions in total IgG levels while minimizing the impact on albumin and LDL cholesterol levels. Protocols that contain long-term treatment extensions will likely include protocol-directed guidelines for the management of any observed lipid abnormalities. While increases in LDL over a short-term treatment duration would not be expected to pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles.

During the three months ended December 31, 2021, we achieved alignment with the FDA Division of Neurology 1 to move forward in MG. We plan to start our Phase 3 study for batoclimab in MG in the first half of calendar year 2022. The trial will include an induction (primary efficacy) period during which we plan to study doses of 680mg and 340mg of batoclimab delivered weekly by subcutaneous injection. The primary efficacy analysis will be based on MG-ADL measured in Acetylcholine Receptor Antibody Positive subjects through 12 weeks of blinded, placebo-controlled therapy. Follow-on treatment with alternative dosing regimens (including potential lower maintenance and higher rescue doses) will be explored in subsequent study periods. The safety and monitoring plan and size of the safety database are expected to be in accordance with FDA guidance and generally consistent with those being used in other similar programs.

For WAIHA, we intend to initiate a randomized, controlled study with a long-term extension in this indication, following expected discussions with the hematology division of the FDA. For TED, we intend to reinitiate a placebo-controlled trial, following expected discussions with the ophthalmology division of the FDA.

We continue to evaluate potential new indications for batoclimab and we remain on track to announce two new indications by August 2022. We expect two of our four indications beyond MG to be initiated as a pivotal trial in the calendar year 2022.

COVID-19 Business Update

We have been actively monitoring the impact of the COVID-19 pandemic on our employees and our business. To date, the COVID-19 pandemic has not had significant effects on the progression of our clinical trials, though it did slow enrollment of our clinical trials prior to our voluntary pause of clinical dosing in February 2021, as previously disclosed. Further, the COVID-19 pandemic has not had significant manufacturing supply interruptions of batoclimab, and we intend to continue to advance the research and development of batoclimab.

We have not experienced material financial impacts as a result of the COVID-19 pandemic. However, the impact of the COVID-19 pandemic on our future results will largely depend on future developments related to the COVID-19 pandemic, which are highly uncertain and cannot be predicted with confidence, such as the ultimate duration of the pandemic, the spread of its variants and the full impact on our enrolling clinical sites, financial markets and the global economy, travel restrictions and social distancing in the U.S. and other countries, and business closures or business disruptions, as well as the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease, including the effectiveness of vaccines and vaccine distribution efforts.

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

Our Key Agreements

License Agreement with HanAll (“HanAll Agreement”)

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

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

Under the HanAll Agreement, the parties may choose to collaborate on a research program directed to the research and development of next generation FcRn inhibitors in accordance with an agreed plan and budget. We are obligated to reimburse HanAll for half of such research and development expenses incurred by HanAll, up to an aggregate reimbursement amount of $20.0 million. Intellectual property created by HanAll pursuant to this research program will be included in our license; intellectual property created by us pursuant to this research program will be included in HanAll’s license. As of December 31, 2021, $0.3 million was payable to HanAll for research and development costs incurred and reported to us pursuant to the HanAll Agreement.

Pursuant to the HanAll Agreement, RSG made an upfront payment of $30.0 million to HanAll. In May 2019, we achieved our first development and regulatory milestone which resulted in a $10.0 million milestone payment that we subsequently paid in August 2019. We will be responsible for future contingent payments and royalties, including up to an aggregate of $442.5 million upon the achievement of certain development, regulatory and sales milestone events. We are also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens on net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of: (A) the date on which the last valid claim of the licensed patents expire, (B) the date on which the data or market exclusivity expires or (C) 11 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country.

Product Service Agreement and Master Services Agreement

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

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

The minimum purchase commitment related to this agreement is estimated to be approximately $36.0 million.

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 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 and any future product candidates.

Research and Development Expenses

We have been primarily engaged in preparing for and conducting clinical trials. Research and development expenses include program-specific costs, as well as unallocated costs.

Program-specific costs include direct third-party costs, which include expenses incurred under agreements with contract research organizations ("CROs") and the cost of consultants who assist with the development of the Company's product candidate on a program-specific basis, investigator grants, sponsored research, and any other third-party expenses directly attributable to the development of the product candidate.

Unallocated costs include:

- costs related to contract manufacturing operations including manufacturing costs in connection with producing materials for use in conducting preclinical and clinical studies, including under our agreement with Samsung;
- 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;
- payments upon the achievement of certain development and regulatory milestones under the HanAll Agreement;
- costs allocated to us under our services agreements with Roivant Sciences, Inc. ("RSI") and 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 program.

Research and development activities will continue to be central to our business model. We expect our research and development expenses to increase significantly in the short term as we plan to start our Phase 3 study for batoclimab in MG and for two other planned pivotal trials in 2022. Our research and development expenses are expected to continue to increase over the next several years as we hire personnel and our compensation costs increase, commence additional clinical trials for batoclimab, expand manufacturing of batoclimab substance and prepare to seek regulatory approval for batoclimab. It is not possible to determine with certainty the duration and completion costs of any clinical trial we may conduct.

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

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals;
- the potential impact of the ongoing COVID-19 pandemic;
- the efficacy and safety profile of the product candidate; and
- the cost of manufacturing.

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

General and Administrative Expenses

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

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

Results of Operations for the Three Months Ended December 31, 2021 and 2020

The following table sets forth our results of operations for the three months ended December 31, 2021 and 2020 (in thousands):

	Three Months Ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 29,756	$ 21,091	$ 8,665
General and administrative	11,515	10,549	966
Total operating expenses	41,271	31,640	9,631
Other expense	114	503	(389)
Loss before benefit for income taxes	(41,385)	(32,143)	(9,242)
Benefit for income taxes	—	(367)	367
Net loss	**$ (41,385)**	**$ (31,776)**	**$ (9,609)**

Research and Development Expenses for the Three Months Ended December 31, 2021 and 2020

The following table summarizes the period-over-period changes in research and development expenses for the three months ended December 31, 2021 and 2020 (in thousands):

	Three Months Ended December 31,		Change
	2021	2020	$
Program-specific costs:			
Neurology diseases	$ 468	$ 970	$ (502)
Endocrine diseases	(25)	2,880	(2,905)
Hematology diseases	264	1,817	(1,553)
Unallocated costs:			
Contract manufacturing costs	11,338	8,062	3,276
Personnel-related expenses including stock-based compensation	9,362	5,686	3,676
Other	8,349	1,676	6,673
Total research and development expenses	**$ 29,756**	**$ 21,091**	**$ 8,665**

Research and development expenses increased by $8.7 million, from $21.1 million for the three months ended December 31, 2020 to $29.8 million for the three months ended December 31, 2021.

Program-specific research and development costs decreased by $5.0 million, from $5.7 million for the three months ended December 31, 2020 to $0.7 million for the three months ended December 31, 2021, primarily reflecting lower clinical activities due to the continued voluntary pause in our clinical trials and adjustments to previously accrued estimated costs related to the conclusion of certain Phase 2 studies.

Unallocated research and development costs increased by $13.6 million, from $15.4 million for the three months ended December 31, 2020 to $29.0 million for the three months ended December 31, 2021. This increase reflected higher costs related to cross-indication clinical studies and clinical research of $6.7 million, higher personnel-related expenses of $3.7 million and an increase in contract manufacturing costs of $3.3 million. The increases in clinical studies and clinical research costs primarily reflected costs to advance the clinical development of batoclimab in current and potential new indications. The increases in contract manufacturing for process development and drug substance manufacturing combined with personnel costs primarily reflected investment spending to support our strategic objectives as we prepare to resume our clinical activities.

General and Administrative Expenses for the Three Months Ended December 31, 2021 and 2020

General and administrative expenses increased by $1.0 million, from $10.5 million for the three months ended December 31, 2020 to $11.5 million for the three months ended December 31, 2021. This increase was primarily due to higher personnel-related costs (including stock-based compensation) of $1.5 million, partially offset by lower legal and other professional costs of $0.6 million.

Results of Operations for the Nine Months Ended December 31, 2021 and 2020

The following table sets forth our results of operations for the nine months ended December 31, 2021 and 2020 (in thousands):

	Nine Months Ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 69,822	$ 49,989	$ 19,833
General and administrative	38,984	29,211	9,773
Total operating expenses	108,806	79,200	29,606
Other expense	825	352	473
Loss before benefit for income taxes	(109,631)	(79,552)	(30,079)
Benefit for income taxes	(72)	(279)	207
Net loss	**$ (109,559)**	**$ (79,273)**	**$ (30,286)**

Research and Development Expenses for the Nine Months Ended December 31, 2021 and 2020

The following table summarizes the period-over-period changes in research and development expenses for the nine months ended December 31, 2021 and 2020 (in thousands):

	Nine Months Ended December 31,		Change
	2021	2020	$
Program-specific costs:			
Neurology diseases	$ 1,016	$ 2,546	$ (1,530)
Endocrine diseases	3,549	5,904	(2,355)
Hematology diseases	1,239	3,572	(2,333)
Unallocated costs:			
Contract manufacturing costs	26,550	20,954	5,596
Personnel-related expenses including stock-based compensation	21,921	11,402	10,519
Other	15,547	5,611	9,936
Total research and development expenses	**$ 69,822**	**$ 49,989**	**$ 19,833**

Research and development expenses increased by $19.8 million, from $50.0 million for the nine months ended December 31, 2020 to $69.8 million for the nine months ended December 31, 2021.

Program-specific research and development costs decreased by $6.2 million, from $12.0 million for the nine months ended December 31, 2020 to $5.8 million for the nine months ended December 31, 2021, primarily reflecting lower clinical activities due to the continued voluntary pause in our clinical trials, partially offset by costs related to clinical activities for analyzing data and the program-wide data review.

Unallocated research and development costs increased by $26.0 million, from $38.0 million for the nine months ended December 31, 2020 to $64.0 million for the nine months ended December 31, 2021. This increase was primarily due to higher personnel-related expenses of $10.5 million, increases related to cross-indication clinical studies and clinical research of $9.9 million and higher contract manufacturing costs of $5.6 million, primarily due to drug substance manufacturing. The increases in personnel and contract manufacturing costs primarily reflected investment spending to support our strategic objectives as we prepare to resume our clinical activities. The increases in clinical studies and clinical research costs primarily reflected costs to advance the clinical development of batoclimab in current and potential new indications.

General and Administrative Expenses for the Nine Months Ended December 31, 2021 and 2020

General and administrative expenses increased by $9.8 million, from $29.2 million for the nine months ended December 31, 2020 to $39.0 million for the nine months ended December 31, 2021. This increase was primarily due to higher personnel-related costs (including stock-based compensation) of $5.2 million, and financial advisory, legal and other professional costs of $4.1 million.

Liquidity and Capital Resources

Overview

As of December 31, 2021, we had cash of $527.0 million. For the nine months ended December 31, 2021 and 2020, we had net losses of $109.6 million and $79.3 million, respectively, and 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 or any future product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, timing of batoclimab manufacturing, HanAll milestone payments and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

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

- incur insurance, legal and other regulatory compliance expenses to operate as a public company.

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

Until such time, if ever, as we can generate substantial product revenue from sales of batoclimab or any future product candidate, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the ongoing COVID-19 pandemic. 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.

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 nine months ended December 31, 2021 and 2020 (in thousands):

	Nine Months Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (73,156)	$ (60,831)
Net cash used in investing activities	(136)	(115)
Net cash provided by financing activities	200,129	382,349

Operating Activities

For the nine months ended December 31, 2021, $73.2 million of cash was used in operating activities. This was primarily attributable to a net loss from operations for the year of $109.6 million, partially offset by non-cash charges of $23.3 million and a net change in operating assets and liabilities of $13.1 million. The non-cash charges consisted mainly of stock-based compensation of $22.4 million, reflecting the higher headcount and incentive equity awards as compared with the prior-year period. The change in our operating assets and liabilities was primarily due to an increase of $17.6 million in accounts payable and accrued expenses, driven by the timing and level of payments related to contract manufacturing and other research and development costs. The change in operating assets and liabilities also reflected $3.8 million of lower prepaid expenses and other current assets, driven by the timing of payments related to clinical research and contract manufacturing activities.

For the nine months ended December 31, 2020, $60.8 million of cash was used in operating activities. This was primarily attributable to a net loss from operations of $79.3 million, non-cash charges of $14.6 million and a net change in operating assets and liabilities of $3.9 million. The non-cash charges consisted mainly of stock-based compensation of $13.3 million. The change in our operating assets and liabilities was primarily due to a decrease of $3.0 million in value-added tax receivable due to settlement of the receivable in April 2020.

Investing Activities

For the nine months ended December 31, 2021 and 2020, cash used in investing activities was related to the purchase of property and equipment.

Financing Activities

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

For the nine months ended December 31, 2020, $382.3 million of cash provided by financing activities consisted of $319.8 million in proceeds from the two issuances of common stock in an underwritten public offering, $65.8 million in proceeds from the issuance of common stock upon warrant redemptions, partially offset by repayment of the note payable to RSL of $3.2 million and the payment of offering costs for two issuances of $1.2 million.

Outlook

Based on our existing cash balance as of December 31, 2021 of $527.0 million, our research and development plans and our timing expectations related to our development programs for batoclimab, we expect to be able to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of this Quarterly Report. However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Contractual Obligations and Commitments

Except as discussed below, 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.

Product Service Agreement and Master Services Agreement

During the three months ended December 31, 2021, we entered into an agreement with Samsung to manufacture a certain quantity of batoclimab drug substance for, among other things, commercial sale, if approved. In connection with this agreement, we have a minimum obligation to Samsung of approximately $36.0 million, of which is $17.7 million is expected to be paid during the fiscal year ending March 31, 2023 and $18.3 million is expected to be paid during the fiscal year ending March 31, 2026. 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 of December 31, 2021, the aggregate maximum amount of milestone payments we could be required to make under the HanAll Agreement is $442.5 million upon the achievement of certain development, regulatory and sales milestone events. We are also required to reimburse HanAll for half of budgeted research and development costs incurred by HanAll with respect to batoclimab, up to an aggregate of $20.0 million.

Sublease Agreements

In June 2020, we entered into two sublease agreements with RSI for the two floors of the building that serve as our headquarters in New York. The subleases will expire on February 27, 2024 and April 29, 2024, respectively, and have scheduled rent increases each year. The future fixed operating lease payments under both sublease agreements are $2.6 million over a lease period of approximately 2.3 years.

In April 2020, we entered into a sublease agreement with an unrelated party for one floor of a building in North Carolina. The sublease will expire on February 28, 2022 and has no scheduled rent increases. The future fixed operating lease payments under the sublease agreement are less than $0.1 million over the remaining lease period of 2 months.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our 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 policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the three and nine months ended December 31, 2021, there were no material changes to our critical accounting policies and use of estimates from those disclosed in the audited consolidated financial statements for the year ended March 31, 2021 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 December 31, 2021, we had cash of $527.0 million. Interest income 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 U.S. and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we are exposed to fluctuations in foreign currency exchange rate risk as a result of entering into transactions denominated in currencies other than U.S. dollars as we have contracted with and may continue to contract with foreign vendors. 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 Risk

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 December 31, 2021.

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 December 31, 2021, 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 December 31, 2021 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 December 31, 2021 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 1 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 success relies upon a sole product candidate, batoclimab, formerly referred to as IMVT-1401 or RVT-1401. In February 2021, we paused all clinical development of batoclimab after elevated lipid levels were observed in some patients dosed with the drug. In December 2021, we announced that we recently achieved alignment with the FDA's Division of Neurology 1 to move forward with batoclimab in patients suffering from MG. Unless we can continue to determine a dosing regimen, target patient population, safety monitoring and risk management for batoclimab in autoimmune diseases for which the risks of lipid elevations and albumin reductions can be mitigated, we will not be able to show adequate benefit to risk ratio and will not be able to continue clinical development or seek or obtain marketing authorization in any jurisdiction.

In February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some trial subjects treated with batoclimab. In our ASCEND GO-2 trial, lipid parameters were assessed at baseline, at week 12, and at week 20 following eight weeks off drug. Based on preliminary, unblinded data, median LDL cholesterol at week 12 was increased by approximately 12 mg/dL in the 255 mg dose group (corresponding to an increase from baseline of approximately 15%), by approximately 33 mg/dL in the 340 mg dose group (corresponding to an increase from baseline of approximately 37%), by approximately 62 mg/dL in the 680 mg dose group (corresponding to an increase from baseline of approximately 52%) and did not increase in the control group. The data analysis indicates a dose-dependent increase in lipids. Average high-density lipoprotein ("HDL") and triglyceride levels also increased but to a much lesser degree. We also observed correlated decreases in albumin levels and the rate and extent of albumin reductions were dose-dependent. Subjects receiving the 255 mg weekly dose ("QW") experienced the smallest reductions in albumin through week 12, with a median reduction of about 16% from baseline, while subjects receiving the 340 mg or 680 mg QW experienced median reductions of albumin of 26% or 40%, respectively. At week 20, both lipids and albumin returned to baseline.

In our open label ASCEND WAIHA trial, only two subjects completed 12 weeks of dosing prior to the program-wide pause in dosing, with three additional subjects partially completing the dosing period. Pre-specified and post-hoc lipid test results from these five subjects were analyzed along with post-hoc lipid test results performed on frozen samples from ASCEND MG subjects (where available) and post-hoc lipid test results from our Phase 1 Injection Site study. LDL elevations observed in the ASCEND WAIHA and ASCEND MG subject populations and in healthy subjects in the Phase 1 Injection Site study also appeared to be dose-dependent and were generally consistent in magnitude with the elevations observed in ASCEND GO-2 subjects. For more information about our ASCEND GO-2, ASCEND WAIHA, ASCEND MG and Phase 1 Injection Site studies, please refer to "*Part I, Item 1. Business*" of our Annual Report on Form 10-K, filed with the SEC on June 1, 2021.

No major adverse cardiovascular events have been reported to date in batoclimab clinical trials.

In order to better characterize the observed lipid findings, we conducted from February 2021 through May 2021 a program-wide data review with input from external scientific and medical experts. Based upon our review and expert input, we intend to resume clinical studies with batoclimab and we are currently drafting study protocols across multiple indications. Utilizing PK and PD data obtained from our Phase 1 and Phase 2 studies, we are selecting dosing regimens for batoclimab which optimize reductions in total IgG levels while minimizing the impact on albumin and LDL cholesterol levels. Protocols that contain long-term treatment extensions will likely include protocol-directed guidelines for the management of any observed lipid abnormalities. While increases in LDL over a short-term treatment duration would not be expected to pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles. We have initiated discussions with the FDA and achieved alignment with the FDA's Division of Neurology 1 in December 2021 to move forward in MG. We plan to start our Phase 3 study for batoclimab in MG in the first half of calendar year 2022. We continue to evaluate potential new indications for batoclimab and we remain on track to announce two new indications by August 2022. We expect two of our four indications beyond MG to be initiated as a pivotal trial in the calendar year 2022.

It is possible we will not be able to agree upon sufficient risk mitigation with regulatory authorities and that our development of batoclimab will not continue. Even if we are able to continue clinical development of batoclimab with such risk mitigations, any future approval and marketing would suffer from the risks of potential long-term lipid and albumin changes and potential impact of mitigating measures, including, among others, limited indication, monitoring, a risk evaluation and mitigation strategy ("REMS"), potential additional safety studies and other adverse labeling.

Batoclimab has caused and may cause adverse events("AEs") or have other properties that could delay or prevent its regulatory approval, cause us to further suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

AEs associated with batoclimab in our clinical trials could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. The most commonly reported AE in our Phase 1 clinical trial was mild erythema and swelling at the injection site, which typically resolved within hours; as previously disclosed, lipid levels were not measured contemporaneously during these Phase 1, ASCEND MG and ASCEND GO-1 clinical trials of batoclimab. If an unacceptable frequency or severity of AEs or new safety signals are reported in our clinical trials for our product candidate, our ability to obtain regulatory approval for such product candidate may be negatively impacted. Treatment-related side effects arising from, or those potentially arising from, our product candidate or those from other companies targeting similar autoimmune indications 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 the trial, 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, in February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some trial subjects treated with batoclimab. Based on our program-wide data review, in our ASCEND GO-2 trial, data analysis indicates a dose-dependent increase in lipids and our ASCEND WAIHA initial preliminary data indicated a similar trend in lipid parameters as compared to those in the ASCEND GO-2 trial. We also observed a decrease in albumin levels and the rate and extent of albumin reductions were dose-dependent. We are progressing discussions with the FDA and are planning to progress discussions with other regulatory authorities to align on the next steps in the continued development of batoclimab. These occurrences have harmed, and any reoccurrences may continue to harm, our business, financial condition and prospects.

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

- regulatory authorities may withdraw, suspend or limit their approval of the product or require a REMS (or equivalent outside the U.S. 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 marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, require other labeling changes or require field alerts or other communications to physicians, pharmacies or the public;
- we may be required to change the way the product is administered or distributed, conduct additional clinical trials, change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;

- we may be required to repeat a nonclinical study or clinical trial or terminate a program, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we may be sued and held liable for harm caused to patients;
- physicians may stop prescribing the product;
- reimbursement may not be available for the product;
- we may elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

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

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

Batoclimab is still in clinical development and will require extensive clinical testing before we are prepared to submit a biologics license application ("BLA") or other similar application for regulatory marketing approval. We cannot provide you any assurance that we will submit a BLA for regulatory approval for our product candidate within our projected timeframes or whether any such application will be approved by the relevant regulatory authorities. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other regulatory authorities may not agree with our proposed analysis plans or trial design for any clinical trials for batoclimab; during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of a BLA or similar application. The FDA may also find that the benefits of batoclimab in any of our target indications do not outweigh its risks, including the risks associated with elevated lipid levels and lower albumin levels, in a manner sufficient to grant regulatory approval. The clinical trial process is also time-consuming and costly and relies on the collaboration with many 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 promising results in earlier trials. Likewise, the results of early nonclinical studies and clinical trials of batoclimab, some of which were not conducted by us, may not be predictive of the results of our planned development programs and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

In February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some trial subjects treated with batoclimab. If we fail to successfully complete our clinical trials of batoclimab and demonstrate the efficacy and safety necessary to obtain regulatory approval to market batoclimab 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 trial or reach a consensus with regulatory authorities regarding the design or implementation of our studies;
- unforeseen safety issues or subjects experiencing severe or unexpected AEs;
- continuation of previously identified safety issues, despite our program-wide safety strategy to characterize the safety profile of batoclimab in response to the previously reported change in albumin and lipids;
- occurrence of AEs in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- resolving any dosing issues or limitations, including those raised by the FDA or other 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 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 or IRB, refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- premature discontinuation of study participants from clinical trials or missing data at a level that impacts study integrity;
- failure to manufacture or release sufficient quantities of our product candidate or placebo or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our 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, disruptions caused by the COVID-19 pandemic increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Further, we, the FDA or another regulatory authority may suspend our clinical trials in an entire country at any time, or an IRB may suspend its clinical trial sites within any country, if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including good clinical practice ("GCP"), that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our 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 candidate could be harmed, and our ability to generate product revenue from our product candidate, if approved, may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause or lead to a termination or suspension of, or delay in, the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidate. We may make formulation or manufacturing changes to batoclimab, in which case we may need to conduct additional nonclinical or clinical studies to bridge our modified product candidate to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidate and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidate could be significantly reduced.

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

In addition, we had no involvement with or control over the nonclinical or clinical development of batoclimab prior to its in-license from HanAll. We are dependent on HanAll having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, accurately reported the results of all nonclinical studies and clinical trials and other research they conducted prior to our acquisition of the rights to our product candidate, correctly collected and interpreted the data from these studies, trials and other research, and supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of this asset.

Problems related to our predecessor could result in increased costs and delays in the development of our product candidate, which could adversely affect our ability to generate any future revenue from sales of our product candidate, if approved.

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

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

Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies or other factors related to COVID-19, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents and our ability to successfully complete prerequisite studies before enrolling certain patient populations. Our product candidate is focused in part on addressing rare autoimmune indications, and we have focused our initial development efforts on the treatment of MG, TED and WAIHA with limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. We are also pursuing a series of other indications.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients once a paused clinical trial has been resumed. For example, in February 2021, we reported that we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some patients treated with batoclimab. While we completed an in-depth review of the preliminary data and are updating our comprehensive strategy to address the relative benefits and risks, it may be more difficult to recruit and retain patients for clinical trials in the future, including our Phase 3 trial in MG expected in the first half of calendar year 2022. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

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

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

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior nonclinical testing and clinical trials. In particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our Phase 1 clinical trial of batoclimab will be observed in any future clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising 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.

We are progressing discussions with the FDA and are planning to progress discussions with other regulatory authorities, with the intent to continue development of batoclimab. For example, while the ASCEND GO-2 trial was terminated and the efficacy results, based on approximately half the anticipated number of subjects who had reached the week 13 primary efficacy analysis at the time of the termination of the trial, were inconclusive, we had further discussions with external experts to determine whether a specific population can be identified to optimize the clinical performance of batoclimab. Based on these analyses and alignment with the FDA's Division of Neurology 1, we intend to start our Phase 3 study for batoclimab in MG in the first half of calendar year 2022. Our failure to successfully complete our clinical trials of batoclimab and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market batoclimab would significantly harm our business.

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

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

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full 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 agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize batoclimab 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 candidate batoclimab on a timely basis or at all.

Batoclimab is a novel therapeutic antibody and its potential therapeutic benefit is unproven. While results from early clinical trials of batoclimab have shown meaningful reductions in IgG antibody levels in healthy volunteers, batoclimab may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for batoclimab in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although we and our licensing partner have evaluated batoclimab nonclinical studies and in early-stage clinical trials, we have not yet advanced batoclimab into a large-scale, pivotal clinical trial for any indication. Positive results from our early-stage clinical trials are not necessarily predictive of the results of our planned clinical trials of batoclimab, including our Phase 3 trial in MG expected to initiate in the first half of calendar year 2022. For example, in February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some trial subjects treated with batoclimab. In order to better characterize the observed lipid findings, we conducted from February 2021 through May 2021 a program-wide data review (including both clinical and nonclinical data) with input from external scientific and medical experts. We are progressing discussions with the FDA and are planning to progress discussions with other regulatory authorities to align on the next steps in the continued development of batoclimab in other indications besides MG. If expectations from our Phase 1 and Phase 2 clinical trials cannot be replicated, we may be unable to successfully develop, obtain regulatory approval for and commercialize batoclimab for the treatment of MG, WAIHA and TED or any other autoimmune indication. As a result, our focus on exploring FcRn inhibition may fail to result in the identification of viable additional indications for batoclimab. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize batoclimab, 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 or any future product candidate, and our ability to generate product revenue will be impaired.

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

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

The time required to obtain approval of a BLA by the FDA or similar 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 substantial discretion of the regulatory authority. Prior to submitting a BLA to the FDA or any comparable application to any other foreign regulatory authorities for approval of any product candidate, we will need to complete pivotal Phase 3 clinical trials to demonstrate favorable results with respect to safety, tolerability and efficacy. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

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

Batoclimab is an antibody protein that could cause an immune response in patients, resulting in the creation of harmful or neutralizing antibodies against these therapeutic proteins, preventing or limiting regulatory approval or our ability to commercialize batoclimab.

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

We have in-licensed the rights to 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 batoclimab.

We have in-licensed the right to develop, manufacture and commercialize 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 batoclimab 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 may delay, limit or deny approval of batoclimab or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs and time to market. If we receive FDA approval for batoclimab and a new and/or serious safety issue is identified in connection with clinical trials of batoclimab conducted by third parties in other jurisdictions outside of our Licensed Territory, the FDA may withdraw their approval of the product or otherwise restrict our ability to market and sell batoclimab or may require additional testing or evaluation. In addition, treating physicians may be less willing to administer our product candidate due to concerns over such AEs, which would limit our ability to commercialize batoclimab. In addition, issues may arise in connection with the manufacturing process for batoclimab utilized by HanAll or any of its sublicensees or collaborators, which could affect our ability to obtain regulatory approval for or commercialize batoclimab.

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

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

We expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases, including multiple agents which are in the same class as batoclimab. We are aware of several FcRn inhibitors that are in clinical development. These include, efgartigimod (argenx SE), nipocalimab (Johnson & Johnson), rozanolixizumab (UCB) and ALXN1830 (AstraZeneca). In December 2021, the FDA approved Vyvgart (efgartigimod) for the treatment of generalized myasthenia gravis (gMG) in adults who test positive for the anti-acetylcholine receptor (AChR) antibody. This is the first approval granted by the FDA for an FcRn inhibitor in the U.S.

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

Fostamatinib (Rigel Pharmaceuticals), a Syk inhibitor, is currently in Phase 3 development for the treatment of WAIHA. A Phase 2 investigator-initiated study of ibrutinib (AbbVie), a BTK inhibitor, in steroid-refractory WAIHA is ongoing. Annexon Biosciences initiated a Phase 2 trial for WAIHA in 2021 for ANX005, an antibody inhibitor of the C1q protein.

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. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

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

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

- develop and commercialize therapies in our target indications that are superior to other products in the market;
- demonstrate through our clinical trials that batoclimab or any future product candidate is differentiated from existing and future therapies;
- attract qualified scientific, product development, manufacturing and commercial personnel;
- obtain patent or other proprietary protection for batoclimab and any future product candidates;
- obtain required regulatory approvals, including approvals to market 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 batoclimab or any future product candidate, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors;

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

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

Additional time may be required to obtain marketing authorizations for our batoclimab pre-filled syringe product candidate because it would be subject to regulation as a combination product.

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

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

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidate is safe and effective for its intended use. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the 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. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets. 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 candidate and services and assuring the safety and efficacy of our product candidate. 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.

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

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, AE reporting, storage, recordkeeping, conduct of potential post-market studies and post-market commitment and requirements, export, import and advertising and promotional activities for such product, among other things, by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with current good manufacturing practice ("cGMP") requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions, including in some cases, a boxed warning be included in the product labeling, which could limit sales of the product. Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although the FDA and other regulatory agencies 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 agencies 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 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 equivalent outside the U.S.);
- Warning or Untitled Letters;
- withdrawal of the product from the market;
- recall of a product;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such product;
- product seizure; or
- lawsuits, injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of batoclimab or any future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We plan to continue to seek orphan drug designation for batoclimab, but we may be unable to obtain such further designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted.

In July 2021, we were granted orphan drug designation in the U.S. by the FDA for batoclimab for the potential treatment of MG and we plan to seek orphan drug designation from the FDA for batoclimab for the treatment of WAIHA and TED and potentially in other orphan indications in which there is a medically plausible basis for its use, and we may seek orphan drug designation for batoclimab in the E.U. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the E.U., the European Medicines Agency's ("EMA") Committee for Orphan Medicinal Products assesses orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the E.U. or a serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the E.U. would be sufficient to justify the necessary investment in developing the drug or biological product and where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

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

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

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

If our 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;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- any foreign partners or collaborators not fulfilling their respective regulatory reporting requirements and any foreign regulatory authorities taking actions with respect to such failures, which would be reportable to the FDA;
- any foreign partners or collaborators not informing us of any new post-marketing safety signals in a timely manner;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- 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) 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, which will be expanded beginning in 2022 to require applicable manufacturers to report such information regarding its payments or other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, 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; 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, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. 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 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 a new “average manufacturer price” calculation for drugs and biologics that are inhaled, infused, instilled, implanted or injected and that are not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) established a new Medicare Part D coverage gap discount program, in which manufacturers currently must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; (6) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability; (7) created a licensure framework for follow-on biologic products; and (8) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017 ("TCJA") was enacted, which included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. 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. 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 2030 unless additional Congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempted to implement several of the former Trump administration proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services ("HHS") finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. In addition, on November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process.

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. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

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

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

In the 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 candidate, 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 candidate profitably, if approved for sale.

Risks Related to Our Business, Financial Position and Capital Requirements

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

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

We cannot be certain that batoclimab will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products, including antibody-based products, are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries that each have differing regulations. We are not permitted to market our product candidate in the U.S. until we receive approval of a BLA or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization. In addition, we have not yet demonstrated our ability to complete later-stage or pivotal clinical trials for our product candidate.

We have not submitted a BLA for batoclimab to the FDA or any comparable application to any other regulatory authority. Obtaining approval of a BLA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of batoclimab for many reasons, including:

- we may not be able to demonstrate that our product candidate is safe and effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our clinical trials of batoclimab for the treatment of MG, TED and WAIHA;
- 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 regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of our product candidate outweigh its safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of our product candidate or may require additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated from our clinical trial sites;
- if our BLA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require development of a REMS or its equivalent as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidate;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

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

In addition, if our product candidate encounters safety or efficacy problems, 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 candidate could be significantly harmed in other indications, which would have a material adverse effect on our business. Further, competitors who are developing product candidates in the autoimmune disease field, including IgG-mediated autoimmune indications, or that target the same indications or use the same mechanism of action as us may experience problems with their product candidates that could suggest problems with our product candidate that would potentially harm our business.

Our business, operations, clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics and pandemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trials and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, suppliers, shippers and others.

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

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

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

In February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some trial subjects treated with batoclimab. Prior to this voluntary pause of our clinical trials, the COVID-19 pandemic impacted clinical site enrollment and some participants' ability to follow office visit schedules and protocols. Given the uncertain course of the COVID-19 pandemic, it is impossible to predict with certainty any future impact it may have on our operations. For example, patient enrollment, including in our Phase 3 trial in MG expected to initiate in the first half of calendar year 2022, could be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations.

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

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

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. We have never generated any product revenue and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was $41.4 million and $31.8 million for the three months ended December 31, 2021 and 2020, respectively, and $109.6 million and $79.3 million for the nine months ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $308.2 million.

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

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

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

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

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

Even if we receive regulatory approval for batoclimab 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 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 and operations as a public company;

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

Because of the numerous risks and uncertainties associated with product development, including delays in subject enrollment or interruptions in clinical trial supplies or investigational product, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if batoclimab 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 candidate 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 candidate 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 candidate 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 and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of batoclimab.

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

We will require additional capital to complete the development and potential commercialization of batoclimab. Because the length of time and activities associated with successful development of our product candidate are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all, and our ability to raise additional capital may be adversely impacted by global economic conditions, including the recent disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the ongoing COVID-19 pandemic. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

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

We do not have any committed external source of funds. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of batoclimab 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, 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 or any future product candidate or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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

We have licensed our core intellectual property relating to 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. We are also required to reimburse HanAll for half of budgeted research and development costs incurred by them with respect to batoclimab, up to an aggregate reimbursement amount of $20.0 million. 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 certain milestone payments, some of which may be triggered prior to our potential commercialization of batoclimab.

We will be responsible for future contingent payments and royalties under the HanAll Agreement, including up to an aggregate of $442.5 million upon the achievement of certain development and regulatory milestone events, which events will occur prior to our planned commercialization of batoclimab. 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. There can be no assurance that we will have the funds necessary to make such payments or be able to raise such funds when needed on terms acceptable to us or at all. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

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

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

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

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

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

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

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

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

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

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

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 and any future product candidates outside the U.S. Doing business internationally involves a number of risks, including but not limited to:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidate, if approved, in various countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the ongoing COVID-19 pandemic;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including the COVID-19 pandemic and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, the 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 security, and information security laws, contractual obligations, self-regulatory schemes, government regulation and standards related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with such obligations could harm our reputation, subject us to significant fines and liability, disrupt our clinical trials or otherwise adversely affect our business.

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

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

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

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

Assisting our customers, partners, and vendors in complying with the GDPR or complying with the GDPR ourselves may cause us to incur substantial operational costs or require us to change our business practices.

In addition, the regulation of data transfers between the EU and U.K. remains subject to post-Brexit uncertainty.Pursuant to a post-Brexit trade deal between the U.K. and the EU, transfers of personal information from the EEA to the U.K. are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers of personal information from the EEA to the U.K. to continue without restriction for a period of four years ending June 27, 2025. During these four years, the European Commission will continue to monitor the legal situation in the U.K. and can intervene if the U.K. deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal information from the EEA to the U.K. will require a valid transfer mechanism and companies making such transfers may be required to implement new processes and put new agreements in place to continue making such transfers. Additionally, although U.K. privacy, data protection and information security law is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

In addition, the GDPR includes restrictions on cross-border data transfers. A recent decision by the Court of Justice of the European Union (the Schrems II ruling), however, has invalidated the E.U.-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe, and raised questions about whether the European Commission's Standard Contractual Clauses ("SCCs"), one of the primary alternatives to the E.U.-U.S. Privacy Shield Framework, can lawfully be used for personal information transfers from Europe to the U.S. or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. The U.K., whose data protection laws are similar to those of the E.U., may similarly determine that the EU-U.S. Privacy Shield Framework is not a valid mechanism for lawfully transferring personal information from the U.K. to the U.S. On June 4, 2021, the European Commission adopted new SCCs, which impose on companies additional obligations relating to data transfers, including the obligation to conduct a transfer impact assessment and, depending on a party's role in the transfer, to implement additional security measures and to update internal privacy practices. If we elect to rely on the new SCCs for data transfers, we may be required to incur significant time and resources to update our contractual arrangements and to comply with new obligations. The new SCCs may increase the legal risks and liabilities under European privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs, any transfers by us or our vendors of personal information from Europe may not comply with European data protection law, which may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of E.U. personal information outside of the E.U. (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products.

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, information security and Processing ("Data Protection Obligations"), including without limitation, operating rules and standards imposed by industry organizations.

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

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

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

We may in the future receive inquiries or be subject to investigations, proceedings or actions by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect on our business, including without limitation, interruptions of or require changes to our business practices, the diversion of resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary Processing, or other remedies that adversely affect our business (See Part I, Item 3 "Legal Proceedings" for additional information). We may in the future face litigation regarding our privacy and information security practices and Processing, including without limitation, class action litigation, which could result in a material adverse effect on our business.

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

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

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

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. In addition to traditional computer "hackers," threat actors, 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, sophisticated nation-state and nation-state-supported actors now engage in attacks (including advanced persistent threat intrusions). We may also be the subject of phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data or other computer assets, adware or other similar issues. Additionally, the COVID-19 pandemic and our remote workforce pose increased risks to our information technology assets and data. Moreover, security incidents can result in the diversion of funds and interruptions, delays or outages in our operations and services, including due to ransomware attacks, which have increased in frequency and severity.

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

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

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

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

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

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

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

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

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

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 regulatory authority actions. If a prolonged government shutdown occurs or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have an adverse effect on our business.

Risks Related to Our Dependence on Third Parties

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

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. We rely on third parties to produce clinical supplies and commercial supplies of batoclimab. 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 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 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 or any future product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, due to the COVID-19 pandemic or otherwise, which would impair our ability to generate revenue from the sale of such product candidate. In addition, batoclimab is a biologic and requires processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. 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 or any future product candidate must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product 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 candidate or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market batoclimab or any future product candidate, if approved. Further, our reliance on third-party manufacturers entails risks, including:

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

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

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

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 are also required by the competent authorities of the member states of the European Economic Area and other comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for 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 healthcare 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 or any future product candidate or jeopardize our ability to commence sales and generate revenue.

Risks Related to Our Intellectual Property

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

In the U.S., the Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. New biologics, such as batoclimab, 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 candidate, batoclimab, as a biological product, should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

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

If the patent applications we hold or have in-licensed with respect to our development programs and our product candidate fail to issue, if their breadth or strength of protection is threatened or if they fail to provide meaningful exclusivity for our product candidate, batoclimab, it could dissuade companies from collaborating with us to develop our product candidate and threaten our ability to commercialize future drugs. Any such outcome could have an adverse effect on our business. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such 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 partes review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

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

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

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

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

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

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

Filing, prosecuting and defending patents on batoclimab 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 candidate 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 candidate are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. The patent family directed to the composition of matter of batoclimab has a natural projected expiration date in 2035 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 or other product candidates that we may identify, our business may be harmed.

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

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

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

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

We do not have rights to develop, manufacture, use or commercialize batoclimab 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 candidate.

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

Our commercial success depends in part on our ability to operate while avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the 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 candidate or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

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

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

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, importing, marketing or otherwise commercializing our product candidate or any future product candidates. Any uncertainties resulting from the initiation and continuation of any litigation could have 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 candidate or any future product candidates, resulting in either an injunction prohibiting our sales or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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

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

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

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

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives or could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the 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 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 the patents we own are owned by our wholly owned subsidiary, ISG, we may not be in a position to obtain a permanent injunction against a third party that is found to infringe our patents.

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

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

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

Changes in 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 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 candidate, 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 candidate or any future product candidates, if approved.

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

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

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

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or affect financial or other obligations under the relevant agreement, 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 our product candidate batoclimab, 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 candidate and not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we, 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 candidate or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, 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.

In August 2021, we entered into a share purchase agreement with RSL pursuant to which we issued and sold 17,021,276 shares of our common stock to RSL at a per share price of $11.75. As of February 1, 2022, RSL beneficially owned approximately 63.1% 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's interests may not always coincide with our corporate interests or the interests of other stockholders and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. In September 2021, RSL completed its business combination with Montes Archimedes Acquisition Corp., a special purpose acquisition corporation, and became a publicly-traded corporation. There has been and 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 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 or any future product candidate and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that BLA or similar application, as the case may be;
- failure to successfully develop and commercialize batoclimab 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 or any future product candidate or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;

- significant lawsuits, including patent or stockholder litigation and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of shares of our common stock;
- sales of a substantial number of shares of shares of our common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell shares;
- sales or purchases of shares of our common stock by our directors or officers subject to Section 16 of the Exchange Act;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands or the public fact of an investigation by a government agency, whether meritorious or not;
- the size of our public float;
- trading liquidity of shares of our common stock;
- investors' general perception of our company and our business;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. For example, we currently have one such putative class-action complaint brought against us. We could incur substantial costs defending this or similar lawsuits, as well as diversion of the time and attention of our management, any or all of which could seriously harm our business. Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, political, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance. The market price of shares of our common stock may decline, and you may lose some or all of your investment.

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

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, in February 2021, a securities class action complaint was filed against us, certain of our officers and a board member of HSAC. The case is still pending. This or any future securities litigation could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities. See Part 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. Our management and other personnel will need to continue to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

Because our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates was less than $560.0 million measured on the last business day of our second fiscal quarter, we qualify again as a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("Section 404"), presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

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

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm as a large-accelerated filer. However, we have qualified again as a smaller reporting company as of the last business day of our second fiscal quarter and expect to qualify as a non-accelerated filer at the end of our fiscal year. As a result, we are currently evaluating the effect of not being required to comply with the auditor attestation requirement for the fiscal year ended March 31, 2022 as a smaller reporting company and non-accelerated filer. To maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and refine and revise a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm, if an auditor attestation is applicable, will be able to conclude that our internal control over financial reporting is effective as required by Section 404.

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

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

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

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

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

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

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

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

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the U.K. and Switzerland), the U.S., Bermuda and other jurisdictions as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of our operations and our financial condition.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including 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.

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.

None.

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 William Macias, dated as of October 25, 2021, as amended.				
10.2††*	Master Services Agreement, between Samsung Biologics Co., Ltd. and Immunovant Sciences GmbH, dated April 30, 2021.				
10.3††*	Product Service Agreement, between Samsung Biologics Co., Ltd. and Immunovant Sciences GmbH, dated November 17, 2021.				
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 Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101)				

* 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.
†† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type that Immunovant, Inc. treats as private or confidential.
# In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this 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: February 4, 2022

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

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

EMPLOYMENT AGREEMENT

This Employment Agreement (this "***Agreement***") is entered into as of October 25, 2021, as amended, by and between William Macias, M.D. Ph.D. (the "***Executive***") and IMVT Corporation (the "***Company***").

RECITALS

A. The Company and Executive previously entered into a Master Consulting Agreement, dated as of April 13, 2021 (the "***Consulting Agreement***").

B. 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.

C. 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.

D. This Agreement supersedes the Consulting Agreement and 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 shall continue to hold the position of Chief Medical Officer of the Company and of Immunovant, Inc (the "***Parent***"). In this position, the Executive will have the duties and authorities normally associated with a Chief Medical Officer of a company. The Executive will report to the Chief Executive Officer of the Company and Parent (the "***CEO***"). The Executive shall 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. Until the Company returns to the office in light of the COVID-19 pandemic, the Executive's principal place of employment shall initially be from home, with an expectation that a meaningful amount of time will also be spent in the Company's New York City office once re-opened. The Executive understands that the Executive's duties also will require periodic business travel to locations other than those set forth above.

1.3 Start Date. The Executive's employment with the Company shall commence on or about October 25, 2021 (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 shall not constitute a breach of this Section.

2. COMPENSATION AND BENEFITS.

2.1 Salary. The Company shall pay the Executive a base salary at the annualized rate of $500,000 (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 shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary shall be subject to periodic review and may be adjusted from time to time in 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 percent (40%) 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. In order 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, shall be prorated for the initial year of employment (on the basis of a three hundred sixty-five (365)-day year) and shall 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.

2.4 Equity Incentive Grant (Options). Subject to the terms of the 2019 Equity Incentive Plan of Parent (the "***Plan***") and approval of the grant by the Parent Board, the Executive will be granted an award of an option to purchase 167,325 common shares of the Parent (the "***Option Award***"). The Option Award will be granted on or about the Friday following the week in which the Executive's employment commences (in the event such Friday is not a day on which Parent's stock trades, the Option Award may be granted on the next trading day following such Friday), 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 2.4 and Sections 5.2 and 5.3 below.

The Option Award will vest over a period of four 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.

2.5 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 112,108 shares of common shares of the Parent (the "***RSU Grant***") pursuant to the Plan. The RSU Grant will be made on or about the Friday following the week in which the Executive's employment commences (in the event such Friday is not a day on which Parent's stock trades, the RSU Grant may be granted on the next trading day following such Friday) and will fully vest on January 1, 2023 and settled in shares of the Parent's common stock as soon as practicable thereafter and no later than 5 business days from such vesting date, provided the 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 2.5 and Section 5.3 below) (the "***RSU Equity Incentive Agreement***") between you and the Parent. In the event of a conflict between the terms of this offer letter 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 shall 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.

2.6 Benefits and Insurance. The Executive shall, 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 shall be subject to the terms and conditions of the applicable plan documents, which may be amended or terminated at any time. The Executive shall 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 shall determine, subject to the business needs of the Company.

2.7 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 shall 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 shall 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 shall 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 timely furnishes to the Company an executed waiver and release of claims in the form substantially similar to that attached hereto as Exhibit B, with any changes that the Company determines are necessary to comply with applicable law (the ***"Release"***), and (iii) the Executive does not revoke and allows the Release to become effective in accordance with its terms, then the Executive shall receive an aggregate amount equal to: (a) nine months of the Executive's then current Base Salary; and (b) nine 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 shall commence within the next payroll cycle following the Release Effective Date and will be subject to required withholding. The date that the Release can no longer be revoked is referred to as the "Release Effective Date."

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 timely furnishes to the Company a Release, and (iii) the Executive does not revoke and allows the Release to become effective in accordance with its terms, then the Executive shall 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 shall immediately vest in full. Such payments shall commence within the next payroll cycle following the Release Effective Date and will be subject to required withholding.

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

(a) ***"Cause"*** shall 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"*** shall 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 shall 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 shall 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 shall 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 shall be deemed to have resigned from any and all positions with the Company.

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) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. A termination of employment shall 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 shall 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 shall 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 shall be made in the later taxable year. The Company makes no representation or warranty and shall 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 shall 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 shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall 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 shall 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 shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, and (iii) such payments shall 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 (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, shall 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 shall be one arbitrator who shall 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 shall 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 shall 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 shall then select an arbitrator in accordance with the Rules. The place of arbitration shall 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 shall 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 shall: (a) have authority to compel discovery which shall 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 shall pay all administrative fees of JAMS in excess of $435 (a typical filing fee in court) but the Company and the Executive shall split any arbitrator's fees and expenses. Each party shall bear its or his/her own costs and expenses (including attorney's fees) in any such arbitration; provided that the arbitrator shall 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 shall 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, shall 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 that the Executive signed at the inception of employment 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 with regard to 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 shall 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 shall 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 shall 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 of New York as applied to contracts made and to be performed entirely within New York.

(f) Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall 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/ William Macias
William Macias

Acknowledged and Agreed:

IMMUNOVANT, INC.

_/s/ Pete Salzmann
Name: Pete Salzmann
Title: Chief Executive Officer

EXHIBIT A:

PERMITTED ACTIVITIES

1. Services on Immunetrics Inc. Board, a modeling company, that will equate to a few hours per year

EXHIBIT B: RELEASE FORM

William Macias [ADDRESS]
[CITY], [STATE] [ZIP]

RE: Separation Agreement and General Release

Dear William,

Your employment with IMVT Corporation will be terminated effective [DATE OF TERMINATION]. This Separation Agreement and General Release (this "Agreement") sets forth the terms and conditions under which IMVT Corporation is offering you additional pay and benefits in exchange for you making and honoring certain commitments, including agreeing not to pursue legal action against the Company as described in Sections 7 and 8.

PLEASE NOTE: THIS DOCUMENT HAS IMPORTANT LEGAL CONSEQUENCES TO YOU. YOU SHOULD CONSULT AN ATTORNEY OF YOUR CHOICE, AT YOUR EXPENSE, PRIOR TO EXECUTING IT.

1. Parties To This Agreement

This letter is a proposed agreement that IMVT Corporation is offering to you. In this document, references to **William Macias** refer to "you" and **IMVT CORPORATION** is referred to as the "Company." Together, you and the Company are referred to as the "Parties."

2. What You Will Receive Regardless of Whether You Enter Into This Agreement

Whether or not you enter into this Agreement, you will receive the following:

a. Your regular base pay (less applicable withholding) through [SEPARATION DATE], provided you remain employed at the Company through that date. You will be receiving your regular pay in the same manner that you normally receive your regular pay, such as direct deposit, consistent with established bi-monthly pay cycles as long as you remain employed; and

b. If you are currently enrolled and participating in the Company's medical/dental/vision benefits, your coverage will extend until the end of [SEPARATION MONTH] (the month in which your separation takes place). Thereafter, you will be able to continue as a member of the Company's Group Health Plans at your expense in accordance with the terms of those plans, as well as COBRA, for the legally required benefit continuation period. You will be receiving a separate letter explaining your rights and responsibilities with regard to electing your COBRA benefits; and

c. Accrued vested benefits under any applicable retirement plans offered by the Company. You will receive information directly from Fidelity and you may direct questions to them at 1-800-603- 4015; and

d. Reimbursement for all approved business-related expenses incurred up to your last day of employment consistent with established travel and expense policies; and

e. As long as you direct reference inquiries from potential employers to **[Contact Name], IMVT Corporation, [320 West 37th Street, New York, NY 10018]** , unless otherwise authorized in writing, the Company will limit information it discloses in response to reference requests to: (1) your dates of employment; and (2) your last position held. Of course, the Company reserves the

right to respond truthfully to any compulsory process of law (such as a subpoena) or as otherwise required by law.

3. What You Will Receive Only If You Enter Into This Agreement.

As long as you timely sign, date and return this Agreement **(BUT IN NO CASE LATER THAN [LAST DATE TO ACCEPT])** , and you comply with the Agreement's requirements, then in addition to those payments and benefits described in Section 2 above:

- You will receive salary continuation benefit payments at your regular Base Salary though [SEVERANCE END DATE] subject to applicable withholdings, unless you choose to resign before [SEPARATION DATE] ("Separation Date");

- If you are currently enrolled and participating in the Company's medical/dental/vision benefits, your coverage will extend until the end of the [SEVERANCE END DATE]. Thereafter, you will be able to continue as a member of the Company's Group Health Plans at your expense in accordance with the terms of those plans[, as well as COBRA, for the legally required benefit continuation period]. You will be receiving a separate letter explaining your rights and responsibilities with regard to electing your COBRA benefits. You will receive COBRA benefit payments through [SEVERANCE END DATE]; and

- Change in Control payments/benefits, if applicable, in accordance with your signed [ ], 2021 Employment Agreement with the Company (the "Employment Agreement") (a copy of which is attached).

Within thirty (30) days after you return the signed and dated Agreement, you will begin receiving the salary continuation benefit, provided you did not resign prior to your anticipated Separation Date.

4. W-2s.

The Company will issue an IRS Form W-2 to you in connection with payments described in Section 3.

5. How To Enter Into This Agreement.

In order to enter into this Agreement, you must take the following steps:

a. You must sign and date the Agreement. Signing and dating the Agreement is how you "Execute" the Agreement.

b. You must return the Executed Agreement to me before [LAST DATE TO ACCEPT], (unless such period is extended in writing by the Company). If I do not receive the signed and dated Agreement by that date, the offer will be deemed withdrawn, this Agreement will not take effect and you will not receive the pay and benefits described in Section 3.

c. You must comply with the terms and conditions of this Agreement.

6. Your Acknowledgments.

By entering into this Agreement, you are agreeing:

- The pay and benefits in Section 3 are more than any money or benefits that you are otherwise promised or entitled to receive under any policy, plan, handbook or practice of the Company or any prior offer letter, agreement or understanding between the Company and you.

- After your employment ends, except as provided for in this Agreement (and without impacting any accrued vested benefits under any applicable tax-qualified retirement or other benefit plans of the Company or applicable equity compensation plans), you will no longer participate or accrue service credit of any kind in any employee benefits plan of the Company or any of its affiliates; provided that the Indemnification Agreement that you signed at the inception of your employment survives as set forth therein.

- Your obligations under the Employment Agreement and the Employee Non-Disclosure, Inventions Assignment and Restrictive Covenant Agreement ("NDIA") executed between you and the Company on [ ], 2021 (also attached), shall remain in full force and effect and you acknowledge and re-affirm those obligations. Those provisions in the Employment Agreement that are intended to survive the termination of your employment shall survive (i.e., arbitration, 409A).

- As long as the Company satisfies its obligation under the Agreement, it will not owe you anything except for the items set forth in Section 2, which you will receive regardless of whether you Execute this Agreement.

- During your employment with the Company, you did not violate any federal, state, or local law, statute, or regulation while acting within the scope of your employment with the Company (collectively, "Violations").

- You are not aware of any Violation(s) committed by a Company employee, vendor, or customer acting within the scope of his/her/its employment or business with the Company that have not been previously reported to the Company; or (ii) to the extent you are aware of any such unreported Violation(s), you will, prior to your execution of this Agreement, immediately report such Violation(s) to the Company.

7. YOU ARE RELEASING AND WAIVING CLAIMS

While it is very important that you read this entire Agreement carefully, it is especially important that you read this Section carefully, because it lists important rights you are giving up if you decide to enter into this Agreement.

What Are You Giving Up? It is the Company's position that you have no legitimate basis for bringing a legal action against it. You may agree or believe otherwise or simply not know. However, if you Execute this Agreement, you will, except for certain exceptions described in Section 11, give up your ability to bring a legal action against the Company and others, including, but not limited to its affiliates. More specifically, by Executing this Agreement, you will give up any right you may have to bring various types of "Claims," which means possible lawsuits, claims, demands and causes of action of any kind (based on any legal or equitable theory, whether contractual, common-law, statutory, federal, state, local or otherwise), whether known or unknown, by reason of any act or omission up to and including the date on which you Execute this Agreement. You are also giving up potential Claims arising under any contract or implied contract, including but not limited to the Employment Agreement or any handbook, tort law or public policy having any bearing on your

employment or the termination of your employment, such as Claims for wrongful discharge, discrimination, hostile work environment, breach of contract, tortious interference, harassment, bullying, infliction of emotional distress, defamation, back pay, vacation pay, sick pay, wage, commission or bonus payment, equity grants, stock options, restricted stock option payments, payments under any bonus or incentive plan, attorneys' fees, costs and future wage loss. This Agreement includes a release of your right to assert a Claim of discrimination on the basis of age, sex, race, religion, national origin, marital status, sexual orientation, gender identity, gender expression, ancestry, parental status, handicap, disability, military status, veteran status, harassment, retaliation or attainment of benefit plan rights. However, as described in Section 11, this Agreement does not and cannot prevent you from asserting your right to bring a claim against the Company and Releasees, as defined below, before the Equal Employment Opportunity Commission or other agencies enforcing non-discrimination laws or the National Labor Relations Board.

Whose Possible Claims Are You Giving Up? You are waiving Claims that you may otherwise be able to bring. You are not only agreeing that you will not personally bring these Claims in the future, but that no one else will bring them in your place, such as your heirs and executors, and your dependents, legal representatives and assigns. Together, you and these groups of individuals are referred to in the Agreement as"Releasors."

Who Are You Releasing From Possible Claims? You are not only waiving Claims that you and the Releasors may otherwise be able to bring against the Company, but also Claims that could be brought against "Releasees," which means the Company and all of their past, present and future:

- shareholders
- officers, directors, employees, attorneys and agents
- subsidiaries, divisions and affiliated and related entities
- employee benefit and pension plans or funds
- successors and assigns
- trustees, fiduciaries and administrators

Possible Claims You May Not Know. It is possible that you may have a Claim that you do not know exists. By entering into this Agreement, you are giving up all Claims that you ever had including Claims arising out of your employment or the termination of your employment. Even if Claims exist that you do not know about, you are giving them up.

What Types of Claims Are You Giving Up? In exchange for the pay and benefits in Section 3, you (on behalf of yourself and the Releasors) forever release and discharge the Company and all of the Releasees from any and all Claims including Claims arising under the following laws (including amendments to these laws):

Federal Laws, such as:

- Title VII of the Civil Rights of 1964;
- Sections 1981 through 1988 of Title 42 of the United States Code;
- The Civil Rights Act of 1991;
- The Equal Pay Act;
- The Americans with Disabilities Act;
- The Rehabilitation Act;
- The Employee Retirement Income Security Act;

- The Worker Adjustment and Retraining Notification Act;
- The National Labor Relations Act;
- The Fair Credit Reporting Act;
- The Occupational Safety and Health Act;
- The Uniformed Services Employment and Reemployment Act;
- The Employee Polygraph Protection Act;
- The Immigration Reform Control Act;
- The Family and Medical Leave Act;
- The Genetic Information Nondiscrimination Act;
- The Federal False Claims Act;
- The Patient Protection and Affordable Care Act;
- The Consolidated Omnibus Budget Reconciliation Act; and
- The Lilly Ledbetter Fair Pay Act.

State and Municipal Laws, such as:

- The New York State Human Rights Law; the New York State Executive Law; the New York State Civil Rights Law; the New York State Whistleblower Law; the New York State Legal Recreational Activities Law; the retaliation provisions of the New York State Workers' Compensation Law; the New York Labor Law; the New York State Worker Adjustment and Retraining Notification Act; the New York State False Claims Act; New York State Wage and Hour Laws; the New York State Equal Pay Law; the New York State Rights of Persons with Disabilities Law; the New York State Nondiscrimination Against Genetic Disorders Law; the New York State Smokers' Rights Law; the New York AIDS Testing Confidentiality Act; the New York Genetic Testing Confidentiality Law; the New York Discrimination by Employment Agencies Law; the New York Bone Marrow Leave Law; the New York Adoptive Parents Child Care Leave Law; the New York City Human Rights Law; the New York City Administrative Code; the New York City Paid Sick Leave Law; and the New York City Charter; and

- [IF EMPLOYEE WAS EVER EMPLOYED IN NJ] The New Jersey Law Against Discrimination; the New Jersey Discrimination in Wages Law; the New Jersey Security and Financial Empowerment Act; the New Jersey Temporary Disability Benefits and Family Leave Insurance Law; the New Jersey Domestic Partnership Act; the New Jersey Conscientious Employee Protection Act; the New Jersey Family Leave Act; the New Jersey Wage Payment Act; the New Jersey Equal Pay Law; the New Jersey Occupational Safety and Health Law; the New Jersey False Claims Act; the New Jersey Smokers' Rights Law; the New Jersey Genetic Privacy Act; the New Jersey Fair Credit Reporting Act; the New Jersey Emergency Responder Leave Law; the New Jersey Millville Dallas Airmotive Plant Job Loss Notification Act (a/k/a the New Jersey WARN Act); and the retaliation provisions of the New Jersey Workers' Compensation Law; and

- [IF EMPLOYEE WAS EVER EMPLOYED IN CA] The California Fair Employment and Housing Act, as amended; the California Constitution, as amended; the California Labor Code, as amended; and all rights under Section 1542 of the California Civil Code, which states, "A GENERAL RELEASE DOES

NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE
DEBTOR." You acknowledge that you may later discover claims or facts in addition to or different from those which you now know or believe to exist with regards to the subject matter of this Agreement, and which, if known or suspected at the time of executing this Agreement, may have materially affected its terms. Nevertheless, you waive any and all Claims that might arise as a result of such different or additional claims or facts; and

- [IF EMPLOYEE WAS EVER EMPLOYED IN NC] The North Carolina Employment Practices Act; the Retaliatory Employment Discrimination Act; the Persons with Disabilities Protection, Discrimination Against Persons with Sickle Cell Trait; Discrimination Based Upon Genetic Testing and Information; Discrimination Based Upon Use of Lawful Products; Discrimination Based Upon AIDS or HIV Status; Hazardous Chemicals Right to Know Act; Jury Service Discrimination; Military Service Discrimination; and all of their respective implementing regulations; and

- [IF EMPLOYEE WAS EVER EMPLOYED IN MA] The Massachusetts Fair Employment Practices Law; the Massachusetts Civil Rights Act; the Massachusetts Equal Rights Act; the Minimum Fair Wage Act; the Massachusetts Plant Closing Law; the Massachusetts Equal Pay Act; the Massachusetts Parental Leave Act; the Massachusetts Sexual Harassment Statute; and all of their respective implementing regulations. By signing this letter agreement, you are acknowledging that this waiver includes any future claims against the Company under Mass. Gen. Laws ch. 149, § 148 - the Massachusetts Wage Act. These claims include, but are not limited to, failure to pay earned wages, failure to pay overtime, failure to pay earned commissions, failure to timely pay wages, failure to pay accrued vacation or holiday pay, failure to furnish appropriate pay stubs, claims for improper wage deductions, and claims for failing to provide proper check-cashing facilities.

You Are Giving Up Potential Remedies and Relief. You are waiving any relief that may be available to you (such as money damages, equity grants, benefits, attorneys' fees, and equitable relief such as reinstatement) under any of the waived Claims, except as provided in Section 11.

This Release Is Extremely Broad. This release is meant to be as broad as legally permissible and applies to both employment-related and non-employment-related Claims up to the time that you execute this Agreement. This release includes a waiver of jury trials and non-jury trials. This Agreement does not release or waive Claims or rights that, as a matter of law, cannot be waived, which include, but are not necessarily limited to, the exceptions to your release of claims or covenant not to sue referenced in Section 11.

8. YOU ARE AGREEING NOT TO SUE

Except as provided in Section 11, you agree not to sue or otherwise bring any legal action against the Company or any of the Releasees ever for any Claim released in Section 6 arising before you Execute this Agreement. You are not only waiving any right you may have to proceed individually, but also as a member of a class or collective action. You waive any and all rights you may have had to receive notice of any class or collective action against Releases for claims arising before you Execute this

Agreement. In the event that you receive notice of a class or collective action against Releasees for claims arising before you Execute this Agreement, you must "opt out" of and may not "opt in" to such action. You are also giving up any right you may have to recover any relief, including money damages, from the Releasees as a member of a class or collective action.

9. Representations Under The FMLA (leave law) And FLSA (wage and hour law).

You represent that you are not aware of any facts that might justify a Claim by you against the Company for any violation of the Family and Medical Leave Act ("FMLA"). You also represent that you have received all wages for all work you performed and any commissions, bonuses, stock options, restricted stock option payments, overtime compensation and FMLA leave to which you may have been entitled, and that you are not aware of any facts constituting a violation by the Company or Releasees of any violation of the Fair Labor Standards Act or any other federal, state or municipal laws.

10. You Have Not Already Filed An Action.

You represent that you have not sued or otherwise filed any actions (or participated in any actions) of any kind against the Company or Releasees in any court or before any administrative or investigative body or agency. The Company is relying on this assurance in entering into this Agreement.

11. Exceptions To Your Release Of Claims And Covenant Not To Sue

In Sections 7 and 8, you are releasing Claims and agreeing not to sue, but there are exceptions to those commitments. Specifically, nothing in this Agreement prevents you from bringing a legal action or otherwise taking steps to:

- Enforce the terms of this Agreement; or
- Challenge the validity of this Agreement; or
- Make any disclosure of information required by law; or
- Provide information to, testify before or otherwise assist in any investigation or proceeding brought by, any regulatory or law enforcement agency or legislative body, any self-regulatory organization, or the Company; or
- Provide truthful testimony in any forum; or
- Cooperate fully and provide information as requested in any investigation by a governmental agency or commission; or
- File a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("Government Agencies"); or
- File a lawsuit or other action to pursue Claims that arise after you Execute this Agreement; or
- Rights under the Indemnification Agreement and any similar rights under the Company or Parent's organizational documents, applicable law and insurance coverage; or
- Vested rights to equity of the Parent.

For purposes of clarity, this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without noticetothe Company. This Agreement does not limit your right to receive an award for information provided to any Government Agencies.

12. Your Continuing Obligations.

You acknowledge and re-affirm your continuing obligations pursuant to the Employment Agreement and the NDIA executed between you and the Company, including your confidentiality obligations under Section 2 of the NDIA and any restrictions under Sections 4 and 5 of the NDIA.

Pursuant to the Defend Trade Secrets Act of 2016, you acknowledge and understand that you will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of the trade secrets of the Company or any of its affiliates that is made by you (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law, or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

13. Return Of Property.

As of your Separation Date, you agree that you have returned to the Company all property belonging to the Company including, but not limited to, electronic devices, equipment, access cards, and paper and electronic documents obtained in the course of your employment.

14. Prior Disclosures.

You acknowledge that, prior to the termination of your employment with the Company, you disclosed to the Company, in accordance with applicable policies and procedures, any and all information relevant to any investigation of the Company's business practices conducted by any governmental agency or to any existing, threatened or anticipated litigation involving the Company, whether administrative, civil or criminal in nature, and that you are otherwise unaware of any wrongdoing committed by any current or former employee of the Company that has not been disclosed. Nothing in this Agreement shall prohibit or restrict you or the Company from (1) making any disclosure of information required by law; (2) providing information to, or testifying or otherwise assisting in any investigation or proceeding brought by any federal or state regulatory or law enforcement agency or legislative body, any self-regulatory organization, or with respect to any internal investigation by the Company or its affiliates; or (3) testifying, participating in orotherwise assisting ina proceeding relating to an alleged violation of the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, any federal, state or municipal law relating to fraud, or any rule or regulation of any self-regulatory organization.

15. Non-Disparagement

The parties agree that neither will, through any medium including, but not limited to, the press, Internet or any other form of communication, disparage, defame, or otherwise damage or assail the reputation, integrity or professionalism of the other party (including the Releasees). Nothing in this Section 15 is intended to restrict or impede the parties participation in proceedings or investigations brought by or before the EEOC, NLRB, or other federal, state or local government agencies, or

otherwise exercising protected rights to the extent that such rights cannot be waived by agreement, including Section 7 rights under the National Labor Relations Act. Notwithstanding the foregoing, the Company's obligations in this Section 15 are limited to making a reasonable instruction to the Board and management not to disparage you and nothing in this Section 15 shall inhibit the Company's ability to operate its business and discuss business matters as necessary.

16. The Company's Remedies For Breach.

If you materially breach any section of this Agreement, including without limitation, Section 7, 8, or 15 or otherwise seek to bring a Claim given up under this Agreement, the Company will be entitled to all relief legally available to it including equitable relief such as injunctions, and the Company will not be required to post a bond.

You further acknowledge that if you materially breach of any section of this Agreement, you will automatically forfeit your right to receive any of the benefits enumerated in Section 3 of this agreement.

You further acknowledge and understand that if the Company should discover any such Violation(s) as described in Section 6 after your execution of this Agreement and/or your separation from employment with the Company, it will be considered a material breach of this Agreement, and all of the Company's obligations to you hereunder will become immediately null and void.

17. Governing Law.

This Agreement is governed by New York law, without regard to conflicts of laws principles.

18. Successors And Assigns.

This Agreement is binding on the Parties and their heirs, executors, successors and assigns.

19. Severability And Construction.

If a court with jurisdiction to consider this Agreement determines that any provision is illegal, void or unenforceable, that provision will be invalid. However, the rest of the Agreement will remain in full force and effect. A court with jurisdiction to consider this Agreement may modify invalid provisions if necessary to achieve the intent of the Parties.

20. No Admission.

By entering into this Agreement, neither you nor the Company admits wrongdoing of any kind.

21. Do Not Rely On Verbal Statements.

- This Agreement sets forth the complete understanding between the Parties.
- This Agreement may not be changed orally.
- This Agreement constitutes and contains the complete understanding of the Parties with regard to the end of your employment, and supersedes and replaces all prior oral and written agreements and promises between the Parties, except that, as set forth in Section 6, your restrictive covenant obligations remain in full force and effect, and, as set forth

in Section 6, the equity agreements and Indemnification Agreement remain in full force and effect.

- Neither the Company nor any representative (nor any representative of any other company affiliated with the Company), has made any promises to you other than as written in this Agreement. All future promises and agreements must be in writing and signed by both Parties.

22. Your Opportunity To Review.

a. **Review Period.** You have **twenty-one (21) calendar days** from the day you receive this Agreement to consider the terms of this Agreement, sign it and return it to **[Contact Name], IMVT Corporation, [320 West 37th Street, New York, NY 10018].** Your opportunity to accept the terms of this Agreement will expire at the conclusion of the twenty-one (21) calendar day period if you do not accept those terms before time expires. That means that your opportunity to accept the terms of this Agreement will expire on [LAST DATE TO ACCEPT]. You may sign the Agreement in fewer than twenty-one (21) calendar days, if you wish to do so. If you elect to do so, you acknowledge that you have done so voluntarily. **Your signature below indicates that you are entering into this Agreement freely, knowingly and voluntarily, with full understanding of its terms.**

b. **Talk To A Lawyer.** During the review period, and before executing this Agreement, the Company advises you to consult with an attorney, at your own expense, regarding the terms of this Agreement.

23. We Want To Make Absolutely Certain That You Understand This Agreement.

You acknowledge and agree that:

- **You have carefully read this Agreement in its entirety;**
- **You have had an opportunity to consider the terms of this Agreement;**
- **You understand that the Company urges you to consult with an attorney of your choosing, at your expense, regarding this Agreement;**
- **You have the opportunity to discuss this Agreement with a lawyer of your choosing, and agree that you had a reasonable opportunity to do so, and he or she has answered to your satisfaction any questions you asked with regard to the meaning and significance of any of the provisions of this Agreement;**
- **You fully understand the significance of all of the terms and conditions of this Agreement; and**
- **You are Executing this Agreement voluntarily and of your own free will and agree to all the terms and conditions contained in this Agreement.**

_____	_____
IMVT CORPORATION	WILLIAM MACIAS
By:	
Dated:	Dated:

CERTAIN PORTIONS OF THIS EXHIBIT (INDICATED BY ***) HAVE BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K BECAUSE THEY ARE BOTH NOT MATERIAL AND ARE THE TYPE THAT THE COMPANY TREATS AS PRIVATE AND CONFIDENTIAL.

MASTER SERVICES AGREEMENT

between

SAMSUNG BIOLOGICS CO., LTD.

and

IMMUNOVANT SCIENCES GMBH

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MASTER SERVICES AGREEMENT

This **Master Services Agreement** (this "***MSA***") is made and entered into as of the date of last signature below (the " ***Effective Date***") by and between **Immunovant Sciences GmbH**, a Swiss limited company with offices at Viaduktstrasse 8, 4051 Basel, Switzerland (" ***Client***"), and **Samsung Biologics Co., Ltd.**, a Korean corporation having its principal place of business at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea (" ***SBL***"). Client and SBL are sometimes referred to herein individually as a "***Party***" and collectively as the "***Parties***".

Whereas, Client and SBL wish to enter into a business relationship whereby SBL will provide Client with certain services related to biologics development and/or manufacturing;

Now, Therefore, in consideration of the mutual promises, covenants and agreements hereinafter set forth and for other valuable consideration, the Parties agree as follows:

1. DEFINITIONS

Capitalized terms as used in this MSA, whether in the singular or plural, shall have the respective meanings set forth below or as otherwise designated in this MSA.

1.1 "***Acceptance Procedure***" means the review of the Batch Related Documents and any reasonably necessary test(s) of a Batch of Product which are performed to verify that the Product delivered meets the Specifications and complies with Regulatory Authority requirements, which are conducted by Client before or after SBL's release of a Batch of Product in accordance with the applicable PSA and QAG.

1.2 "***Affected Party***" means the Party affected by Force Majeure under Section 16.3.

1.3 "***Affiliate***" means any corporation, company, partnership or other entity which directly or indirectly, controls, is controlled by or is under common control with either Party hereto. A corporation or other entity shall be regarded as controlling another corporation or other entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other entity, or if possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.

1.4 "***Annual Service Fees***" means the total Service Fees paid or payable by Client to SBL in a given calendar year (excluding costs of Raw Materials, SBL handling fees, and other expense or cost reimbursements) pursuant to a particular Product Service Agreement.

1.5 "***Applicable Laws***" means any and all laws, rules, or regulations of any jurisdiction which are applicable to the Parties in carrying out activities described in this MSA or any PSAs that may be in effect from time to time.

1.6 "***Assignment***", "***Assigning***", or to "***Assign***" means a merger, change of control, sale of stock, inheritance of stock, transfer of all or substantially all of the assets, or transfer of all or substantially all rights to any Product.

1.7 "***Background IP***" means any Intellectual Property related to a Product and/or its use, or the Manufacture of such Product, in each case, which is owned and/or controlled by a Party prior to the Effective Date.

1.8 "***Batch***" means the quantity of Product Manufactured by SBL which results from a single run of the applicable Manufacturing Process.

1.9 "***Batch Failure***" means that a Batch is Non-Conforming Product as reasonably determined by the Core Team during Manufacture of a Batch and prior to SBL's batch release.

1.10 "***Batch Record***", if not defined in the applicable QAG, means the document, proposed by SBL and approved by Client, which defines the manufacturing methods, test methods, and other procedures, direction, and controls associated with the manufacture and testing of Product.

1.11 "***Batch Related Documents***" means Manufacturing Documentation in support of SBL's release of a Product.

1.12 "***Cell Line***" means, in respect of a given Product, the cell bank vials supplied or otherwise made available to SBL by Client to perform the Services.

1.13 "***Certificate of Analysis***", means an approved document that certifies test results against product specifications for a given Batch of Drug Substance or Drug Product with listing of all applicable acceptance criteria and test results.

1.14 "***Certificate of Compliance***" means a certificate for a given Batch of Drug Substance or Drug Product prepared by Quality Assurance that states the Batch is acceptable for release based on SBL's batch disposition procedure and has been manufactured in compliance with cGMP, SBL's procedures and required Specifications.

1.15 "***Change***" means any modification, alteration, adjustment, or correction to the Manufacturing Process, Services, or Specifications.

1.16 "***Client***" is defined in the preamble.

1.17 "***Client Invention***" means any Invention that is conceived and first reduced to practice by either Party and does not constitute an SBL Invention.

1.18 "***Client Materials***" means Client reagents and other materials supplied by Client or its third-party supplier to be used in the Service hereunder. In the case of a Drug Product PSA, Client Materials may also include Drug Substance and/or other active pharmaceutical ingredients, which may or may not have been Manufactured by SBL.

1.19 "***Client Technology***" means know-how, technology, research and other information of Client including and relating to the Services, Manufacturing Process, analytical methods, quality control analysis, specifications, transportation and storage requirements provided by Client to SBL in connection with this MSA and applicable PSA.

1.20 "***Clinical Exit***" means a final decision by Client not to proceed with, as applicable, further clinical development and/or submission of any BLAs or other equivalent applications for Regulatory Approval for, the Product for any indication anywhere in the world due to the Product's failure or inability to obtain Regulatory Approval based on Client's reasonable determination [* * *].

1.21 "***Clinical Product***" means a Drug Substance or Drug Product which is Manufactured by SBL pursuant to a PSA and which is to be used by Client in a research study or studies that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1.22 "***Commercial Product***" means a Drug Substance or Drug Product which is Manufactured by SBL which is intended for commercial sale and use by humans and, for Drug Substance, is those manufactured after SBL obtains the Regulatory Approval certifying that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP; provided, however, for Drug Substance, "***Commercial Product***" shall also include PAI Batches and Process Validation Batches intended for commercial sale and use by humans after applicable Regulatory Approval that are manufactured prior to SBL obtaining the Regulatory Approval for the Facility certifying that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP.

1.23 "***Commercially Reasonable Efforts***" means with respect to an activity to be carried out by a Party pursuant to this MSA, the carrying out of such activity in a diligent manner, and using efforts and resources comparable to the efforts and resources commonly used in the contract manufacturing of biologics (in the case of SBL) or in the biopharmaceutical industry (in the case of Client) by companies with resources and expertise similar to those of such Party. "***Commercially Reasonable Efforts***" requires prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress with respect to such task or activity but does not require the taking of actions (a) [* * *], (b) [* * *], or (c) [* * *].

1.24 "***Confidential Information***" means any and all scientific, business, financial, contractual, marketing and technical information of or about a party or a Product which has been or may be disclosed, or to which access is provided, by such party ("***Disclosing Party***") or any of its representatives to the other Party ("***Receiving Party***") or any of its representatives, which (a) if in writing, is marked "confidential", "proprietary", or other similar marking at the time of disclosure, or (b) if provided orally or visually, is identified as confidential at the time of disclosure, or (c) Receiving Party knows or has reason to know is confidential, trade secret, or proprietary information of the Disclosing Party at the time of disclosure because of legends or other markings, the circumstances of disclosure, or the nature of the information itself. For clarity, the existence and terms of this MSA shall be deemed to be the Confidential Information of both Parties.

1.25 "***Core Team***" means a committee composed of no less than [* * *] and no more than [* * *] representatives from each of SBL and Client to oversee, review, and coordinate the day-to-day performance of the Services and/or Manufacture with the goal of ensuring effective communication between the Parties.

1.26 "***Critical Raw Material***" means [* * *] and any other Raw Materials with [* * *], as reasonably agreed between the Parties.

1.27 "***Current Good Manufacturing Practices***" or "cGMP" means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Regulatory Authority, including as promulgated under and in accordance with (i) the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210, 211, 600, 601 and 610, (ii) relevant EU legislation, including European Directive 2003/94/EC or national implementations of that Directive, (iii) relevant guidelines, including the EU Guidelines for Good Manufacturing Practices for Medicinal Products (Eudralex Vol. 4 and Annexes thereto), (iv) International Conference on Harmonisation Good Manufacturing Practice Guide for Active Pharmaceuticals Ingredients and (v) and any analogous set of regulations, guidelines or standards as defined, from time to time, by any relevant Regulatory Authority having jurisdiction over the development, manufacture, or commercialization of the Product, as applicable, in each case as in effect as of the date such manufacturing for the Product are or were conducted. Without limiting the generality of the foregoing, and for the avoidance of doubt, "***Current Good Manufacturing Practices***" or "cGMP" also includes (a) the data integrity requirements under the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210 and 211 ("***Data Integrity Requirements***") and (b) the electronic records requirements under the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Part 11 ("***Electronic Records Requirements***").

1.28 "***Customized or Dedicated Raw Materials***" means (1) [* * *], and (2) any other Raw Materials that are identified in the applicable PSA or agreed upon by the Parties during the Term as (a) [* * *] and/or (b) [* * *].

1.29 "***Damages***" means any direct damages, costs, expenses, fines, penalties (including reasonable attorneys' fees and costs), losses and liabilities.

1.30 "***Decision Memo***" means a binding memorandum summarizing and memorializing the Parties' discussion, understanding, and agreement as to any aspect of the Manufacture that are not directly and/or specifically elaborated in the MSA, PSA, QAG, or any previous Decision Memo.

1.31 "***Drug Product***" means a finished dosage form, for example, vials or pre-filled syringes etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. This term also applies to the final dosage form used as placebo, which does not contain active drug ingredient.

1.32 "***Drug Substance***" means any substance intended to be used in the manufacture of a drug, which substance becomes an active ingredient of such a drug and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body, but does not include intermediates used in the synthesis of such ingredient.

1.33 "***Effective Date***" is defined in the preamble.

1.34 "***EMA***" means the European Medicines Agency, or any successor agency.

1.35 "***Engineering Batch***" means a Batch manufactured prior to Commercial Products with the purpose of confirming successful transfer and/or implementation of the Manufacturing Process to the Facility.

1.36 "***External Laboratory***" means a third party laboratory agreed upon by the Parties to conduct activities required to complete certain Services as discussed and agreed upon by the Parties including but not limited to Mycoplasma testing, viral clearance studies, and adventitious virus screening.

1.37 "***Facility***" means one or more of the facilities of SBL where the Services shall be performed, as further specified in each PSA.

1.38 "***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

1.39 "***Firm Period***" means the portion of the Forecast that is binding on both Parties.

1.40 "***Forecast***" means a projection of Client's requirements for delivery of Product.

1.41 "***Force Majeure Event***" means any event or occurrence which is beyond the non-performing Party's reasonable control, including fire, explosion, flood, landslide, epidemics, or other acts of God; acts, regulations, export and/or import restrictions, embargos (including but not limited to those promulgated by any U.S. Regulatory Authority), or laws of any government; terrorism, war; failure of public utilities; acts of decisions of duly constituted municipal, state, national or supra-national governmental authorities or of courts of law; or impossibility to obtain Raw Materials, equipment, supplies, fuel or other required materials or the occurrence of other supply or manufacture interruptions (at its and/or third-party facilities), in spite of having acted with Commercially Reasonable Efforts.

1.42 "***Implementation Plan and Budget***" means an estimated plan and budget of the reasonable and necessary costs that would be incurred by SBL as a result of the implementation of any such Change(s), including, but not limited to (i) process and analytical development; (ii) equipment and/or the Facility modifications, qualification, validation, maintenance, and decommissioning/disposal; (iii) process and analytical validation; (iv) document revisions or changes, the Facility, equipment, and system modifications or changes; (v) additional stability testing; and (vi) preparing submissions to Regulatory Authorities.

1.43 "***Indemnified Party***" means the Party claiming indemnification under Sections 12.3 and 13.2.

1.44 "***Indemnifying Party***" means the Party subject to an indemnification claim from the other Party.

1.45 "***Intellectual Property***" means: (i) patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, know-how, and any other intellectual property rights, in each case whether registered or unregistered; (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing sub-clause (i); and (iii) all rights and applications that are similar or equivalent to the rights and applications described in the foregoing sub-clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.

1.46 "***Invention***" means any Intellectual Property created by either Party which arises out of or results from the Service under the MSA.

1.47 "***Joint Steering Committee***" or "***JSC***" means a committee composed of an equal number of representatives from each of SBL and Client, generally at least Director-level or equivalent to provide guidance to the Core Team and resolve any issues or disputes which in good-faith are not able to be resolved by the Core Team.

1.48 "***Manufacturing***" or to "***Manufacture***" means the manufacturing of the Product, and any services relating to such manufacturing, including, but not limited to, raw materials, testing, quality control, documentations, quality assurance, archiving, packaging, and up to release of the Product, to be performed by SBL under the MSA and any applicable PSA.

1.49 "***Manufacturing Documentation***" means with respect to a given Product, the data acquired and generated, documents and records describing or otherwise related to the Manufacturing Process including, without limitation: documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications; analytical methods, process trend and variability data; validation protocols and reports; Batch Records; Batch Related Documents, and SOPs.

1.50 "***Manufacturing Process***" means, with respect to a given Product, the mutually agreed production process for the Manufacturing of the Product, which shall be deemed to commence at the OOF date for Drug Substance and the thawing date for Drug Product and end with SBL's release of the Product.

1.51 "***Non-Affected Party***" means the Party other than the Affected Party under Section 16.3.

1.52 "***Non-Conforming Product***" means a Batch of Product that fails to conform to (i) cGMP (but only with respect to Product being Manufactured under cGMP per the applicable PSA, excluding any Engineering Batches or Pilot Batches which are not meant to be Manufactured under cGMP), (ii) the Specifications, and/or (iii) other mutually agreed upon written express requirements for SBL to follow (including applicable Batch Records), in each case from (i) through (iii) above, resulting in a [* * *] on the quality of Product as reasonably determined by the relevant document, record, or data as defined within the parameters established in the QAG.

1.53 "***OOF***" or "***Out-of-Freeze***" means the thawing of the cell bank vials.

1.54 "***Other Raw Material***" means any Raw Material other than Critical Raw Material and Customized or Dedicated Raw Material.

1.55 "***Party***" and "***Parties***" is defined in the preamble.

1.56 "***Pilot Batch***" means a Batch of Product manufactured through non-GMP lab scale run, with the purpose of supporting pre-clinical evaluation but not in compliance with cGMP or the Specifications).

1.57 "***Pre-Approval Inspection***" or "***PAI***" means an on-site inspection of the Facility by the Regulatory Authority prior to granting the Regulatory Approval for Commercial Product as required by various Regulatory Authorities to ensure that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP.

1.58 "***Process Validation Batch***" means a Batch of Product produced from a process validation run conducted by SBL hereunder to (i) demonstrate and document the consistency and reproducibility of the Manufacturing Process at the Facility, and (ii) support the Regulatory Approval of both the Product Manufactured and the Manufacturing Process at the Facility.

1.59 "***Product***" means Clinical Product or Commercial Product to be Manufactured by SBL pursuant to this MSA and any applicable PSA.

1.60 "***Product-in-process***" means any unfinished Product under the Manufacturing Process.

1.61 "***Product Purchase Commitment***" means the minimum number of Batches of Commercial Product (excluding PAI and Process Validation Batches) that Client shall be obligated to purchase in any given calendar year.

1.62 "***Product Service Agreement***" or "***PSA***" means a separate agreement specific to each Product and/or Services (Drug Substance, Drug Product, Cell Line Development, etc.), entered into and mutually agreed from time to time by duly authorized representatives of the Parties. Each PSA shall refer to and be integrated in this MSA and shall be in alignment with the QAG, and may include, without limitation, details such as (i) a high level scope of work of the Services to be performed under such PSA which describes key activities and assumptions, (ii) the Product for which SBL will perform such Services for Client, (iii) fees to be paid to SBL by Client for the Services, and (iv) any other deliverables.

1.63 "***PSA Effective Date***" means the effective date of any PSA entered into between the Parties.

1.64 "***Purchase Order***" is a commercial document issued by Client to SBL indicating, among other things, the quantity of Product to be manufactured, the agreed prices for Product or Service, and the estimated delivery date to be later confirmed and fixed in accordance with Section 4.12.2(b).

1.65 "***Quality Agreement***" or "***QAG***" means the quality agreement entered into by the Parties that governs the responsibilities related to quality systems and quality requirements for the Product(s) Manufactured hereunder, including quality assurance, quality control, testing, batch approval and batch release of such Product(s) at the Facility entered into by the Parties.

1.66 "***Quarter***" means each period of three (3) consecutive calendar months beginning on January 1, April 1, July 1, or October 1.

1.67 "***Raw Materials***" means a chemical entity used in the Manufacturing Process that becomes part of the process stream and procured by SBL for the Services, including, but not limited to, media, buffers, water-for-injection, chromatography resins, chemicals, reagents, filters, excipients, disposable consumables, and secondary packaging materials. Raw Materials exclude the Client Materials.

1.68 "***Regulatory Approval***" means all approvals, licenses, registrations or authorizations thereof of any national, regional, state or local regulatory agency, department, bureau or other governmental entity in any jurisdiction where the Product is marketed or intended to be marketed, necessary for the manufacture and sale of the Product manufactured by SBL at the Facility.

1.69 "***Regulatory Authority***" means any national (e.g., the FDA), supra-national (*e.g.*, the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction responsible for granting the Regulatory Approval.

1.70 "***Reserved Capacity***" means the capacity for Manufacturing the Product within SBL's Facility reserved and dedicated to Client, the costs of which shall be calculated based on the Service Fees for Batches that were scheduled to be Manufactured using the Reserved Capacity.

1.71 "***SBL Assignable Error***" means [* * *] on the part of employees, agents or representatives of SBL.

1.72 "***SBL Invention***" means any Invention that is conceived and first reduced to practice solely by one or more employees or officers of SBL (or its third party consultant or subcontractor) and which is not derived from, or arises out of Client Background IP or Client's Confidential Information or any other proprietary right of Client or its third party vendors, contractors, or other partners or clients.

1.73 "***Scope of Work***" means the document generally forming part of a PSA, specifying in detail the scope and schedule of the Services and the Service Fees as mutually agreed upon by the Parties.

1.74 "***Service***" or "***Services***" means any service related to development and/or manufacturing for Client as specified in a PSA and in accordance with the terms and conditions of this MSA.

1.75 "***Service Fee***" is the fee due and payable to SBL in consideration for SBL's performance of Services and other obligations, but excluding the costs of Raw Materials, SBL handling fees, and other expense or cost reimbursements pursuant to this MSA and/or the applicable PSA.

1.76 "***Specification(s)***" means the criteria for the Products, Client Materials, or Raw Materials, as the case maybe, which details are provided in documentation as reviewed and approved in writing by the Parties.

1.77 "***Standard Operating Procedure(s)***" or "***SOP(s)***" means the standard operating procedures established by and mutually agreed upon by both Parties regarding the Manufacturing Process.

1.78 "***Tax***" means all taxes, charges, customs duties, fees, levies, imposts, or withholding of whatever nature imposed by any law or regulations in any country in respect of the Services, importation or exportation of Raw Materials, Client Materials, Batches, and Product.

1.79 "***Technology Transfer***" means the activities by the Parties necessary for SBL to perform the Services as further described in the applicable PSA which may include, among other things: (i) transfer of the Background IP and Client Material from Client to SBL; (ii) implementation of the Manufacturing Process at the Facility; (iii) Manufacturing Process fit activities, and (iv) tests and studies.

1.80 "***Term***" means the duration for which this MSA stays in effect, which shall begin as of the Effective Date and will be in effect for as long as any PSA is in effect.

1.81 "***Warehouse***" means SBL's warehouse for storage of the Product located at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea.

2. RELATED AGREEMENTS AND EXHIBITS

2.1 Product Service Agreements. SBL will perform Services for Client as specified in PSAs and in accordance with the terms and conditions of this MSA, the applicable PSA(s), and the QAG. In the event of a conflict between any provision of this MSA and the PSA, this MSA shall control, except where the PSA specifically states otherwise and references this Section 2.1.

2.2 Quality Agreement (QAG). As required, the Parties shall agree upon a Quality Agreement applying to such Services, and such Quality Agreement shall be incorporated into this MSA. Conflicts between the QAG and either any provision of this MSA or any PSA, will be handled pursuant to Section 7.1.

3. MANAGEMENT OF SERVICE

3.1 General. SBL shall adequately staff the Facility with personnel with necessary expertise and credentials, including without limitation, adequate training on cGMPs and such other regulations applicable to Manufacturing Product, to perform its obligations under the MSA, QAG, and the applicable PSA. Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions affecting the Service in a regular and timely manner. SBL and Client shall at all times make Commercially Reasonable Efforts to complete the Services in accordance with the estimated timelines set forth in the applicable PSA. Client shall supply to SBL all information or materials that are set forth in the applicable QAG and PSA or otherwise requested by SBL and that are reasonably required by SBL to perform the Services, and SBL shall not [* * *]. Client shall be responsible for [* * *].

3.2 Core Team and Joint Steering Committee.

3.2.1 Core Team and Joint Steering Committee. The Parties shall establish the Core Team, which shall attempt to resolve any issues arising from the Services including but not limited to those relating to changes to the project assumptions and timelines, development activities, process/product quality requirements, Specifications, or Manufacturing Process. The Parties shall also establish a Joint Steering Committee providing guidance to the Core Team and resolving any issues or disputes which in good-faith are not able to be resolved by the Core Team.

3.2.2 Meetings and Decision Making. The Core Team and JSC shall meet on schedules and in manners that are acceptable to their respective members. The JSC meetings shall be held [* * *]a year or less during the term of the applicable PSA. Either Party may request an ad-hoc meeting of the JSC to discuss issues that due to urgency need to be addressed prior to the next scheduled JSC meeting. Each Party may appoint temporary or permanent substitutes for any of such Party's members on the Core Team or JSC and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend Core Team or JSC meetings. Each Party shall be responsible for its own expenses of traveling to and participating in any Core Team or JSC meeting. All decisions of the JSC and Core Team shall be made by the unanimous agreement of all of their members or their designated representatives, and shall be reflected in written meeting reports. Written reports of the JSC and Core Team shall be subject to approval by the authorized representatives of the Parties; *provided*, *however*, that the JSC and Core Team may not amend or waive any provision of the MSA, QAG or applicable PSA except by the terms of this MSA.

3.2.3 Disputes. In the event that the Core Team, is unable, despite the good faith efforts of the members, to resolve a disputed issue that is within the purview of the Core Team for a period of [* * *] days, one Party shall formally request referral of the issue to the JSC. If the dispute still cannot be resolved within an additional [* * *] days after referral to the JSC, the matter may be handled in accordance with Section 15.

3.3 Person in Plant. Client may request up to [* * *] of its representatives to be on-site at the Facility (but no more than [* * *] Client representatives within the Facility's cGMP area) to observe and consult with SBL during the performance of Services under this MSA and such additional personnel in such numbers as deemed necessary shall be accommodated upon mutual agreement. Reasonable expenses associated with such on-site Client representatives shall be passed through to Client by SBL. While at the Facility, all such Client representatives shall have reasonable access to all areas as are relevant to SBL's performance of the Service hereunder, provided that SBL may reasonably restrict Client representatives' access to the Facility as it deems necessary, and all such Client representatives shall agree to and comply with confidentiality obligations to third parties, SBL policies and procedures related to safety, confidentiality, and cGMP, and all instructions of SBL employees at the Facility. Client shall remain responsible at all times for the compliance with the terms of this MSA, QAG and PSA by its employees and representatives.

3.4 Subcontract. SBL may subcontract any portion of the Services with prior approval from the Client, which shall not be unreasonably withheld, delayed, or conditioned. In the event SBL subcontracts any portion of the Services, SBL shall be primarily obligated to Client for ensuring that such subcontracted services are carried out as intended; provided however that, SBL shall not be responsible for any delay or breach caused solely by External Laboratories despite SBL's exercise of reasonable care and efforts commonly used and customary in the industry. All costs associated with activities outsourced to third parties or External Laboratories (*e.g.* viral clearance, Mycoplasma, adventitious virus screen, etc.) will be passed through to Client at cost with an additional [* * *] handling fee.

3.5 Development and Manufacturing Site. Unless otherwise agreed by Client, all Services shall be performed by SBL at the Facility.

3.6 Manufacturing Documentation. SBL shall maintain Manufacturing Documentation to be true and accurate pursuant to the Data Integrity Requirements Electronic Records Requirements, and shall keep in strict confidence and shall not use for purposes other than providing or performing the Service or other obligations hereunder. SBL shall maintain all such Manufacturing Documentation for at least that period specified in the applicable QAG. Upon written request of Client and at mutually agreeable times, Client shall have the right to review Manufacturing Documentation at the Facility or through a secured/encrypted server (*e.g.* Sharepoint) as further defined in the applicable QAG. Client may also request scanned or printed copies of such Manufacturing Documentation, but shall be responsible for reasonable costs associated therewith. SBL shall record and maintain such records, data, documentation and other information in the language as so required in the applicable QAG or as so required by a Regulatory Authority and in compliance with Applicable Law. To the extent necessary, SBL may redact or withhold Manufacturing Documentation provided pursuant to this MSA or any applicable PSA to protect the confidential information of its other clients or third parties. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, source documents, quality control testing documentation, quality assurance records, and laboratory notebooks are the exclusive property of SBL. Notwithstanding anything to the contrary, SBL's redacted version of general operating SOPs, not specific to the Client's Products, may be provided to Client for on-site review or through a secured/encrypted server if deemed necessary by both SBL and Client. Such SOPs cannot be removed from the SBL premises or the secured/encrypted server, copied, photographed or otherwise replicated.

4. SERVICE DESCRIPTIONS

4.1 Technology Transfer. Client shall transfer to and grant SBL the license set forth below in Section 10 in respect of the Client Technology, Client Materials, and Cell Line to SBL in accordance with the plan, timelines and quantities agreed upon by the Parties. In the event that Client agrees to utilize SBL's SharePoint portal for Technology Transfer, Client agrees that (a) in the event of any relevant change that affects a Client user's authorization to use such portal, Client shall promptly notify SBL so that SBL may disable their usernames and remove / change passwords in order to secure the SBL Portal and (b) Client shall use Commercially Reasonable Efforts to ensure that all of Client users have up-to-date antivirus software installed on the computer devices used to access such portal.

4.2 Engineering Batch. SBL makes no warranty that Engineering Batches will meet the Specifications or be successful, and thus under no circumstances shall SBL be obligated to re-Manufacture an Engineering Batch for [* * *], provided however that, if the Engineering Batch is [* * *] due to [* * *], and if re-Manufacturing the Engineering Batch is reasonably necessary for the successful Manufacture of subsequent Batches, [* * *], then SBL shall, upon Client's request, re-Manufacture the Engineering Batch at SBL's cost.

4.3 Process Validation Batch. Prior to commencement of Process Validation Batches, SBL and Client shall agree to a validation plan identifying the validation requirements with a mutually agreed acceptance criteria for the Manufacturing Process. The costs of process validation activities are excluded from the price of Process Validation Batches and shall be paid for by Client at the price set forth in the applicable PSA, subject to the Client's prior approval on the scope and nature of such validation activities per the QAG.

4.4 Facility Modification and Equipment. Client and SBL will agree on what equipment in the Facility is necessary to perform the Services, and if Client reasonably deems it necessary to procure additional equipment beyond that which is in the Facility as of the applicable PSA Effective Date, SBL shall procure such equipment at Client's expense in accordance with Section 8.2.4 and SBL shall be responsible during the Term for validation, calibration, installation, maintenance, repairs, commissioning, and decommissioning at SBL's expense, unless otherwise agreed in writing by the Parties, all in accordance with the QAG. Thereafter, if any additional equipment is necessary, such costs shall be dealt with by Section 5 of this MSA. Notwithstanding anything to the contrary in this MSA, the ownership of any and all such equipment shall remain at all times with SBL, and SBL shall in good faith and in accordance with its obligations under this MSA or applicable PSA, make available such equipment for Client's use during the Manufacturing schedule reserved by Forecast or binding Purchase Order during the term of the applicable PSA. Any modifications to the Facility, equipment, Raw Materials (including the applicable suppliers thereof), or Manufacturing Process shall be subject to the change control procedures set forth in Section 5 of this MSA, QAG, and any applicable PSA.

4.5 Additional Work. Should the Parties mutually agree to any additional work to be added to the Scope of Work, the Service Fees for such additional work shall, unless otherwise agreed in writing by both Parties, be based on SBL's standard pricing at the time of adding such additional work, and depending on the nature of such additional work, the Parties shall execute a Decision Memo or an amended Projected Plan accordingly. In the event of changes to the Services based on Client's request, Client shall, unless otherwise agreed in writing by both Parties, bear all additional costs and expenses associated therewith; provided, however, SBL shall not commence any such additional work unless the Parties execute a Decision Memo or an amended Projected Plan accordingly.

4.6 Raw Materials.

4.6.1 Management. SBL shall procure and maintain a reasonable quantity of Raw Materials, required for the Services in accordance with the MSA, QAG and any applicable PSA. On a per-Product basis, SBL shall prepare the categorization of the Raw Materials into (i) Critical Raw Materials, (ii) Customized or Dedicated Raw Materials, and (iii) Other Raw Materials, and send the categorization to Client for approval as soon as practicable after the Effective Date. Client shall approve the categorization in accordance with this MSA and any applicable PSA no later than [* * *] after the receipt of such a categorization from SBL. SBL shall not be [* * *]. The list of Raw Materials may be amended from time to time, subject to the Parties' mutual agreement; provided however that, unless otherwise agreed in writing by both Parties, Client shall at all times be solely responsible for the costs of Raw Materials including those used in small scale runs during Technology Transfer, which is not included in the Service Fees. During Technology Transfer, the Core Team shall agree on estimates for Raw Materials anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Raw Materials used in excess of the agreed-upon estimate; provided, however, that SBL shall be responsible for any excess use, loss, spoilage, or waste of such Raw Materials to the extent caused by [* * *]. The Parties shall, in good faith and based on industry standard, mutually agree to strategies regarding Raw Material safety stock and sourcing from qualified vendors. In the event SBL is not able to utilize any Reserved Capacity for Manufacturing Product according to an agreed-upon forecast or manufacturing plan due to [* * *], then Client shall be responsible for the costs of such Reserved Capacity [* * *].

4.6.2 Raw Material Specifications. Client and SBL shall agree on the Specifications of Raw Materials, including without limitation analytical methods, supplier information including supplier site information, and other information concerning the stability, storage, and safety thereof that are required for the Manufacturing hereunder, as further described in the applicable QAG.

4.6.3 Testing and Evaluation. SBL or vendors qualified by SBL shall perform all testing and evaluation of Raw Materials as required by the Specifications for the Raw Materials and the cGMPs, as further described in the applicable QAG.

4.6.4 Storage. SBL shall secure sufficient and suitable storage for the Raw Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect Raw Materials from loss after receipt by SBL and during the Term and except for loss due to [* * *], Client shall be responsible for [* * *]. SBL shall only use unexpired Raw Materials for performance of the Services, including Manufacturing Product. At the end of each [* * *] of the relevant PSA, Client shall be responsible for the loss of Raw Material (except for loss due to [* * *]) to the extent purchased in reliance on [* * *].

4.6.5 Handling Fee Related to Raw Material. Raw Materials will be charged on a cost-plus basis to Client in accordance with Sections 8.1(ii) and 8.2.2, subject to any changes as agreed between the Parties in writing.

4.7 Client Materials.

4.7.1 Management. Client shall provide, either by itself or through its third-party supplier, to SBL free of charge, Client Materials in amounts reasonably necessary to carry out the Services as agreed by the Parties. SBL shall make Commercially Reasonable Efforts to import the Client Materials to the Republic of Korea in a timely manner, and Client shall provide reasonable assistance necessary for such a timely importation. Delivery conditions for the Client Materials shall be [* * *] (INCOTERMS 2020) provided that the title and risk of loss to such Client Materials shall remain at all times with the Client and shall not transfer to SBL. During Technology Transfer, the Core Team shall agree on estimates for Client Material anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Client Materials used in excess of the agreed-upon estimate; provided, however, that (a) SBL shall be responsible for any excessive use, loss, spoilage, or waste of such Client Materials to the extent caused by [* * *] and (b) notwithstanding anything to the contrary, SBL will not [* * *]. The Parties will, in good faith and based on industry standard, mutually agree to strategies regarding Client Material safety stock and sourcing from qualified vendors. In the event SBL is not able to utilize any Reserved Capacity reserved for Manufacturing Product according to an agreed-upon forecast or manufacturing plan due to [* * *], then Client shall be responsible for the costs of such Reserved Capacity [* * *].

4.7.2 Client Material Specifications. Client shall provide SBL with the Specifications of the Client Materials, including without limitation analytical methods, supplier information, and other information concerning the stability, storage, and safety thereof that are required for the Manufacturing hereunder, as may be further described in the applicable QAG.

4.7.3 Testing and Evaluation. SBL shall perform testing of the Client Materials in accordance with the applicable QAG and/or Client's instruction prior to the performance of the Manufacturing hereunder, in order to determine whether such Client Materials meet the Specification described in the applicable QAG (if applicable). SBL shall inform Client of (a) any damage to the Client Materials received that is visually obvious (e.g., damaged or punctured containers and temperature monitoring results outside of predetermined Specifications) within [* * *] days after SBL's receipt of the Client Materials and (b) any non-conformance of the Client Materials to Specification either: (i) within [* * *] days after SBL's receipt of the Client Materials or (ii) if release testing of Client Materials is not performed until it is needed for Manufacture, within [* * *] days after such release testing is performed; or (iii) as otherwise agreed between the Parties. If, prior to performing any Service on the Client Materials, SBL determines that such Client Materials are defective or damaged, SBL shall not perform the Service on such Client Materials and shall follow Client's written instructions regarding disposal or return of such Client materials to Client [* * *]; provided, however, (a) SBL shall be responsible for any such costs to the extent the defect in or damage to such Client Materials is caused by [* * *] and (b) notwithstanding anything to the contrary, SBL will not [* * *].

4.7.4 Storage. SBL shall secure sufficient and suitable storage for the Client Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise Commercially Reasonable Efforts to preserve and protect the Client Materials from loss or damage after receipt by SBL and prior to Manufacture; provided, however, (a) SBL shall be responsible for any loss or damage of such Client Materials to the extent caused by [* * *] and (b) notwithstanding anything to the contrary, SBL will not [* * *].

4.7.5 Handling Fee Related to Client Material. Handling fees relating to the Client Material will be charged to Client in accordance with Sections 8.1(iii) and 8.2.3.

4.8 Forecasts. For each Commercial Product (excluding PAI and Process Validation Batches, which shall be forecasted and reserved by Purchase Orders), the Parties shall determine a mutually agreeable mechanism for forecasting of each Product, which shall be detailed in writing in each relevant PSA. For Clinical Product, the Parties shall agree upon the number and schedule of Batches to be Manufactured by SBL in the applicable PSA. In the event SBL is not able to utilize any Reserved Capacity for Manufacturing Product according to an agreed-upon forecast or manufacturing plan due to a reason reasonably attributable to Client, then Client shall be responsible for the costs of such Reserved Capacity [* * *].

4.9 Purchase Orders. For each Clinical Product or Commercial Product, Client shall notify SBL in a binding form and procedure to be agreed upon in the applicable PSA requesting a specific amount of Product to be Manufactured in the Purchase Order. The Parties acknowledge that, with or without a Purchase Orders issued in advance, an invoice may be issued in accordance with this MSA, PSA, or applicable Decision Memo for Services, Raw Materials, handling fees and Equipment, and such invoices shall be processed and paid in accordance with Section 8.3.

4.10 Product Purchase Commitment. As expressly set forth in a PSA, during the Term, the Parties may agree that Client will purchase a Product Purchase Commitment, subject however to any relief such as Clinical Exit or other relief mutually agreed upon by the Parties or otherwise set forth in each applicable PSA.

4.11 Batch Failure during Manufacture

4.11.1 If, during Manufacture of a Batch and prior to SBL's release, Client and/or the Core Team determines that a Batch is Non-Conforming Product (a "***Batch Failure***"), SBL shall take Commercially Reasonable Efforts to promptly re-Manufacture and deliver to Client a replacement Batch on a date to be mutually agreed by the Parties, which Service Fees and associated costs/fees (as set forth in Section 8.1 below) shall be invoiced and paid for by the Client. The remedies contained in Section 4.11 of this MSA shall be [* * *] and a Batch Failure shall not constitute a material breach of this MSA or a PSA unless SBL fails to provide the remedies contained in this Section 4.11.

4.11.2 The Parties shall conduct a root cause analysis of the Batch Failure, which shall be done through the deviation process under the requirements of the QAG and which result will be reviewed and confirmed by the JSC. If either the Core Team does not agree on the Batch Failure root cause, or the JSC does not agree on the results of the Core Team's Batch Failure root cause analysis, the Parties shall refer to an independent mutually agreed-on laboratory or firm with international repute, acting as a neutral arbiter, to conduct a root cause analysis of the Batch Failure. The costs of the independent laboratory will be shared by the Parties equally; provided, however, that the Party that is determined to be incorrect as to the Batch Failure will be responsible for those reasonable costs and must reimburse the correct Party for its share of the reasonable costs incurred. The decision of the independent laboratory must be in writing and will be binding on the Parties.

4.11.3 The PSA applicable to such Product Batch Failure shall set forth responsibility among the Parties of the following costs in the event of a Batch Failure: (1) the SBL Service Fee to Manufacture the failed Batch; (2) SBL's costs to [* * *] plus applicable SBL [* * *]; (3) [* * *]; and (4) [* * *] which amount is to be calculated based on the actual costs of such materials as supported by reasonable documentary evidence (as opposed to the market value thereof)[* * *]. To the extent the Batch Failure is caused [* * *], SBL shall be responsible for (1) – (4) above, and in all other Batch Failure cases Client shall be responsible for (1) – (4) above. Any such cost responsibility shall be issued as a credit against future invoices by SBL or a refund to Client if the credit exceeds the value of future invoices. Notwithstanding anything to the contrary, SBL shall not be responsible in the event of Batch Failure for: (a) [* * *] and (b) [* * *].

4.11.4 In the event that any of the foregoing procedures result in a Batch being delivered in a different year than the year in which the original Batch was ordered for delivery by Client, the Service Fee for such re-Manufactured Batch shall be the Service Fee in effect in the year in which such re-Manufactured Batch is actually delivered by SBL.

4.12 Storage, Packaging and Delivery.

4.12.1 Service Deliverables other than Products. Storage, packaging and delivery of the Service deliverables other than Products Manufactured and the Products Manufactured hereunder shall be made in accordance with the terms of this MSA, applicable PSA, applicable QAG and the Applicable Laws.

4.12.2 Products.

(a) Release by SBL and Acceptance by Client.

(i) SBL shall perform all testing in accordance with the Specifications of the Product-in-process and the Product and release the Product in accordance with the terms of the applicable QAG. SBL may not release a Batch of Product if there is any outstanding deviations. Upon such release, SBL shall deliver to Client the Batch Related Documents, including a Certificate of Analysis and Certificate of Compliance, in accordance with the applicable QAG;

(ii) Acceptance of Product. Client will complete the Acceptance Procedure and determine the acceptability of such Product in accordance with the applicable QAG and notify SBL of the result within [* * *] days of Client's receipt of the Batch Related Documents. Upon Client's acceptance, SBL will have [* * *]; provided, however, the foregoing shall not [* * *]. If Client does not reject such Product within the [* * *] day period, the Product will be deemed to have been [* * *] accepted by Client and SBL will have [* * *]; provided, however, the foregoing shall not [* * *].

(iii) Non-Conforming. If, during the Acceptance Procedure, any Product is reasonably determined by Client as Non-Conforming Product, and SBL confirms such non-conformity, or such non-conformity is confirmed pursuant to Section 4.11.2, such non-conformity shall be treated as a Batch Failure, and the remedy set forth in Section 4.11 above shall apply to the Non-Conforming Product mutatis mutandis. Notwithstanding anything to the contrary, Client agrees to [* * *]. The remedies contained in this Section 4.12.2 shall be [* * *]; provided, however, the foregoing shall not [* * *].

(b) Delivery. Shipping conditions for the Product Manufactured hereunder shall be [* * *] (INCOTERMS 2020), unless otherwise agreed to in the applicable PSA. The title to Product hereunder shall be transferred from SBL to Client when [* * *]. The Parties further agree as follows:

(i) After SBL's release of the Product and prior to each pick-up by Client or Client's designated carrier, SBL shall propose to Client a delivery schedule of the Product, in order for the Parties to agree on it in advance for each pick-up. SBL shall schedule Delivery with the carrier selected and paid for by Client;

(ii) SBL shall not deliver the Product until it has been instructed to by Client in accordance with the applicable QAG. Client shall confirm specific delivery instructions with SBL prior to SBL's release. Upon SBL's release of Product, SBL shall store the Manufactured Product as described in Section 4.12.2(c) and Client shall compensate SBL for storage costs for the Manufactured Product as set forth in the applicable PSA;

(iii) SBL shall provide Client with invoice, packing lists, supporting export documents as specified by Client by separate delivery and shipment documentation instructions, together with each shipment of the Product (or such other deliverables); and

(iv) In cooperation with Client and subject to the delivery schedule agreed by the Parties, SBL shall adhere to[* * *] in shipping all released Product..

(c) Storage, Packaging and Shipping Container.

(i) Pursuant to the terms of this MSA and any applicable PSA and QAG, and subject to the availability of space and storage conditions, SBL shall adequately store the Products Manufactured hereunder.

(ii) SBL shall store, package, label and prepare shipment according to the Specifications for the Product Manufactured hereunder, the applicable QAG and the SOPs, and using storage and/or shipping containers determined in the applicable PSA.

(iii) If Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within [* * *]days of Client's receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse, subject to the availability of space and storage conditions, and Client shall pay storage fees to SBL as set forth in Section 8.1 for the period of storage at the Warehouse until the actual delivery date; *provided however* that under no circumstances shall the period of storage in the Warehouse exceed [* * *] days. SBL shall be responsible for risk of loss and damage to Manufactured Product in the event of [* * *].

5. CHANGES TO THE SPECIFICATIONS, ANALYTICAL METHODS, MANUFACTURING PROCESS, FACILITY OR EQUIPMENT

5.1 Approval for Change. Change shall be implemented only with mutual agreement between the Parties acting reasonably and in good faith and in accordance with the applicable QAG.

5.2 Changes Required by cGMP, Regulatory Authorities or Requested by Client. Except as otherwise expressly set forth to the contrary in the applicable QAG, in the event that cGMP, a Regulatory Authority, Applicable Law, or any other regulatory or legal authority requires, or Client requests, a Change, SBL shall accommodate such requirements or requests, subject to the following:

(a) Client shall promptly notify SBL in writing of the required and/or requested Change(s), and provide information necessary for SBL to evaluate the effect of such Change(s), and SBL shall promptly advise Client as to any (i) additional equipment required, modifications to the Facility or equipment, and/or additional equipment and the Facility qualification and validation requirements; (ii) Manufacturing Process development, transfer, scale-up, testing, qualification, or validation requirements; (iii) regulatory requirements pursuant to such Changes; (iv) changes to the Manufacturing scheduling and/or Product delivery schedule; and (v) other impacts on the Facility or SBL's ability to manufacture products (including the Products) in the Facility, if any, which may result from such Change(s). The notification and formal approval procedure of such Changes shall be in accordance with the applicable QAG (i.e., change control procedures) (if applicable). The Parties shall meet in a timely manner to identify and discuss such Changes as appropriate;

(b) Prior to implementation of any such Change(s), SBL shall provide Client with an Implementation Plan and Budget. Following review and approval by Client of such Implementation Plan and Budget, subject to the Core Team's approval and agreement followed by the Parties' written agreement pursuant to Section 16.9 (if applicable), SBL shall commence implementation of such Change(s);

(c) During any such implementation, SBL shall provide Client with regular updates on the progress of implementation. Subject to any timeframe imposed by Applicable Law, SBL shall exercise Commercially Reasonable Efforts to implement the Change according to the Implementation Plan and Budget's target completion date. SBL shall provide written notice to Client if SBL becomes aware of any cause which may create delay with the implementation of Changes. Following any such notice, both Parties shall discuss an amendment of Implementation Plan and Budget; and

(d) Upon the approval of the Implementation Plan and Budget for Change(s), both Parties shall negotiate in good faith to determine the allocation of the costs incurred by SBL for the implementation of any such Change(s) between the Parties, in accordance with the following principles:

(i) the costs for the [* * *], shall be borne by SBL, provided that where the Change relates [* * *] shall be borne by Client [* * *], respectively;

(ii) the costs for the Changes other than (i) above, and [* * *] shall be borne by Client; and

(iii) the costs for the Changes other than (i) and (ii) above shall be discussed in good faith by the Parties to achieve equitable allocation of costs.

6. REGULATORY APPROVALS AND INSPECTIONS.

6.1 Regulatory Approvals. To the extent applicable, SBL shall provide reasonable assistance and cooperation in order for Client to obtain and maintain the Regulatory Approvals. The costs and fees associated with such assistance and cooperation, to the extent not detailed in the MSA or PSA shall be borne by Client. As specified in the applicable PSA, the Parties shall discuss and agree on which Regulatory Approvals are to be obtained.

6.2 Regulatory Approvals for the Facility. To the extent applicable, SBL shall obtain and maintain all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity (other than the Regulatory Approvals, which will be obtained or maintained by Client) that are required to Manufacture the Product at the Facility and perform the Services.

6.3 Regulatory Support Activities. Any regulatory support activities (including Pre-Approval Inspections) required and agreed to by Client to support Regulatory Approval of the Product from the Facility shall be performed and supported by SBL as reasonably requested by Client. All such regulatory support activities are excluded from the price of Process Validation Batches, shall be approved by the Client in advance, and shall be paid for by the Client at the price set out in the applicable PSA. SBL shall notify Client according to the applicable QAG provisions of any contacts or inquiries by the Regulatory Authorities, including inspections, Pre-Approval Inspections, sample requests, and written correspondence and its result, related to the Product.

6.4 Regulatory Inspections. SBL shall notify Client within a time period set by the QAG if an authorized agent of any Regulatory Authority (a) plans to visit the Facility, or (b) makes an inquiry, each case (a) and (b), relating directly and specifically to the Manufacturing of the Products (e.g. Pre-Approval Inspection). With respect to a visit described in the first sentence of this Section 6.4, Client shall have the right to be present at any visit and shall have the right to review in advance and comment on any response to the communication or investigation submitted by SBL for any response arising therefrom. SBL shall cooperate fully with such Regulatory Authority and with Client in providing the information needed for any such communication. SBL shall provide to Client copies of any Form 483 or equivalent document delivered by a Regulatory Authority to SBL as a result of any visit related to the Services, including any finding or other action relating to the underlying quality system used by SBL in the Manufacturing of Products.

7. QUALITY COMPLIANCE

7.1 Quality Agreement. Both Parties shall adhere to the provisions of the applicable QAG and the Parties agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the applicable QAG. In the event of a conflict between a Quality Agreement and either any provision of this MSA or any PSA, the MSA or PSA shall control except with respect to matters directly and specifically related to Product quality or regulatory requirements, in which case, the Quality Agreement will control.

7.2 Records & Audit.

7.2.1 Audit by Client. Upon Client's request, but no more than [* * *], SBL shall accept a formal audit of the Facility, QC laboratories and, if necessary, the Warehouse, by Client and allow Client to inspect the Facility, QC laboratories and, if necessary, the Warehouse, and Manufacture of the Product during provision of the Services solely to ascertain compliance by SBL with the terms of this MSA or any applicable PSA (a "***Standard Audit***"); provided, however that in the event Client uses a designee, SBL must [* * *]. SBL shall be reimbursed for its reasonable costs for audits beyond Standard Audits and For Cause Audits (as defined below). SBL will make Commercially Reasonable Efforts to require vendors or subcontractor to accept an audit of their facilities by Client upon similar notice as described in Section 7.2.2 below and in the QAG. In addition to Standard Audits, upon notice as described in Section 7.2.2. below, Client may request a "for cause" audit due to [* * *] (a "***For Cause Audit***"). Upon receiving Client's request for For Cause Audit, SBL shall schedule such an audit to be conducted within [* * *] days of receiving such a request.

7.2.2 Audit Notice. Client shall provide SBL with a written notice of a Standard Audit at least [* * *] prior to the initiation of the Standard Audit of the Facility and, if necessary the Warehouse, set forth in Section 7.2, which shall be conducted on a mutually agreeable date and time, and with [* * *]. Notwithstanding the foregoing, for For Cause Audits, the foregoing sentence shall not apply and Client may conduct such audit or visit by providing SBL with a prior notice by email. Access to SBL's facilities shall be coordinated with SBL so as to minimize disruption to SBL's ability to perform services for its other clients. Client representatives must comply with all of SBL's cGMP, confidentiality and security procedures and protocols during such observations, consultations, and inspections. SBL shall at all times cooperate and provide all the necessary documents reasonably required by Client during such audit; provided that, to the extent necessary, SBL may redact or withhold documents to protect the confidential information of its other clients. Client shall be solely responsible for any costs and liability caused by Client's or its representatives' failure to comply with SBL's security, safety or confidentiality procedures that are communicated to Client before or during such audit or that Client or its employees know or should know are generally expected to be complied with in such audit.

8. CONSIDERATION AND PAYMENT TERMS

8.1 Consideration. In consideration for SBL's performance of the Service and other obligations undertaken by SBL pursuant to a PSA, Client shall pay SBL (i) the Service Fees as set forth in the applicable PSA; (ii) a handling surcharge of [* * *]Raw Materials paid by SBL (including but not limited to Taxes); (iii) a handling surcharge of [* * *](which shall be based on the actual costs of such materials as supported by reasonable documentary evidence as opposed to the market value thereof and which include Taxes); and (iv)[* * *].

8.2 Invoices.

8.2.1 Service Fee of the Project Stages and Batches. The Service Fees for any Batches including but not limited to Engineering Batch, Process Validation Batch, PAI Batch, Batches for Commercial Products shall be invoiced [* * *]. All other Service Fees shall be invoiced [* * *]. SBL's invoices pursuant to this MSA shall be electronic, unless otherwise agreed by the Parties.

8.2.2 Raw Materials. With respect to the Raw Materials, SBL shall submit invoices to Client for the applicable Raw Materials cost (including any safety stock) as set forth according to Section 8.1 as follows. SBL shall submit an invoice to Client (i) for the cost of Critical Raw Materials, and Customized or Dedicated Raw Materials upon receipt of the invoice from vendors/suppliers; and (ii) for the cost of Other Raw Materials used upon [* * *] as applicable. In each case, for all Raw Materials, SBL shall prepare a billing summary detailing the Raw Materials used and send the same to Client in accordance with Section 8.2.5. Within [* * *] of receiving the billing summary for Raw Materials from SBL, Client shall either (1) accept and issue a purchase order for the Raw Material in accordance with the billing summary or (2) reject the billing summary based on reasonable grounds, in which case SBL shall promptly re-issue the billing summary. Client's failure to accept or reject a billing summary within the [* * *] week period shall be deemed an acceptance of the billing summary, and SBL will issue the corresponding invoice with or without a previously issued purchase order from Client.

8.2.3 Client Materials. With respect to the Client Materials, which shall be supplied by Client to SBL at [* * *] during SBL's performance of the Service, SBL shall submit an invoice to Client in an amount as set forth in Section 8.1 [* * *].

8.2.4 Equipment. With respect to Equipment, SBL shall submit an invoice to Client subject to Section 4.4 upon receipt of the relevant invoice from equipment vendor/supplier.

8.2.5 Disclosure of Original Invoices. For any Raw Materials or Equipment purchased from third party vendors, Client agrees and acknowledges that SBL shall be under no obligation to disclose the original invoice or any confidential information therein from the vendors due to its confidentiality obligation with such vendors, and that not furnishing such documents shall not constitute a valid ground for rejecting SBL's billing summary or invoice. Client may, however, request a third party audit at Client's expense upon [* * *], and confirm through the auditor the sole issue of whether there is any discrepancy or inaccuracy between the vendor's invoices and SBL's billing summary or invoice (without the auditor disclosing any confidential information of the vendor to Client). Should a discrepancy or inaccuracy be found through such an audit, SBL shall be responsible for the costs of such an audit and promptly re-issue the invoice with the correct amount and/or reimburse the amount paid in excess of the correct amount.

8.3 Payment.

8.3.1 Mode of Payment; Foreign Exchange. All payments to SBL due under the MSA or any applicable PSA that are not disputed in good faith or based on reasonably justifiable grounds shall be made in US$ within [* * *] days from the receipt of SBL's invoice in US$ by means of telegraphic transfer to the account with the bank designated by SBL in the applicable invoice without any deduction, deferment, set-off or lien. If Client disputes any portion of an invoice, then Client shall so notify SBL prior to the payment due date and shall pay the undisputed amounts as set forth above in the preceding sentence and the Parties shall use good faith efforts to reconcile the disputed amounts as soon as practicable. For the purpose of computing payment amounts incurred by SBL in a currency other than US$, such currency shall be converted into US$ using the Standard Rate published by the [* * *] at the opening of business on such invoice date.

8.3.2 Taxes. All prices and charges are exclusive of any Taxes, which shall be paid by Client. For the avoidance of doubt, the foregoing shall not include any taxes imposed on the income or profit of SBL levied on any payment to be made by Client to SBL, each of which shall be solely borne by SBL. Client shall pay or reimburse SBL for all Taxes in connection with the purchase, sale, storage, importation or exportation of any Raw Materials, Client Materials, Batches, or Product or the provision of Services, except to the extent such Taxes are recoverable by or refundable to SBL. SBL agrees to use Commercially Reasonable Efforts to assist Client in claiming exemption under double taxation or similar agreement or treaty from time to time in force to obtain a refund of any customs duties, value added taxes, and other taxes payable by SBL.

8.3.3 Price Adjustments. Unless otherwise expressly set forth in the applicable PSA, the Service Fees as set forth in the applicable PSA, shall be adjusted annually on [* * *] of each year during the Term, effective immediately, by the lower of (i) the [* * *]or (ii) [* * *]. The relevant date for price adjustment under this Section shall be the issue date of SBL's invoice.

8.3.4 Default Interest. Any amount that is (a) not disputed in good faith or based on reasonably justifiable grounds, and (b) not paid by a Party to the other when due under the MSA or any PSA shall bear default interest at the rate of [* * *] per annum on a pro rata basis from the day following the due date until paid in full. In the event there is such an amount which is invoiced by SBL, but not paid by Client for more than [* * *] months after the due date, such event shall be considered a material breach of the relevant PSA.

9. CONFIDENTIALITY

9.1 Confidential Information. Both Parties agree to maintain the Disclosing Party's Confidential Information in confidence and not to disclose the Disclosing Party's Confidential Information, in whole or in part, to any third party, and not use the Disclosing Party's Confidential Information for any purpose other than performing the obligations under the MSA, QAG, or applicable PSA. The Receiving Party recognizes the proprietary nature of the Disclosing Party's Confidential Information and agrees that no right, title, ownership, license, or interest of any character in the Disclosing Party's Confidential Information other than as specifically granted herein, is conveyed or transferred to the Receiving Party. Each Party shall guard such Confidential Information using the same degree of care as it normally uses to guard its own confidential or proprietary information of like importance, but in any event no less than reasonable care. The Receiving Party shall limit disclosure of the Disclosing Party's Confidential Information to its and its Affiliates' directors, officers, employees, consultants and agents ("***Representatives***") only on a need-to-know basis, provided that, the Receiving Party shall undertake procedures such that each of its Representatives to whom the Disclosing Party's Confidential Information is disclosed has signed a confidentiality agreement containing, or is otherwise bound by, confidentiality obligations at least as restrictive as those in this MSA

9.2 Exceptions. Notwithstanding Section 9.1 above, Confidential Information shall not include the information, which as evidenced by written records: (a) was at the time of disclosure by the Disclosing Party hereunder publicly known or available; (b) after disclosure by the Disclosing Party hereunder, became publicly known or available by publication or otherwise, other than by an unauthorized act or omission by the Receiving Party; (c) was in the possession of the Receiving Party without confidentiality restriction at the time of the disclosure by the Disclosing Party hereunder; (d) was lawfully received from any third party having the lawful right to make such disclosure, without obligation of confidentiality; or (e) was independently developed by the Receiving Party's directors, officers or employees without reference to the Confidential Information, as demonstrated by records contemporaneous with such development.

9.3 Authorized Disclosures. Disclosure is permitted in the event that (a) the Disclosing Party's Confidential Information is reasonably required to obtain or maintain any Regulatory Approvals for the Products in any or all jurisdictions or (b) the Disclosing Party needs to disclose such Confidential Information to comply with Applicable Law; provided that such Receiving Party shall exercise its Commercially Reasonable Efforts to limit disclosure of the Disclosing Party's Confidential Information to that which is necessary for compliance and to otherwise maintain the confidentiality of the Confidential Information.

9.4 Survival of confidential obligations. The confidential obligations of the Receiving Party shall survive for a period of [* * *] years from the expiration or termination of this MSA.

9.5 Return of the Confidential Information. All written, printed or other tangible Confidential Information of the Disclosing Party disclosed under the MSA, and all copies thereof shall be returned to the Disclosing Party (or destroyed at the Disclosing Party's request) by the Receiving Party within [* * *] days from the written request by the Disclosing Party. All Confidential Information disclosed electronically shall be completely deleted and destroyed by the Receiving Party within [* * *] days from the written request by the Disclosing Party. Notwithstanding the foregoing, (i) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, and (ii) a single copy of the Confidential Information may be retained in the secured files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under the MSA provided that the Receiving Party shall keep such Confidential Information in confidence and will use the Confidential Information solely to comply with the terms of the MSA as well as Applicable Laws.

10. OWNERSHIP OF MATERIALS AND INTELLECTUAL PROPERTY

10.1 Background Intellectual Property. It is acknowledged that each Party owns or controls Background IP and nothing in this MSA shall affect such rights in Background IP. Client hereby grants SBL a non-transferrable, royalty-free, irrevocable, sublicensable (to the extent necessary to conduct the Services) and fully-paid-up right and license to use Client's Confidential Information and Intellectual Property during the Term for the sole purposes of performing the Services in accordance with this MSA. Except as otherwise provided herein, the Parties shall not acquire any right, title, or interest in any Background IP of the other Party. The Parties acknowledge and agree that (a) nothing herein shall impact the ownership of Intellectual Property developed or arising under the Master Development Services Agreement between SBL and IMVT Corporation (formerly known as Immunovant, Inc.) dated December 18, 2018 (the "***MDSA***"), and such Intellectual Property shall continue to be governed by, and subject to, the MDSA and (b) Product IP (as defined in the MDSA) shall be considered Client's Background IP under this MSA.

10.2 Inventions.

10.2.1 Client Invention. SBL shall notify Client of any Client Invention(s) immediately after such conception and reduction to practice, and shall take all reasonable measures so that Client would have the sole and exclusive ownership of any and all Client Invention. Without limiting the generality of the foregoing, SBL shall and hereby does assign all right, title, and interest in and to all Client Inventions to Client. Client may use any Client Invention for any purpose, including filing patent application and SBL shall provide reasonable cooperation to Client at the expense of Client as to all reasonable out-of-pocket expenses incurred by SBL.

10.2.2 SBL Invention. SBL Invention shall be the property of SBL and shall not be deemed to be Client Invention or joint invention for the purposes of the MSA: *provided*, *however*, that SBL grants to Client a worldwide, irrevocable, non-transferable (except to permitted assignees under this MSA), sublicensable (with a prior written by SBL not to be unreasonably withheld, conditioned, or delayed), royalty-free and fully-paid-up right and license under such SBL Invention to make, use, sell, offer to sell, export and import and otherwise exploit the Product to the extent such SBL Invention is incorporated into the Product or its manufacture.

11. WARRANTIES.

11.1 The Parties General Warranties. Each Party warrants and represents that: (i) it has the corporate power and authority to enter into this MSA and has taken all necessary action on its part required to authorize the execution, delivery and performance of this MSA; (ii) it is aware of no legal, contractual or other restriction, limitation or condition that might adversely affect its ability to enter into this MSA and perform its obligations hereunder and it will not, during the Term, agree to any legal, contractual or other restriction, limitation or condition that might adversely affect its ability to perform its obligations hereunder; (iii) it is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (iv) this MSA (a) has been duly executed and delivered by a duly authorized representative of it, and (b) is the legal, valid and binding obligation of it, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally; and (v) the execution, delivery and performance of this MSA by it does not and will not (a) violate any Applicable Laws applicable to it, or (b) violate or conflict with any provision of its Articles of Incorporation or By-laws or other organizational documents.

11.2 Client's Warranties. Client represents and warrants to SBL that as of the Effective Date of the MSA and during the Term: (a) the formulation, composition, use, distribution, marketing, or sale of the Product shall comply with all Applicable Laws and that, during the Term, Client will perform all obligations and take other necessary actions to be in compliance with such requirements, Applicable Laws, rules and regulations, including applicable cGMPs; (b) Client will comply with all Applicable Laws, and that it will keep SBL informed of any information known to Client which would affect SBL's provision of the Service hereunder; (c) all Client Technology, Client Materials, and Cell Line provided to SBL by or on behalf of Client will be [* * *]; and (d) to the best of its knowledge, SBL's use of the Client Materials, Manufacturing Process, and Client Technology [* * *] will not infringe any third party's Intellectual Property rights.

11.3 SBL's Warranties. SBL represents and warrants that:

11.3.1 As of the Effective Date and during the Term, (i) SBL is the lawful owner, lessee, operator, or licensee of the Facility, equipment, machinery, as well as permissions required, to enable SBL to perform its obligations under this MSA, and (ii) to the best of SBL's knowledge, none of the SBL Inventions or SBL Background IP infringes any third party Intellectual Property Right.

11.3.2 All Product Batches, at the time of delivery to Client's designated carrier, shall (a) be Manufactured, packaged, handled and stored in compliance with the requirements of cGMPs (except for Pilot Batches and Engineering Batches which are not meant to be Manufactured under cGMP), the applicable PSA, the QAG, and all Applicable Laws; (b) comply with the [* * *]; and (c) be transferred free and clear of any liens, claims or encumbrances of any kind.

11.3.3 It will assign to the performance of Services, professional personnel qualified to perform the activities set forth in a PSA and otherwise in connection with this MSA in a manner consistent with the technical requirements of such PSA.

11.3.4 Neither SBL nor any person employed or used by SBL has been debarred under § 306(a) or§ 306(b) of the Federal Food, Drug and Cosmetic Act (codified at 21 U.S.C. § 335(a) and (b)) and that no debarred person will in the future be employed or used by SBL to perform any Services or any other activities in connection with this MSA. Neither SBL nor any person employed or used by SBL has a conviction on their record for which a person can be debarred as described in§ 306(a) or § 306(b) of the Federal Food, Drug and Cosmetic Act. SBL further represents and warrants that should SBL or any person employed by SBL be convicted in the future, of any act for which a person can be debarred as described in§ 306(a) or§ 306(b) of the Federal Food, Drug and Cosmetic Act, SBL shall immediately notify of such conviction.

11.3.5 Each Certificate of Analysis will accurately reflect the results of the tests conducted on the Batch of Product to which it relates, each Certificate of Compliance will be accurate and true, and the Batch Records will accurately reflect in all material respects the processes and procedures followed by SBL in Manufacturing the applicable Product.

11.3.6 It will not transfer to any third party any Client Materials or Products Manufactured for Client, other than (i) for the purpose of tests at any testing lab as permitted under this MSA, including Sections 4.6.3 and 4.7.3, (ii) to a designee of Client, or (iii) to any subcontractor in accordance with Section 3.4.

11.3.7 It has obtained (or will obtain prior to Manufacturing Product), and will remain in compliance with during the Term, all permits, licenses, and other authorizations which are required under Applicable Laws for its performance of this MSA.

11.4 No Other Warranties. THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS MSA ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND THE PARTIES HEREBY EXPRESSLY DISCLAIM AND NEGATE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED (ARISING BY OPERATION OF LAW OR OTHERWISE), INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, EVEN IF THAT PURPOSE IS KNOWN.

12. INDEMNIFICATION AND INSURANCE

12.1 Indemnification by SBL. SBL shall indemnify and hold harmless Client, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude Client Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands, or actions based upon [* * *], except to the extent that such Damages are caused by the causes as set forth in Section 12.2 for which Client is obliged to indemnify.

12.2 Indemnification by Client. Client shall indemnify and hold harmless SBL, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude SBL Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands or actions based upon (i) gross negligence or willful misconduct of Client or its officers, directors, employees or agents, (ii) any product liability claims related to manufacture, sale, or distribution of Products that have been accepted by Client under Section 4.12.2, or (iii) any claim that [* * *] pursuant to the MSA or any PSA (including but not limited to use of the Client Materials, Manufacturing Process and Client Technology, [* * *]) infringes any third party's Intellectual Property rights (excluding any infringement based upon any SBL Inventions or SBL Background IP); in each case (i), (ii) and (iii) except to the extent that such Damages are caused by the causes as set forth in Section 12.1 for which SBL is obliged to indemnify.

12.3 Indemnification Procedure. The foregoing indemnification by SBL or Client shall be conditioned, if and to the extent Damages are based on or related to a third party claim, upon a Party who intends to claim indemnification under Sections 12.1 and 12.2 (the "***Indemnified Party***") (i) providing written notice to the other Party ("***Indemnifying Party***") within [* * *] days after the Indemnified Party have been given written notice of such third party claim, provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim; (ii) permitting the Indemnifying Party, upon timely notice by the Indemnified Party, the opportunity to assume full responsibility (at the Indemnifying Party's cost and expense) for the investigation and defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, provided, however, that the Indemnifying Party shall keep the Indemnified Party informed as to the progress of the defense of any claim and that the Indemnified Party shall cooperate in such defense and shall make available all records, materials and witness reasonably requested by the Indemnifying Party in connection therewith; and (iii) not settling or compromising any such claim without the Indemnifying Party's prior written consent, with such consent not to be unreasonably denied, withheld or conditioned.

12.4 Insurance. Both Parties shall obtain and maintain insurance coverage (whether through purchasing policies, self-insurance, or a combination of both) appropriate to cover their respective liabilities under this MSA, which level of coverage shall be reasonably similar to that of a company in such Party's industry of similar size and activity.

13. DISCLAIMER OF CONSEQUENTIAL DAMAGES; LIMITATION OF LIABILITY

13.1 Disclaimer of Consequential Damages. NEITHER PARTY WILL BE LIABLE FOR ANY SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR OTHER INDIRECT DAMAGES OF ANY TYPE OR NATURE, WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUES.

13.2 Limitation of Liability. Except as set forth in Section 13.3, each Party agrees that the other Party's aggregate total liability in respect of any Damages arising under or in connection with this MSA or a PSA (whether in contract, tort, negligence, or otherwise however arising) shall be capped at an amount equal to (i) [* * *], and (ii) [* * *].

13.3 Exclusions from Limitation of Liability. Notwithstanding anything contained herein to the contrary, on a claim-by-claim basis, each Party's liability to the other Party for (i) indemnification obligations under Section 12, (ii) [* * *], or (iii) breach of its confidentiality obligations under Section, shall be capped at an amount equal to (x) [* * *], and (y) [* * *].

14. TERM AND TERMINATION OF AGREEMENT

14.1 Term. This MSA will become effective as of the Effective Date and will be in effect for as long as a PSA is in effect. Each PSA will have its own initial term as stated therein and shall automatically renew for successive terms of [* * *] years each unless either Party gives written notice to the other Party of its intention to terminate the Product Service Agreement at least [* * *] months prior to the end of the then current PSA term.

14.2 Termination. This MSA or a PSA may be earlier terminated as set forth in this Section 14.2.

14.2.1 Material Breach. A Party may terminate any PSA for a material breach by the other Party; provided, however, that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party fails to commence Commercially Reasonable Efforts to cure that breach within [* * *] days after receipt of such written notice, then the non-breaching Party may terminate the PSA on [* * *] days written notice after expiration of such [* * *] day period. This MSA shall terminate if all effective PSAs are terminated.

14.2.2 Insolvency. This MSA may be terminated by either Party upon written notice at any time during the MSA if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

14.2.3 Force Majeure. Either Party may terminate a PSA if a Party is unable to perform its obligations pursuant to a PSA in the event of a Force Majeure Event in accordance with Section 16.3.

14.2.4 Other Specified Events. The Parties may additionally terminate a PSA as set forth in the applicable PSA.

14.2.5 Clinical Exit. Client may have an option to terminate a PSA based on Clinical Exit if such an option is expressly provided in such PSA.

14.3 Effect of Expiration or Termination.

14.3.1 Payment of Amounts Due. Expiration or termination of the MSA or PSA for any reason shall not exempt either Party from paying to the other Party any amounts owing at the time of such expiration or termination.

14.3.2 Survival. Any termination or expiration of this MSA shall not affect any outstanding obligations due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the Parties may have under this MSA. For greater certainty, except as otherwise expressly provided, termination or expiration of this MSA, irrespective of the cause, shall not affect any rights or obligations which, from the context thereof, are intended to survive termination or expiration of this MSA, including but not limited to Sections 8, 9, 10, 11, 12, 13, 14, 15, and 16.

14.3.3 Effect of Termination. Upon termination of a PSA for any reason, SBL shall cease and refrain from the Services described in any applicable PSA (including the Manufacturing and supplying the Product) for Client unless otherwise provided in this Section 14.3.3, and both Parties shall pursue decommissioning activities as set forth hereunder:

(a) Settlement of Payment. SBL shall be compensated no later than [* * *] days after a termination for:

(i) all undisputed Service Fees incurred up to the date of termination including the undisputed Service Fees for completing the Manufacture of Product-in-process, subject however to Section 14.3.3(b) below;

(ii) all costs incurred through the date of termination, including the costs of procuring Raw Materials used or purchased for use in connection with Services; and

(iii) any unreimbursed procurement fee of additional equipment that SBL has purchased on behalf of Client pursuant to Section 4.4.

(b) Delivery. Unless [* * *] , SBL shall continue Manufacturing Product-in-process as of the date of termination and deliver the fully manufactured Product to Client in accordance with the schedule then agreed upon by the Parties. As soon as practically possible after the termination and provided that [* * *], SBL shall deliver to Client and Client shall accept (1) any Raw Material purchased for use in connection with Services, (2) any Client Material then in possession of SBL; provided however that the Parties may mutually agree instead to destroy or discard such Raw Material or Client Material, in which case SBL shall promptly destroy or dispose of the same without making any further use of such materials. Any costs incurred in connection with such a delivery or destruction, as the case may be, shall be borne by the Party responsible for termination in accordance with (c) and (d) below; provided that, for all other cases, the Parties shall negotiate in good faith the allocation of all such costs and expenses.

(c) Termination by SBL pursuant to Sections 14.2.1 or 14.2.2. In the event of termination by SBL pursuant to Section 14.2.1 or Section 14.2.2, the outstanding binding obligations to purchase Product as of the date of termination shall survive termination of such PSA, including but not limited to a Firm Period, Binding Forecast, Purchase Order, and Product Purchase Commitment, and the Client shall be responsible for the costs incurred in connection with delivery or disposal of Raw Materials, Client Material, or equipment during decommissioning activities.

(d) Termination by Client pursuant to Sections 14.2.1 14.2.2 or 14.2.5. In the event of termination by Client pursuant to Section 14.2.1 or Section 14.2.2 or Section 14.2.5, Client shall be released from any outstanding binding obligations to purchase Product as of the date of termination including but not limited to any obligation pursuant to a Firm Period, Binding Forecast, Purchase Order, and Product Purchase Commitment, except the decommissioning activities set forth in this Section 14.3.3 of the MSA which shall be binding on both Parties.

(e) Termination by either Party based on Section 14.2.3. Both Parties shall negotiate in good faith and based on industry standards for the handling and delivery of the fully Manufactured Product, Product-in-process, Client Materials, and Raw Materials and the allocation of costs and expenses between the Parties.

14.3.4 Effect of Expiration. Upon expiration of a PSA at the end of the Term or any renewed Term, SBL shall cease and refrain from the Services described in any applicable PSA (including the Manufacturing and supplying the Product), and Section 14.3.3 above shall apply mutatis mutandis, and both Parties shall negotiate in good faith the allocation of related costs and expenses for such decommissioning activities.

15. ARBITRATION

15.1 Informal Discussions. Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this MSA, or the rights or obligations of the Parties hereunder, the Parties shall first try to settle their differences amicably between themselves through the Core Team and then JSC level. Thereafter, either Party may initiate informal dispute resolution on the Executive level by sending written notice of the dispute to the other Party, and within [* * *] days after such notice appropriate Executives of the Parties shall attempt resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said [* * *] days, either Party may refer the matter by written notice to the Chief Executive Officer of the other Party, or his/her designee, and the Chief Executive Officer of such Party, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within [* * *] days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this Article 15.

15.2 Arbitration. If the Parties do not fully settle a dispute pursuant to Section 15.1, and a Party wishes to pursue the matter, each such dispute, controversy or claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the International Chamber of Commerce ("***ICC***"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof to enforce the arbitration award. The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business, and within [* * *] days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [* * *] days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be New York, New York, United States and all proceedings and communications shall be in English. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this MSA, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's direct compensatory damages, and in all cases, any decision or determination by the arbitrators shall comply with Article 14, as applicable. The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this MSA, neither Party may terminate this MSA until final resolution of the dispute through arbitration or other judicial determination.

15.3 Costs and Fees. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators. Absent the filing of an application to correct or vacate the arbitration award as permitted by Applicable Law, each Party shall fully perform and satisfy the arbitration award within [* * *]days after the service of the award on such Party.

16. MISCELLANEOUS

16.1 Notices. Any notice required or permitted under the MSA shall be in writing with duly authorized signature and made to the following addresses:

If to Client:

Immunovant Sciences GmbH
Viaduktstrasse 8
4051 Basel, Switzerland
Attention: Legal Department

With a copy to:

Immunovant, Inc.
320 West 37th Street, 6th Floor
New York, NY 10018
Attention: Legal Department

If to SBL:

Samsung Biologics Co., Ltd.
300, Songdo bio-daero, Yeonsu-gu
Incheon 21987, South Korea
Attention: SBL Legal Team

Either Party may change its designated address by notice to the other Party in the manner provided in this Section 16.1.

Any notice shall be deemed to have been delivered on the date of delivery if delivered personally, or on the third day after being delivered by a national or internationally recognized overnight or two-day courier service, or on the fifth day of posting if sent by registered or certified mail with return receipt requested and postage prepaid.

16.2 Governing Law. This MSA shall be construed and interpreted in accordance with the laws of State of New York, United States and all rights and remedies shall be governed by such laws without regard to principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by the MSA.

16.3 Effect of Force Majeure Event. A Party shall be excused from performing its obligations under this MSA if its performance is delayed or prevented by a Force Majeure Event; provided that such performance shall be excused only to the extent of and during such disability and the Affected Party shall use Commercially Reasonable Efforts to resume performance as soon as reasonably practicable and minimize the loss or inconvenience suffered by the Parties.

Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under the MSA. Any time specified for completion of performance in PSA and falling during or subsequent to the occurrence of any or all such events shall be automatically extended for a commercially reasonable period of time to enable the Affected Party to recover from such disability. If a condition constituting Force Majeure Event as defined herein exists for more than [* * *] consecutive days, the Parties shall negotiate a mutually satisfactory solution to the problem, if practicable, including termination of this MSA or the impacted PSA(s) upon [* * *] consecutive days, written notice from the failure of reaching a mutually satisfactory solution to the Force Majeure Event, or the use of a third party to fulfill the obligations hereunder of the party invoking Force Majeure Event, at the expense of the party invoking Force Majeure Event.

16.4 Assignment.

16.4.1 This MSA and all rights and obligations hereunder may not be Assigned or transferred by either Party, by operation of law or otherwise, without the express prior written consent of the other Party, which shall not be unreasonably withheld; provided that Client may assign this MSA to an Affiliate or in connection with the sale of substantially all of the assets related to the Products. For clarity, withholding consent in the event of the potential assignee's refusal to agree in writing to assume all rights and obligations under this MSA or a PSA shall not be deemed unreasonable. Any attempted Assignment in violation of this Section shall be deemed null and void for all purposes.

16.4.2 In the event of an Assignment, the Party Assigning this MSA or all rights and obligations hereunder shall be responsible for any and all additional costs and expenses incurred as a result of such an Assignment, including but not limited to any additional Services that need to be performed by SBL.

16.5 No Grant of License. Nothing in the MSA shall affect, or grant any right to, patents, know-how or other Intellectual Property owned by either Party prior to the commencement of the MSA unless otherwise expressly provided in the MSA.

16.6 No Right to Use Names. Except as expressly provided herein, no right, expressed or implied, is granted by the MSA to use in any manner the name of either of the Parties or any other trade name, symbol, logo or trademark of the other Party in connection with the performance of the MSA, without the prior written consent of the other Party.

16.7 Independent Contractors. The Parties hereto are independent contractors and nothing contained in the MSA shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

16.8 Integration. This MSA constitutes the entire agreement between the Parties relating to the subject matter of the MSA and supersedes all previous oral and written communications between the Parties with respect to the subject matter of the MSA, excluding the MDSA.

16.9 Decision Memo; Amendment; Waiver. A Decision Memo may be entered into by the Core Teams or JSCs with a binding effect, with it being understood that, in the event of a conflict between a Scope of Work, or Decision Memo and a later executed Decision Memo, the later executed Decision Memo shall prevail. Except as otherwise expressly provided herein, no alteration of or modification to the MSA shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of the MSA in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of the MSA may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver.

16.10 Corporate Policy. SBL acknowledges that the corporate policy of Client requires that Client's business must be conducted within the letter and spirit of the law. By signing this MSA, SBL agrees to conduct the Services contemplated herein in a manner that is consistent with both Applicable Laws and good business ethics.

16.10.1 In connection with SBL's performance of Services hereunder, SBL shall not make any payment, either directly or indirectly, of money or other assets, including but not limited to the compensation SBL derives from this MSA (hereinafter collectively referred as a "***Questionable Payment***"), to government or political party officials, officials of public international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "***Officials***") where such payment would constitute violation of any Applicable Law. In addition, regardless of legality, SBL shall make no payment either directly or indirectly to Officials if such payment is for the purpose of influencing decisions or actions with respect to the subject matter of this MSA or any other aspect of the business of Client.

16.10.2 The failure of SBL to abide by the provisions of this Section 16.10 shall be deemed a material breach of this MSA.

16.11 Severability. The Parties do not intend to violate any Applicable Law. However, if any sentence, paragraph, clause or combination of the MSA is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall be deleted and the remainder of the MSA shall remain binding, provided that such deletion does not alter the basic purpose and structure of the MSA and if deletion of such provision materially alters the basis of this MSA, then the Parties shall negotiate a good faith alternative.

16.12 Construction. The Parties mutually acknowledge that they have participated in the negotiation and preparation of the MSA. Ambiguities, if any, in the MSA shall not be construed against any Party, irrespective of which Party may be deemed to have drafted the MSA or authored the ambiguous provision.

16.13 Interpretation. The captions and headings to the MSA are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of the MSA. Unless context otherwise clearly requires, whenever used in the MSA: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”; (b) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to the MSA; (c) all references to the word “will” are interchangeable with the word “shall” and shall be understood to be imperative or mandatory in nature. All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters, or calendar years. Whenever any matter hereunder requires consent or approval, such consent or approval shall not be unreasonably withheld or delayed.

16.14 Counterparts. This MSA may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[**Signatures on Following Page**]

In Witness Whereof, the Parties have executed the MSA as of the date first above written.

IMMUNOVANT SCIENCES GMBH

Signature: /s/ Nandini Devi
Name: Nandini Devi
Title: Sole Signatory
Date: April 29, 2021

SAMSUNG BIOLOGICS CO., LTD.

Signature: /s/ John Rim
Name: John Rim
Title: Representative Director and President
Date: May 5, 2021

CERTAIN PORTIONS OF THIS EXHIBIT (INDICATED BY ***) HAVE BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K BECAUSE THEY ARE BOTH NOT MATERIAL AND ARE THE TYPE THAT THE COMPANY TREATS AS PRIVATE AND CONFIDENTIAL.

SAMSUNG BIOLOGICS CO., LTD.

PRODUCT SERVICE AGREEMENT — COMMERCIAL PRODUCT DRUG SUBSTANCE

This Product Service Agreement (this " ***PSA***") is made effective as of the date of last signature below (the " ***PSA Effective Date***") by and between Immunovant Sciences GmbH a Swiss limited company with offices at Viaduktstrasse 8, 4051 Basel, Switzerland ("***Client***") and Samsung Biologics Co., Ltd., a Korean corporation having its principal place of business at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea ("***SBL***"). Client and SBL are sometimes referred to herein individually as a "***Party***" and collectively as the " ***Parties***".

WHEREAS, Client and SBL entered into a Master Services Agreement effective April 30, 2021 (the " ***MSA***") and whereas pursuant to Section 2.1 of the MSA, the Parties wish to enter into this PSA whereby SBL will provide certain Services for Commercial Product as detailed herein;

NOW, THEREFORE, the Parties agree as follows:

1. Relationship to the MSA. All capitalized terms not defined in this PSA will have the meanings given to them in the MSA. This PSA is hereby incorporated by reference into the MSA.

2. Definitions

(a) "***Annual Forecast***" is Client's annual projection of its requirement for delivery of Commercial Product during each Year. For the avoidance of doubt, the Parties acknowledge and agree that while the PPQ Batches and PAI Batches may be used for commercial purposes, they are excluded from any Annual Forecast.

(b) "***Campaign***" shall mean a series of Batches of the Product that are produced in sequence using the same manufacturing equipment (including but not limited to the same bioreactor) followed by validated cleaning of such equipment and purification suite, and for the purposes of counting the number of Product Batches in a Campaigns in a given period, the start date of such Campaign shall be the determining factor. A Campaign will be deemed to end upon the completion of such cleaning.

(c) "***Firm Period***" means the first [* * *] of Annual Forecast, during which period the Forecast shall be one-hundred percent (100%) firm and binding on both Parties.

(d) "***New Batch***" means Batches of Commercial Product that are requested to be delivered in a new Year entering the Firm Period of Annual Forecast. For the avoidance of doubt, for the very first Annual Forecast, all the Batches in the Firm Period of the Annual Forecast shall be considered New Batch(es).

(e) "***Product Purchase Commitment Shortfall***" means the number of Batches of Commercial Product falling short of the Product Purchase Commitment.

(f) "***Year***" means each one (1) year period that begins on January 1 and ends on December 31.

3. General Information.

(a) **Scope**: [* * *] PPQ Batches OOF in [* * *], [* * *] PAI Batches OOF in [* * *], and Commercial Product Batches. PPQ Batches and PAI Batches are intended for commercial use. The aforementioned timeline for PPQ and PAI Batches are estimates only and may change based on the Parties' mutual agreement.

(b) **Commercial Product**: IMVT-1401 Commercial Drug Substance.

(c) **Commercial Product Specification**: The Product Specification is established in Facility as of the Effective Date. Product Specification will be finalized by Client prior to Client's BLA submission to the Regulatory Authority.

(d) **Cell Line**: [* * *]

(e) **Manufacturing Facility**: [* * *].

4. **Raw Materials.**

(a) **Client Materials**. Client Materials to be supplied by Client to SBL free of charge by itself or a third party designee.

(i) **List**: See Exhibit A: Client Materials

(ii) **Handling Fee**:

(1) Cell Line: [***].

(2) Other Raw Materials delivered by Client: [* * *] of the invoice of third party suppliers from whom Client purchased the Raw Materials.

(iii) **Timing of provision of Client Materials to SBL**: sufficiently in advance of Manufacturing, the exact timing of which to be reasonably agreed upon by the Parties.

(b) **Raw Materials**. As set forth in Section 4.6.1 of the MSA, the Parties shall finalize the categorization of Raw Materials to be used in performing the Services of this PSA into (i) Critical Raw Materials, (ii) Dedicated or Customized Raw Materials, and (iii) Other Raw Materials, which list shall form part of this PSA as Exhibit B.

(i) **Handling Fee for Customized or Dedicated Raw Materials and Other Raw Materials to be procured by SBL at Client's expense**: [* * *].

(ii) **Handling Fee for Critical Raw Materials to be procured by SBL at Client's expense** : [* * *].

5. **Technology Transfer, Manufacturing, and Supply Services**. SBL shall perform the Services as set forth in this Section 5.

(a) **Services**.

(i) SBL shall provide the Services as set forth in the Scope of Work (Exhibit E) at the Service Fees set forth in Exhibit D. If any Service or Manufacture reasonably cannot be performed without [* * *] , SBL shall not [* * *].

(ii) **Fees and invoicing**.

(1) Services shall be invoiced upon completion of activities by SBL, or as otherwise agreed by the Parties.

(2) Batches of Commercial Product shall be invoiced according to Section 8.2.1 of the MSA.

(b) **Service Fees**. In consideration for SBL's performance of the Services pursuant to this Section 5, Client shall pay the Service Fees as set forth in Exhibit D. Additional Service Fees and costs may be detailed in an amendment to this PSA or in accordance with the MSA.

(c) **Excess Production**. If, in the course of manufacturing pursuant to a Client Purchase Order, SBL manufactures more than the amount ordered in the Client's Purchase Order due to the mutually agreed manufacturing plan, such additional Batches shall be purchased by Client as if manufactured pursuant to the Purchase Order.

(d) **Forecasts / Purchase Orders**

(i) **Annual Forecast**.

(1) Each Year of the PSA term, Client shall provide to SBL [* * *] Annual Forecast at least by the [* * *]. The first Annual Forecast shall be provided by [* * *] as the Annual Forecast does not include [* * *]. Upon receipt, SBL shall provide a written confirmation of acceptance or rejection with comments on the Annual Forecast within [* * *] days of receipt; provided that in the event SBL does not reject the Annual Forecast in writing prior to the expiration of such [* * *] day period, then the Annual Forecast shall be deemed accepted by SBL. Upon SBL's acceptance, the Firm Period shall be one-hundred percent (100%) firm and binding as to the total number of Batches of Commercial Product that are to be delivered in each Year of the Firm Period. The [* * *] of each Annual Forecast shall be partially binding on Client as follows: when the [* * *] of any Annual Forecast[* * *] of the next Annual Forecast, such [* * *]of the previous Annual Forecast, rounded up to the nearest Batch, and provided that so long as [* * *] is between these parameters [* * *] . By way of example, if Client submits an Annual Forecast [* * *].

(2) Each Annual Forecast issued by Client shall be consistent with the Product Purchase Commitment in Section 5(e) of this PSA and the previously issued Annual Forecast in terms of Batches of Commercial Product forecasted for each Year falling in the Firm Period.

(ii) Notwithstanding anything to the contrary, upon Client's written request, SBL shall use Commercially Reasonable Efforts to Manufacture Batches in excess of the number of Batches set forth in any Firm Period subject to SBL's existing commitments.

(1) Each time Client submits an Annual Forecast to SBL pursuant to Section 5(d)(i), SBL and Client shall discuss in good-faith the Manufacturing schedule for each New Batch; provided however that, Annual Forecast shall only specify which Year Client wishes for such Batches to be delivered and, notwithstanding anything to the contrary, SBL shall only be obligated to Manufacture and deliver the Batches at any time at SBL's discretion within the Year without any obligation to meet a more specific timeline such as a specific date, week, month, or quarter within such Year. The Parties shall discuss in good-faith for up to [* * *] days and shall agree upon a manufacturing schedule for the Year for the New Batches covered by the Annual Forecast, upon which Client shall issue a binding Purchase Order for each New Batch, consistent with the Parties' agreement and Annual Forecast. The Purchase Order shall detail the Batch requested, and estimated delivery date(s) for such Batch, which delivery date shall be non-binding and for information purpose only, subject to the first sentence of this Section 5(d)(ii)(1), and finalized upon SBL's release of the Batch pursuant to Section 4.12 of the MSA.

(2) When deciding a manufacturing schedule for the New Batches, the Parties agree that (a) all Manufacturing shall be on [* * *] basis as more specifically illustrated in the "***Maximum number of Campaigns***" in Exhibit F, and (b) if the number of Campaigns exceeds the " ***Maximum number of Campaigns***" in Exhibit F, then Client will be subject to a changeover fee of [* * *] per additional Campaign during the specified timeframe; provided, however, that no changeover fee shall be charged if an additional Campaign per Year is required due to [* * *]. If the Parties agree to add additional Batches to a Campaign that was already scheduled pursuant to a previous Annual Forecast, Client shall re-issue the previously issued Purchase Orders to align with such new agreement.

(e) Purchase Commitments.

(i) Purchase Commitments under this PSA shall be as follows :

(1) Upon execution of this PSA, Client shall issue a Purchase Order for [* * *] which shall be fully binding on a minimum take or pay basis.

(2) Notwithstanding anything to the contrary, during every other Year between 2026-2029, both inclusive, Client shall pay SBL, on a minimum take or pay basis, for the greater of (a) [* * *] as set forth in Exhibit F and (b) [* * *]. For the avoidance of doubt, Client shall place an order for and SBL shall Manufacture [* * *]. For the avoidance of doubt, [* * *].

(ii) Each Year or every other Year, as the case may be, Client shall pay to SBL the price set forth in this PSA for each of the Product Purchase Commitment Shortfall, if any. For any Year for which a Product Purchase Commitment Shortfall payment is owed to SBL, such payment shall be made within [* * *] days of Client's receipt of the applicable invoice which shall be issued by SBL to Client shortly after either: (a) on [* * *] of such Year if Client notifies SBL prior to such Year that there will be a Product Purchase Commitment Shortfall, or (b) on [* * *] of the Year when there is a Product Purchase Commitment Shortfall for such Year.

6. Regulatory Approvals. The Regulatory Approvals covered by this PSA are FDA, EMA, MHRA, Health Canada, PMDA, and NMPA. If Regulatory Approval from any additional Regulatory Authorities are needed, both parties shall discuss and evaluate.

7. Storage. Pursuant to Section 4.12 of the MSA, if Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within [* * *] days of Client's receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse and Client shall pay storage fees to SBL for the period of storage at the Warehouse until the actual delivery date which shall be no longer than [* * *] days after Client's receipt of the Batch Related Documents. Storage fees shall be as follows:[* * *].

8. Clinical Exit. By no later than January 2024, Client shall have the right to exercise Clinical Exit under this PSA by notifying SBL in writing of such Clinical Exit and terminate this PSA upon 30 days' notice, in which case Client shall be fully liable for (i) reasonable non-cancellable Service Fees and costs (including raw materials and equipment, if any, purchased by SBL on Client's behalf) incurred by SBL until the PSA termination date and (ii) all batches of Product scheduled to be manufactured in the two (2) years period after the termination of this PSA regardless of whether such manufacturing slots are utilized or not**.**

9. Term. This PSA will commence as of the PSA Effective Date and will continue in full force and effect until the later of December 31, 2029 and completion of the Services stated in this PSA, unless earlier terminated in accordance with the termination provisions of this PSA and/or the MSA.

The Parties have entered into this PSA as of the PSA Effective Date by their respective duly authorized representatives.

Samsung Biologics Co., Ltd.
By: /s/ John Rim

Name: John Rim

Title: Representative Director & President

Date: November 17, 2021

Immunovant Sciences GmbH
By: /s/ Christian Mauriand

Name: Christian Mauriand

Title: Managing Director

Date: November 11, 2021

Exhibit A: Client Materials

[* * *]

Exhibit B: Categorization of Raw Materials

[* * *]

Exhibit C — Estimated Timeline

[* * *]

Exhibit D: Services Fees

[* * *]

Exhibit E: Scope of Work

[* * *]

Appendix B. Standard Process Validation Study List

[* * *]

Exhibit F: Product Purchase Commitment & Maximum number of Campaigns

[* * *]

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: February 4, 2022

/s/ Peter Salzmann, M.D.
Peter Salzmann, M.D.
Chief 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: February 4, 2022

/s/ Eva Renee Barnett
Eva Renee Barnett
Chief Financial 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 December 31, 2021, 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: February 4, 2022

/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 December 31, 2021, 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: February 4, 2022

/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.