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, 2019

OR

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

For the transition period from to

Commission File Number 001-38906

Immunovant, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**83-2771572**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
320 West 37th Street, 3RD FL New York, NY	**10018**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**IMVT**	**The Nasdaq Stock Market LLC**
Warrants to receive one half of one share of Common Stock	**IMVTW**	**The Nasdaq Stock Market LLC**
Units, each consisting of one share of Common Stock and one Warrant to receive one half of one share of Common Stock	**IMVTU**	**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 and post such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, anon-accelerated filer, smaller reporting company, or an emerging growth company. See the definition 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 14, 2020, there were 56,455,376 shares of common stock, $0.0001 par value per share, issued and outstanding.

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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), SEC filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our stockholders and the public about our company, our product candidates, and other matters. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Immunovant, Inc.
Condensed Combined and Consolidated Balance Sheets
(Unaudited)
(In thousands, except per share data and par value)

	December 31, 2019	March 31, 2019
Assets		
Current assets:		
Cash	$ 123,530	$ 6,985
Prepaid expenses	44	2,632
Income tax receivable	—	49
Value-added tax receivable	2,996	2,913
Total current assets	126,570	12,579
Property and equipment, net	49	54
Deferred offering costs	—	1,195
Total assets	$ 126,619	$ 13,828
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,812	$ 206
Accrued expenses	8,705	6,225
Due to Roivant Sciences Ltd.	3,134	58
Income tax payable	106	—
Total liabilities	14,757	6,489
Commitments and contingencies (Note 10)		
Stockholders' equity:*		
Series A preferred stock, par value $0.0001 per share, 10,000 shares authorized, issued and outstanding at December 31, 2019 and no shares authorized at March 31, 2019	—	—
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and no shares authorized at March 31, 2019	—	—
Common stock, par value $0.0001 per share, 500,000,000 shares authorized, 56,455,376 shares issued and 54,655,376 shares outstanding at December 31, 2019 and 489,066,238 shares authorized, 38,590,381 shares issued and outstanding at March 31, 2019	5	4
Common stock subscribed	—	(3)
Additional paid-in capital	182,679	31,830
Accumulated other comprehensive (loss) income	(147)	346
Accumulated deficit	(70,675)	(24,838)
Total stockholders' equity	111,862	7,339
Total liabilities and stockholders' equity	$ 126,619	$ 13,828

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

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

Immunovant, Inc.
Condensed Combined and Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development (includes $311 and $2,683 of stock-based compensation expense for the three and nine months ended December 31, 2019, respectively, and $198 and $997 of stock-based compensation expense for the three and nine months ended December 31, 2018, respectively)(1)	$ 4,953	$ 7,683	$ 33,759	$ 17,763
General and administrative (includes $1,103 and $2,440 of stock-based compensation expense for the three and nine months ended December 31, 2019, respectively, and $39 and $78 of stock-based compensation expense for the three and nine months ended December 31, 2018, respectively)(2)	6,088	1,201	11,836	1,729
Total operating expenses	11,041	8,884	45,595	19,492
Interest expense	376	—	625	—
Other (income)/expense, net	(221)	(43)	(539)	63
Loss before provision for income taxes	(11,196)	(8,841)	(45,681)	(19,555)
Income tax expense	100	8	156	12
Net loss	$ (11,296)	$ (8,849)	$ (45,837)	$ (19,567)
Net loss per common share – basic and diluted(3)	$ (0.28)	$ (0.24)	$ (1.16)	$ (1.16)
Weighted-average common shares outstanding – basic and diluted(3)	41,035,055	36,735,341	39,408,236	16,815,727

(1) Includes $0 and $152 of costs allocated from Roivant Sciences Ltd. for the three and nine months ended December 31, 2019, respectively, and $475 and $3,209 of costs allocated from Roivant Sciences Ltd. for the three and nine months ended December 31, 2018, respectively.

(2) Includes $487 and $1,001 of costs allocated from Roivant Sciences Ltd. for the three and nine months ended December 31, 2019, respectively, and $637 and $930 of costs allocated from Roivant Sciences Ltd. for the three and nine months ended December 31, 2018, respectively.

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

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

Immunovant, Inc.
Condensed Combined and Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Net loss	$(11,296)	$(8,849)	$(45,837)	$(19,567)
Other comprehensive (loss)/income:				
Foreign currency translation adjustment	(148)	(62)	(493)	79
Total other comprehensive (loss)/income	(148)	(62)	(493)	79
Comprehensive loss	$(11,444)	$(8,911)	$(46,330)	$(19,488)

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

Immunovant, Inc.
Condensed Combined and Consolidated Statements of Stockholders' Equity*
(Unaudited)
(In thousands, except share data)

	Series A Preferred Stock Shares	Series A Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Common Stock Subscribed	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at March 31, 2019	—	$ —	38,590,381	$ 4	$ (3)	$ 31,830	$ 346	$ (24,838)	$ 7,339
Capital contribution – stock-based compensation	—	—	—	—	—	35	—	—	35
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	331	—	—	331
Stock-based compensation		—	—	—	—	537	—	—	537
Foreign currency translation adjustment		—	—	—	—	—	(291)	—	(291)
Net loss	—	—	—	—	—	—	—	(20,059)	(20,059)
Balance at June 30, 2019	—	$ —	38,590,381	$ 4	$ (3)	$ 32,733	$ 55	$ (44,897)	$ (12,108)
Settlement of Common Stock Subscription	—	—	—	—	3	(2)	—	—	1
Capital contribution – stock-based compensation	—	—	—	—	—	18	—	—	18
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	220	—	—	220
Stock-based compensation	—	—	—	—	—	3,119	—	—	3,119
Foreign currency translation adjustment	—	—	—	—	—	—	(54)	—	(54)
Net loss	—	—	—	—	—	—	—	(14,482)	(14,482)
Balance at September 30, 2019	—	$ —	38,590,381	$ 4	$ —	$ 36,088	$ 1	$ (59,379)	$ (23,286)
Conversion of convertible promissory notes	—	—	3,499,995	—	—	35,587	—	—	35,587
Issuance of preferred and common stock, net of deferred offering costs upon Business Combination & Recapitalization (see Note 3)	10,000	—	12,565,000	1	—	109,275	—	—	109,276
Capital contribution – stock-based compensation	—	—	—	—	—	82	—	—	82
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	315	—	—	315
Stock-based compensation	—	—	—	—	—	1,332	—	—	1,332
Foreign currency translation adjustment	—	—	—	—	—	—	(148)	—	(148)
Net loss	—	—	—	—	—	—	—	(11,296)	(11,296)
Balance at December 31, 2019	10,000	$ —	54,655,376	$ 5	$ —	$182,679	$ (147)	$ (70,675)	$ 111,862

* Retroactively restated for reverse recapitalization as described in Note 1.

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

Immunovant, Inc.
Condensed Combined and Consolidated Statements of Stockholders' Equity (continued)*
(Unaudited)
(In thousands, except share data)

	Series A Preferred Stock Shares	Series A Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Common Stock Subscribed	Additional Paid-In Capital	Net Parent Investment	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at March 31, 2018	—	$ —	—	$ —	$ —	$ —	$ (1,658)	$ 161	$ —	$ (1,497)
Net transfers from parent	—	—	—	—	—	—	5,419	—	—	5,419
Foreign currency translation adjustment	—	—	—	—	—	—	—	35	—	35
Net loss	—	—	—	—	—	—	(4,368)	—	—	(4,368)
Balance at June 30, 2018	—	$ —	—	$ —	$ —	$ —	$ (607)	$ 196	$ —	$ (411)
Common stock subscription	—	—	4,890,662	—	—	—	—	—	—	—
Balance at July 6, 2018 (date of formation)	—	$ —	4,890,662	$ —	$ —	$ —	$ (607)	$ 196	$ —	$ (411)
Common stock subscription	—	—	31,789,305	3	(3)	—	—	—	—	—
Transfer to Accumulated Deficit	—	—	—	—	—	—	607	—	(607)	—
Cash contribution	—	—	—	—	—	7,021	—	—	—	7,021
Capital contribution – stock-based compensation	—	—	—	—	—	481	—	—	—	481
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	1,472	—	—	—	1,472
Stock-based compensation	—	—	—	—	—	1	—	—	—	1
Foreign currency translation adjustment	—	—	—	—	—	—	—	106	—	106
Net loss	—	—	—	—	—	—	—	—	(6,350)	(6,350)
Balance at September 30, 2018	—	$ —	36,679,967	$ 3	$ (3)	$ 8,975	$ —	$ 302	$ (6,957)	$ 2,320
Issuance of common stock, net	—	—	1,273,609	1	—	9,767	—	—	—	9,768
Roivant cash contribution	—	—	—	—	—	3,973	—	—	—	3,973
Capital contribution – stock-based compensation	—	—	—	—	—	225	—	—	—	225
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	—	—	575	—	—	—	575
Stock-based compensation	—	—	—	—	—	12	—	—	—	12
Foreign currency translation adjustment	—	—	—	—	—	—	—	(62)	—	(62)
Net loss	—	—	—	—	—	—	—	—	(8,849)	(8,849)
Balance at December 31, 2018	—	$ —	37,953,576	$ 4	$ (3)	$ 23,527	$ —	$ 240	$ (15,806)	$ 7,962

* Retroactively restated for reverse recapitalization as described in Note 1.

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

Immunovant, Inc.
Condensed Combined and Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended December 31,	
	2019	2018
Cash flows from operating activities		
Net loss	$ (45,837)	$(19,567)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,123	1,074
Depreciation expense	15	5
Unrealized currency translation adjustment	(493)	79
Loss on disposal of property and equipment	13	—
Gain on extinguishment of convertible notes payable	(38)	—
Write-off of deferred offering costs	1,628	—
Changes in operating assets and liabilities:		
Prepaid expenses	2,591	(579)
Income tax receivable	49	(56)
Value-added tax receivable	(83)	(2,943)
Accounts payable	2,604	(816)
Accrued expenses	3,827	3,935
Due to Roivant Sciences Ltd.	188	2,970
Income tax payable	106	—
Net cash used in operating activities	(30,307)	(15,898)
Cash flows from investing activities		
Purchase of property and equipment	(21)	(52)
Net cash used in investing activities	(21)	(52)
Cash flows from financing activities		
Capital contributions	866	13,041
Net parent investment	—	5,064
Proceeds from issuance of common stock	—	10,000
Payment of deferred offering costs	(2,917)	(52)
Proceeds from notes payable to Roivant Sciences Ltd.	7,907	—
Repayment of convertible promissory note payable to Roivant Sciences Ltd.	(2,500)	—
Proceeds from convertible promissory notes payable	35,000	—
Repayment of convertible promissory notes payable	(2,500)	—
Settlement of common stock subscribed	1	—
Recapitalization transaction	111,016	—
Net cash provided by financing activities	146,873	28,053
Net change in cash	116,545	12,103
Cash – beginning of period	6,985	—
Cash – end of period	$123,530	$ 12,103
Non-cash investing and financing activities		
Purchase of property and equipment in accounts payable and amounts due to Roivant Sciences Ltd.	$ 3	$ 13
Reclassification of net parent investment to accumulated deficit	$ —	$ 607
Conversion of convertible promissory notes to common stock	$ 35,000	$ —
Common stock issuance costs in accrued expenses	$ —	$ 232
Deferred offering costs in accrued expenses	$ 574	$ 590
Cancellation of interest on convertible promissory notes recorded in equity	$ 587	$ —

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

Immunovant, Inc.
Notes to Condensed Combined and Consolidated Financial Statements
(Unaudited)

Note 1 — Description of Business and Liquidity

[A] Description of Business

Immunovant, Inc. together with its wholly owned subsidiaries (the "Company" or "Immunovant") (formerly known as Health Sciences Acquisitions Corporation) is a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. The Company is developing a fully human monoclonal antibody ("IMVT-1401") that selectively binds to and inhibits the neonatal fragment crystallizable receptor. The Company intends to develop IMVT-1401 for indications in which there is robust evidence that pathogenic immunoglobulin G antibodies drive disease manifestation and in which reduction of these antibodies should lead to clinical benefit for patients with debilitating autoimmune diseases.

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

Reverse Recapitalization

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

The Business Combination was accounted for as a reverse recapitalization and HSAC was treated as the "acquired" company for accounting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of ISL issuing stock for the net assets of HSAC, accompanied by a recapitalization. Accordingly, all historical financial information presented in these condensed combined and consolidated financial statements represents the accounts of ISL and its wholly owned subsidiaries "as if" ISL is the predecessor to the Company. The shares and net loss per common share, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (0.48906624 Immunovant, Inc. shares for 1.0 ISL Share).

ISL was founded on July 6, 2018 as a Bermuda exempted limited company and a wholly owned subsidiary of RSL. In July and August 2018, ISL incorporated as its wholly owned subsidiaries, Immunovant Sciences Holdings Ltd. ("ISHL"), a private limited company incorporated under the laws of England and Wales, IMVT Corporation (formerly, Immunovant, Inc.), a Delaware corporation based in the United States of America, and Immunovant Sciences GmbH ("ISG"), a limited liability company formed under the laws of Switzerland. ISG holds all of the Company's intellectual property rights. HSAC was incorporated in Delaware on December 6, 2018 and was formed as a blank check company for the purpose of effecting a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses. References herein to "date of formation" or "date of inception" refer to the founding of ISL.

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

[B] Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2019, the Company's cash totaled $123.5 million and its accumulated deficit was $70.7 million.

Prior to the Business Combination, ISL's operations were financed through capital contributions from RSL or RSL's wholly owned subsidiaries, Roivant Sciences, Inc. ("RSI") and Roivant Sciences GmbH ("RSG"), the issuance of equity instruments, and the issuance of notes payable. The Company has not generated any revenues to date and does not anticipate generating any revenues unless and until it successfully completes development and obtains regulatory approval for IMVT-1401 or any future product candidate. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

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

Note 2 — Summary of Significant Accounting Policies

[A] Basis of Presentation

The Company's fiscal year ends on March 31. The accompanying interim condensed combined and consolidated balance sheet as of December 31, 2019 and the interim condensed combined and consolidated statements of operations, comprehensive loss, cash flows and stockholders' equity for the three and nine months ended December 31, 2019 and 2018 are unaudited. The unaudited interim condensed combined and consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission ("SEC") for interim 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 interim condensed combined and consolidated financial statements have been prepared on the same basis as the audited combined and consolidated financial statements. 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 interim condensed combined and consolidated financial statements include all the adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's consolidated financial position and the combined and consolidated results of its operations and cash flows for the interim periods presented. The results for the three and nine months ended December 31, 2019 are not necessarily indicative of the results to be expected for the year ending March 31, 2020 or for any future period. The condensed combined and consolidated balance sheet as of March 31, 2019 included herein was derived from the audited financial statements as of that date. These interim condensed combined and consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Company's definitive proxy statement filed with the SEC on November 29, 2019.

Prior to July 6, 2018 (date of formation), the Company's financial statements were derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with product candidate IMVT-1401, that have been contributed to the Company by RSL, from RSL's financial statements. Because the transfer of assets and liabilities in the formation of the Company were between entities under the common control of RSL and/or its wholly owned subsidiaries, the financial statements of the Company have been presented as if the Company had been a separate business since the acquisition of IMVT-1401 by RSG on December 19, 2017. Prior to July 6, 2018 (date of formation), the Company's financial statements include reasonable allocations for assets and liabilities and expenses attributable to the Company's operations. Beginning on July 6, 2018 (date of formation), the condensed combined and consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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

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

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

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

[B] Use of Estimates

The preparation of condensed combined and consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed combined and consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based

compensation, research and development costs and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

[C] Risks and Uncertainties

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

[D] Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash. At December 31, 2019, the cash balance is deposited in one banking institution that the Company believes is of high credit quality and is in excess of federally insured levels. The Company maintains its cash with an accredited financial institution and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses on its cash deposits.

[E] Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. At December 31, 2019, cash consisted of cash in bank deposits held at a financial institution. There were no cash equivalents as of December 31, 2019 or March 31, 2019.

[F] Research and Development Expense

Research and development costs with no alternative future use are expensed as incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of product sales over the remaining useful life of the asset. Research and development expenses primarily consist of employee-related costs and expenses from third parties who conduct research and development activities on behalf of the Company. The estimated costs of research and development activities conducted by third-party service providers, which primarily include the conduct of clinical trials and contract manufacturing activities, are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. The estimate of the work completed is developed through discussions with internal personnel and external services providers as to the progress toward completion of the services and the agreed-upon fee to be paid for such services. As actual costs become known, the accrued estimates are adjusted. Such estimates are not expected to be materially different from amounts actually incurred, however the Company's understanding of the status and timing of services performed, the number of subjects enrolled, and the rate of subject enrollment may vary from estimates and could result in reporting amounts that are higher or lower than incurred in any particular period. The estimate of accrued research and development expense is dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers.

[G] Financial Instruments

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

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

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

The Company's financial instruments consist of cash, accounts payable, accrued expenses and amounts due to Roivant Sciences Ltd. These financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

[H] Foreign Currency

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

[I] Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted-average number of common shares 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 shares 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 shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total common shares 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:

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Preferred stock as converted	10,000	—	10,000	—
Restricted stock (unvested) (See Note 3)	1,800,000	—	1,800,000	—
Options	4,209,573	118,843	4,209,573	118,843
Warrants	5,750,000	—	5,750,000	—
Total	11,769,573	118,843	11,769,573	118,843

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

The shares and net loss per common share, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (0.48906624 Immunovant, Inc. shares for 1.0 ISL Share).

[J] Deferred Offering Costs

Offering costs comprised of legal, and accounting fees and other costs incurred through June 30, 2019 were directly related to ISL's proposed initial public offering ("IPO"). In August 2019, ISL's board of directors determined to suspend ISL's IPO registration process. Accordingly, the Company has written off deferred offering costs previously capitalized to general and administrative expense within the accompanying condensed combined and consolidated statement of operations for the nine months ended December 31, 2019.

[K] Common Stock Warrants

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

The warrants are freestanding financial instruments that are legally detachable from the shares of common stock that were issued at the same time. The warrants are redeemable at the Company's option in certain conditions. The warrants require settlement to be in physical shares of common stock only. The terms of all of the outstanding warrant contracts expressly state there are no requirements for the Company to net cash settle the warrants under any circumstances. Accordingly, the Company has accounted for the warrants as equity instruments.

[L] Recently Adopted Accounting Pronouncements

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

Note 3 — Business Combination and Recapitalization

As discussed in Note 1, on December 18, 2019, HSAC completed the acquisition of ISL and acquired 100% of the ISL Shares in exchange for 42,080,376 shares of HSAC common stock issued to the Sellers and 10,000 shares of HSAC Series A preferred stock issued to RSL. The Business Combination was accounted for as a reverse recapitalization whereby HSAC was treated as the "acquired" company for accounting purposes. This determination was primarily based on the fact that subsequent to the Business Combination, the Sellers have a majority of the voting power of the combined company, ISL will comprise all of the ongoing operations of the combined entity, a majority of the governing body of the combined company, and ISL's senior management will comprise all of the senior management of the combined company. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of ISL issuing stock for the net assets of HSAC, accompanied by a recapitalization. The net assets of HSAC were stated at historical cost with no goodwill or other intangible assets recorded. Reported amounts from operations included herein prior to the Business Combination are those of ISL. The shares, options and net loss per share available to holders of the Company's common stock, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (0.48906624 Immunovant, Inc. shares for 1.0 ISL Share).

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

In connection with the Business Combination, the Company incurred direct and incremental costs of $2.8 million, consisting of legal, accounting, financial advisory and other professional fees, which are included in additional paid-in capital in the condensed combined and consolidated balance sheet as of December 31, 2019. The Company incurred additional financial advisory fees related to the Business Combination of $2.3 million that have been included in general and administrative expense within the accompanying condensed combined and consolidated statement of operations for the three and nine months ended December 31, 2019.

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

Earnout Shares

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

(i) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least $17.50 per share; and

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

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

Sponsor Restricted Stock Agreement

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

Registration Rights

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

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

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

See Note 8 – Stockholders' Equity for details of the Company's capital stock prior to and subsequent to the Business Combination.

Note 4 — Material Agreements

License Agreement

On December 19, 2017, RSG, a wholly owned subsidiary of RSL, entered into a license agreement (the "HanAll Agreement") with HanAll. Under the HanAll Agreement, RSG received (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to develop, import, use and commercialize the antibody referred to as IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, in the United States, Canada, Mexico, the European Union, the United Kingdom, Switzerland, the Middle East, North Africa and Latin America (the "Licensed Territory").

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

- Upfront, non-refundable payment of $30.0 million;
- Up to $20.0 million in shared (50%) research, development, andout-of-pocket costs incurred by HanAll;
- Up to an aggregate of $452.5 million upon the achievement of certain development, regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens on net product sales subject to reduction on aproduct-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 11th anniversary of the first commercial sale of such product in such country.

Since acquisition of IMVT-1401, RSL and the Company have performed all the development associated with IMVT-1401 and no amounts were incurred by HanAll to research or develop the technology for the nine months ended December 31, 2018 and 2019.

On August 18, 2018, RSG entered into a sublicense agreement (the "Sublicense Agreement") with ISG to sublicense this technology, as well as RSG's know how and patents necessary for the development, manufacture or commercialization of any compound or product that pertain to immunology. On December 7, 2018, RSG issued a notice to terminate the Sublicense Agreement with ISG and entered into the Assignment and Assumption Agreement to assign to ISG all the rights, title, interest, and future obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 from RSG in the Licensed Territory, for an aggregate purchase price of $37.8 million. As a result of the assignment of IMVT-1401 by RSG to ISG, the Company recorded a Swiss value-added tax receivable of $2.9 million as of December 31, 2019 and March 31, 2019, respectively, which is reflected as a capital contribution from RSL as of December 31, 2019.

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

Note 5 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2019	March 31, 2019
Research and development expenses	$ 4,136	$ 4,815
Legal and other professional fees	3,592	1,106
Other expenses	977	304
Total accrued expenses	$ 8,705	$ 6,225

Note 6 — Related Party Transactions

In addition to the agreements discussed in Note 4, 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. The condensed combined and consolidated financial statements also include third-party expenses that have been paid by RSI, RSG and RSL since the inception of the Company. Total expense, inclusive of base

salary, fringe benefits and stock-based compensation, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company's matters. For the three and nine months ended December 31, 2019, the Company was charged $0.4 million and $1.0 million, respectively, by RSI, RSG and RSL of which $0.3 million and $0.9 million, respectively, were treated as capital contributions and $0.1 million and $0.2 million, respectively, were treated as amounts due to Roivant Sciences Ltd. in the accompanying condensed combined and consolidated financial statements. For the three and nine months ended December 31, 2018, the Company was charged $0.6 million and $2.0 million, respectively, by RSI, RSG and RSL which were treated as capital contributions in the accompanying condensed combined and consolidated financial statements.

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

On July 17, 2019, the Company entered into an interest-free promissory note payable with RSL in the amount of $2.9 million (the "July Promissory Note"). The July Promissory Note has a 180-day term and is payable on demand upon the expiration of the term. The July Promissory Note along with $0.2 million other payables due to RSL are included in amounts due to Roivant Sciences Ltd. in the accompanying condensed combined and consolidated balance sheet as of December 31, 2019.

Note 7 — Income Taxes

The Company's effective tax rates for the three and nine months ended December 31, 2018 were (0.09)% and (0.06)%, respectively, and for the three and nine months ended December 31, 2019 were (0.90)% and (0.34)%, respectively, driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

Note 8 — 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, 2019.

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

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

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

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

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

In the event of the Company's liquidation, dissolution, or winding up, the holder(s) of the Series A preferred stock will receive first an amount per share equal to $0.01 and then the holders of the Series A preferred stock and the common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of the Company's debts and other liabilities, subject to the rights of any blank check preferred stock then outstanding.

Preferred Stock

In connection with the closing of the Business Combination, the Company authorized 10,010,000 shares of preferred stock par value $0.0001 per share. The board of directors has the authority, without further action by the stockholders to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, voting, and other rights, preferences and privileges of the shares. Other than the 10,000 shares designated Series A preferred stock, there were no issued and outstanding shares of preferred stock as of December 31, 2019.

Common Stock

In connection with the closing of the Business Combination, the Company authorized 500,000,000 shares of common stock, par value $0.0001 per share. Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared by the board of directors since the Company's inception.

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

	December 31, 2019	March 31, 2019
Conversion of Series A preferred stock	10,000	—
Options outstanding	4,209,573	189,269
Options available for future option grants	5,478,728	3,478,728
Common stock warrants	5,750,000	—
Total	15,448,301	3,667,997

Common Stock Warrants

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

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

See Note 3 – Business Combination and Recapitalization for a description of the Company's Earnout Shares and Sponsor Restricted Shares, and related impact on Stockholders' Equity.

Note 9 — Stock-Based Compensation

2019 Equity Incentive Plan

In December 2019, in connection with the Business Combination, the Company's stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") and reserved 5,500,000 shares of common stock for issuance thereunder. The 2019 Plan became effective immediately upon the closing of the Business Combination. The number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on April 1 of each year, beginning on April 1, 2020 and continuing through April 1, 2029, by 4.0% of the total number of shares of common stock outstanding on the last day of the preceding month, or a lesser number of shares as may be determined by the board of directors. The maximum number of shares of common stock that may be issued pursuant to the

exercise of incentive options under the 2019 Plan is 16,500,000. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards under the plan. Generally, each option will have an exercise price equal to the fair market value of the Company's common shares on the date of grant and a ten-year contractual term. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common shares on the date of grant and the option will have a five-year contractual term. Options that are forfeited or expire are available for future grants. As of December 31, 2019, options to purchase 21,272 shares of common stock had been granted under the 2019 Plan and 5,478,728 shares remained available for future grant.

2018 Equity Incentive Plan

In September 2018, ISL adopted its 2018 Equity Incentive Plan (the "2018 Plan"), under which 3,667,997 common shares were reserved for grant. In July 2019, the 2018 Plan was amended and restated to increase the number of common shares reserved for grant to 4,768,396. As discussed in Note 3, upon the closing of the Business Combination, the Company assumed all outstanding options, whether or not vested, under the 2018 Plan, with such options henceforth representing the right to purchase a number of shares of the Company's common stock equal to approximately 0.48906624 multiplied by the number of shares of ISL common stock previously represented by such options. For accounting purposes, however, the Company is deemed to have assumed the 2018 Plan. The exchange of the stock options did not result in any incremental compensation expense, since there were no changes to the vesting terms of the awards. As of the effective date of the 2019 Plan, no further stock awards have been or will be made under 2018 Plan. As of December 31, 2019, 4,188,301 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:

	Options Outstanding			
	Number of options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance – March 31, 2019	189,269	$ 4.12	9.64	$ 707
Granted	4,590,731	$ 8.04		
Cancelled	(570,427)	$ 7.13		
Balance – December 31, 2019	4,209,573	$ 7.86	9.50	$ 33,177
Exercisable – December 31, 2019	169,275	$ 6.93	7.40	$ 1,514

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable stock options and the fair value of the Company's common stock at December 31, 2019. There were no options exercised during the nine months ended December 31, 2019. The options granted during the three and nine months ended December 31, 2019 had a weighted-average fair value of $5.70 and $3.02 per share, respectively, at the grant date.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes option pricing model applying the weighted-average assumptions in the following table:

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Risk-free interest rate	1.61% – 1.78%	2.97%	1.61% – 2.25%	2.97%
Expected term, in years	5.97 – 6.11	6.04	5.75 – 6.11	6.04
Expected volatility	75.55% – 76.01%	74.79%	74.69% – 76.01%	74.79%
Expected dividend yield	— %	— %	— %	— %

For the three and nine months ended December 31, 2019 and 2018, 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,	
	2019	2018	2019	2018
Research and development expenses	$ 311	$ 10	$2,680	$ 11
General and administrative expenses	1,021	2	2,308	2
Total stock-based compensation	$1,332	$ 12	$4,988	$ 13

At December 31, 2019, total unrecognized compensation expense related tonon-vested stock option awards was $20.5 million and is expected to be recognized over the remaining weighted-average service period of 3.40 years. The Company accounts for forfeitures as they occur.

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 $0.1 million was recorded for the three and nine months ended December 31, 2019, respectively, in the accompanying combined and consolidated statements of operations. Stock-based compensation expense of $0.2 million and $1.1 million was recorded for the three and nine months ended December 31, 2018, respectively, in the accompanying combined and consolidated statements of operations.

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

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

Note 10 — Commitments and Contingencies

As of December 31, 2019, the Company did not have any ongoing material financial commitments. The Company expects to enter into other commitments as the business further develops. In the normal course of business, the Company enters into agreements with contract service providers to assist in the performance of its R&D activities. Expenditures to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") represent significant costs in the Company's clinical development of its product candidates. Subject to required notice periods and the Company's obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

Note 11 — Convertible Notes Payable

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

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

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

Immediately prior to the closing of the Business Combination, the Convertible Promissory Notes were automatically converted into an aggregate of 7,156,495 ISL Shares, which were then exchanged for an aggregate of 3,500,000 shares of the Company's common stock upon the closing of the Business Combination. Accrued interest of $0.6 million on the Convertible Promissory Notes was waived and cancelled immediately prior to the closing of the Business Combination in accordance with the terms of the Convertible Promissory Notes and was recorded within additional paid-in capital on the accompanying condensed combined and consolidated statement of stockholders' equity upon conversion of the underlying notes.

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 combined and consolidated financial statements and the related notes thereto for the year ended March 31, 2019, included in our registration statement on Form S-1 filed with the Securities and Exchange Commission, or the SEC, on January 17, 2020. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q 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. On December 18, 2019, we completed the Business Combination with Immunovant Sciences Ltd., a private company. For accounting purposes, Health Sciences Acquisitions Corporation was deemed to be the acquired entity.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "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 on Form 10-Q 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 on Form 10-Q, 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 patients with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits FcRn. IMVT-1401 is the product of a multi-step, multi-year research program to design a highly potent FcRn antibody optimized for subcutaneous delivery. These efforts have resulted in a product candidate that has been dosed at small volumes (2 mL or less) and with a small gauge needle, while still generating therapeutically relevant pharmacodynamic activity, important attributes that we believe will drive patient preference and market adoption. In nonclinical studies and in clinical trials conducted to date, IMVT-1401 has been observed to reduce IgG antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe IMVT-1401 has the potential for broad application in these disease areas. We intend to develop IMVT-1401 for debilitating autoimmune diseases in which there is robust evidence that pathogenic IgG antibodies drive disease manifestation and in which reduction of IgG antibodies should lead to clinical benefit.

We intend to develop IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule. As a result of our rational design, we believe that IMVT-1401, if approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases, (e.g., Myasthenia Gravis, or MG, Graves' Ophthalmopathy, or GO, Warm Autoimmune Hemolytic Anemia, or WAIHA, idiopathic thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, bullous pemphigoid, neuromyelitis optica, pemphigus foliaceus, Guillain-Barré syndrome and PLA2R+ membranous nephropathy). In 2017, these diseases had an aggregate prevalence of over 240,000 patients in the United States and 380,000 patients in Europe. To the extent we choose to develop IMVT-1401 for certain of these rare diseases, we plan to seek orphan designation in the United States and Europe. Such designations would primarily provide financial and exclusivity incentives intended to make the development of orphan drugs financially viable. However, we have not yet sought such designation for any of our three target indications (MG, GO and WAIHA), and there is no certainty that we would obtain such designation, or maintain the benefits associated with such designation, if or when we do.

In August 2019, we initiated dosing in our ASCEND-MG trial, a Phase 2a clinical trial in patients with MG. We plan to report top-line results from this trial in the first half of 2020. In May 2019, we initiated dosing in our ASCEND-GO 1 trial, a Phase 2a clinical trial in Canada in patients with GO. We anticipate reporting initial results from this trial in the first quarter of 2020. Enrollment is ongoing in our ASCEND-GO 2 trial, a Phase 2b clinical trial for GO in the United States, Canada and Europe. We plan to report initial results from this trial in early 2021. In November 2019, we submitted our investigational new drug application, or IND, to the U.S. Food and Drug Administration, or the FDA, for WAIHA, and in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020.

ISL was incorporated in July 2018 and its operations prior to the closing of the Business Combination (as defined below) were limited to organizing and staffing ISL, acquiring the rights to IMVT-1401, and preparing for and conducting clinical trials. To date, we have not generated any revenue and have generated significant operating losses since our inception. As of December 31, 2019, we had an accumulated deficit of $70.7 million. We recorded net losses of $11.3 and $45.8 million for the three and nine months ended December 31, 2019, respectively, and $8.8 million and $19.6 million for the three and nine months ended December 31, 2018, respectively.

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

Business Combination and Recapitalization

On December 18, 2019, Health Sciences Acquisition Corporation, or HSAC, completed its acquisition of Immunovant Sciences Ltd., or ISL, pursuant to the share exchange agreement dated as of September 29, 2019, or the Share Exchange Agreement, by and among HSAC, ISL, the stockholders of ISL, or the Sellers, and RSL, as representative of the Sellers. As of the closing of the Business Combination, the Sellers owned 100% of the issued and outstanding common shares of ISL. At the closing, HSAC acquired 100% of the issued and outstanding ISL Shares, in exchange for 42,080,376 shares of HSAC common stock issued to the Sellers and 10,000 shares of HSAC Series A preferred stock issued to RSL, or the Business Combination. Upon the closing of the Business Combination, ISL became a wholly owned subsidiary of HSAC and HSAC was renamed "Immunovant, Inc." The aggregate value of the consideration paid by HSAC in the Business Combination was $420.9 million, consisting of 42,090,376 shares of HSAC capital stock valued at $10.00 per share.

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

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

Our Key Agreements

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, RSG entered into the HanAll Agreement. Under the HanAll Agreement, RSG received (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to develop, import and use the antibody referred to as IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, and to commercialize such products, in the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America, or the Licensed Territory, for all human and animal uses, during the term of the agreement. In December 2018, we obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 from RSG in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and its wholly owned subsidiary, ISG, for an aggregate purchase price of $37.8 million plus Swiss value-added tax of $2.9 million.

Under the HanAll Agreement, the parties will 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 and intellectual property created by us pursuant to this research program will be included in HanAll's license. Since the acquisition of IMVT-1401, we, along with RSL, have performed all the development associated with IMVT-1401 and no amounts were due to HanAll for further research or development of the technology.

Pursuant to the HanAll Agreement, RSG made an upfront payment of $30.0 million to HanAll. We will be responsible for future contingent payments and royalties, including up to an aggregate of $452.5 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 and (C) 11 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country. 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.

Services Agreements with RSI and RSG

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

RSL Information Sharing and Cooperation Agreement

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

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

Financial Operations Overview

Revenue

We have not generated any revenue and have incurred significant operating losses since inception. We do not expect to generate any revenue from the sale of any products unless or until we obtain regulatory approval of and commercialize IMVT-1401 or any future product candidates. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of IMVT-1401 and any future product candidates.

Research and Development Expenses

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

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

Research and development activities will continue to be central to our business model. We expect our research and development expenses to be significant over the next several years as we increase personnel and compensation costs and commence additional expected clinical trials for IMVT-1401 and prepare to seek regulatory approval for our product candidate. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct.

The duration, costs and timing of clinical trials of IMVT-1401 and any future product candidates will depend on a variety of factors that include, but are not limited to:

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

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

General and Administrative Expenses

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

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

Interest Expense

Interest expense consists of interest incurred on our convertible promissory notes.

Other (Income)/Expense, Net

Other (income)/expense, net consists primarily of foreign currency transaction gains and losses related to the impact of transactions denominated in foreign currencies.

Results of Operations

The following table sets forth our results of operations for the three months ended December 31, 2019 and 2018 (in thousands).

	Three Months Ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 4,953	$ 7,683
General and administrative	6,088	1,201
Total operating expenses	11,041	8,884
Interest expense	376	—
Other income, net	(221)	(43)
Loss before provision for income taxes	$(11,196)	$(8,841)
Income tax expense	100	8
Net loss	$(11,296)	$(8,849)

Research and Development Expenses

Research and development expenses decreased by $2.7 million, from $7.7 million for the three months ended December 31, 2018 to $5.0 million for the three months ended December 31, 2019. This decrease was primarily due to a $5.4 million decrease in contract manufacturing, costs related to manufacturing and process development. Other decreases include lower third-party research and development costs of $0.8 million and non-clinical studies of $0.4 million, both of which were driven by lower expenses related to toxicology, bioanalysis and consulting. The overall decrease was partially offset by an increase in contract research organizations, or CRO, costs of $2.7 million, personnel-related expenses of $0.7 million, stock-based compensation expense of $0.1 million and other research and development expenses of $0.4 million, all of which were driven by the advancement of our clinical trials for the treatment of autoimmune disease, as well as higher headcount to support our clinical operations.

General and Administrative Expenses

General and administrative expenses increased by $4.9 million, from $1.2 million for the three months ended December 31, 2018 to $6.1 million for the three months ended December 31, 2019. This increase was primarily due to higher legal and professional fees of $2.5 million, higher personnel-related costs of $1.2 million, higher stock-based compensation expense of $1.1 million, and an increase in other costs of $0.3 million. The overall increase was partially offset by a decrease in allocations to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters of $0.2 million.

Interest Expense

Interest expense was $0.4 million for the three months ended December 31, 2019 and was related to the interest accrued on our convertible promissory notes issued in 2019.

Other Income, Net

Other income, net increased by $0.2 million from $43,000 for the three months ended December 31, 2018 to $0.2 million for the three months ended December 31, 2019. This increase was primarily due to foreign exchange fluctuations.

The following table sets forth our results of operations for the nine months ended December 31, 2019 and 2018 (in thousands).

	Nine Months Ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 33,759	$ 17,763
General and administrative	11,836	1,729
Total operating expenses	45,595	19,492
Interest expense	625	—
Other (income)/expense, net	(539)	63
Loss before provision for income taxes	$(45,681)	$(19,555)
Income tax expense	156	12
Net loss	$(45,837)	$(19,567)

Research and Development Expenses

Research and development expenses increased by $16.0 million, from $17.8 million for the nine months ended December 31, 2018 to $33.8 million for the nine months ended December 31, 2019. This increase was primarily due to $10.0 million related to the achievement of the first development and regulatory milestone under the HanAll Agreement in May 2019. Other increases include higher CRO costs of $6.2 million, other third-party costs of $2.0 million and CMO costs of $0.5 million, all of which were driven by the advancement of our clinical trials for the treatment of autoimmune disease, as well as higher personnel-related expenses of $2.1 million and stock-based compensation expense of $1.7 million, both of which were due to our higher headcount to support our clinical operations. The overall increase was partially offset by decreases in costs billed to us under the Services Agreements of $4.7 million, non-clinical studies of $1.6 million, and licensing fee of $0.2 million.

General and Administrative Expenses

General and administrative expenses increased by $10.1 million, from $1.7 million for the nine months ended December 31, 2018 to $11.8 million for the nine months ended December 31, 2019. This increase was primarily due to higher legal and professional fees of $5.4 million, higher stock-based compensation expense of $2.3 million, higher personnel-related costs of $1.8 million, and an increase in other costs of $0.6 million.

Interest Expense

Interest expense was $0.6 million for the nine months ended December 31, 2019 and was related to the interest accrued on our convertible promissory notes issued in 2019.

Other (Income)/Expense, Net

Other (income)/expense, net changed from an expense of $0.1 million for the nine months ended December 31, 2018 to income of $0.5 million for the nine months ended December 31, 2019. This increase was primarily due to foreign exchange fluctuations.

Liquidity and Capital Resources

For the three and nine months ended December 31, 2019, we had net losses of $11.3 million and $45.8 million, respectively. As of December 31, 2019, we had an accumulated deficit of $70.7 million and cash of $123.5 million. Prior to the Business Combination, our operations were historically financed through capital contributions from RSL or its affiliates, the issuance of equity instruments, and the issuance of notes payable.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We have never generated any revenue and we do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for IMVT-1401 or any future product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- fund our ongoing ASCEND-MG trial;
- fund our ongoing ASCEND-GO 1 and ASCEND-GO 2 trials;
- commence our planned ASCEND-WAIHA trial;
- launch any potential Phase 2 proof-of-concept studies of IMVT-1401 in additional indications;
- achieve milestones under our agreements with third parties, including the HanAll Agreement, that will require us to make substantial payments to those parties;
- seek to identify, acquire, develop and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- commence the number of trials required for approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval; and
- operate as a public company.

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

Until such time, if ever, as we can generate substantial product revenue from sales of IMVT-1401 or any future product candidate, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended December 31, 2018 and 2019 (in thousands):

	Nine Months Ended December 31,	
	2019	2018
Cash used in operating activities	$ (30,307)	$(15,898)
Cash used in investing activities	(21)	(52)
Cash provided by financing activities	146,873	28,053

Cash Used in Operating Activities

For the nine months ended December 31, 2019, $30.3 million of cash was used in operating activities. This was primarily attributable to a net loss for the period of $45.8 million, non-cash charges of $6.2 million, and a net change in operating assets and liabilities of $9.3 million. Thenon-cash charges consisted of stock-based compensation of $5.1 million and $1.6 million from the write-off of deferred offering costs, partially offset by an unrealized foreign currency exchange translation adjustment of $0.5 million. The change in our operating assets and liabilities was primarily due to an increase of $6.4 million in accounts payable and accrued expenses, a decrease of $2.6 million in prepaid expenses, an increase of $0.2 million in amounts due to RSL, and an increase in income tax payable of $0.1 million.

For the nine months ended December 31, 2018, $15.9 million of cash was used in operating activities. This was primarily attributable to a net loss for the period of $19.6 million, partially offset a net change in operating assets and liabilities of $2.5 million and stock-based compensation of $1.1 million. The change in our operating assets and liabilities was primarily due to a net increase of $3.1 million in accounts payable and accrued expenses and $2.9 million due to Roivant Sciences GmbH, partially offset by an increase of $2.9 million in VAT receivable and $0.6 million in prepaid expenses.

Cash Used in Investing Activities

For the nine months ended December 31, 2019 and 2018, cash used in investing activities was related to the purchase of property and equipment.

Cash Provided by Financing Activities

For the nine months ended December 31, 2019, $146.9 million of cash provided by financing activities was due to $111.0 million in cash received as a result of the Business Combination, $35.0 million in proceeds from the issuance of convertible promissory notes, $7.9 million from the issuance of promissory notes to RSL, and $0.9 million in capital contributions by RSL, partially offset by $5.0 million in repayments of convertible promissory notes, and the payment of deferred offering costs of $2.9 million.

For the nine months ended December 31, 2018, $28.1 million of cash provided by financing activities was primarily due to $13.0 million in capital contributions by RSL, $10.0 million in proceeds from the issuance of common stock, and $5.1 million of investments made by RSL.

Outlook

Based on our expected cash resources, our research and development plans and our timing expectations related to the commencement of our development programs for IMVT-1401, we expect to be able to fund our operating expenses and capital expenditure requirements through at least the second half of 2021. However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Contractual Obligations and Commitments

As of March 31, 2019, and December 31, 2019, other than contingent payments pursuant to the HanAll Agreement, we did not have any ongoing material financial commitments, such as lines of credit or guarantees that we expect to affect our liquidity over the next several years.

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for nonclinical studies, manufacturing, and other services and products for operating purposes, which are cancelable at any time by us, subject to payment of our remaining obligations under binding purchase orders and, in certain cases, nominal early termination fees. These commitments are not deemed significant.

We have not included the future payments potentially due under the HanAll Agreement in a table of contractual obligations because the payment obligations under this agreement are contingent upon future events. As of December 31, 2019, 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 IMVT-1401, up to an aggregate of $20.0 million.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

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

Our combined and consolidated financial statements are derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with product candidate IMVT-1401, that have been contributed to us by RSL, from RSL's financial statements. Because the transfer of assets and liabilities in our formation on July 6, 2018 was between entities under the common control of RSL and/or its wholly owned subsidiaries, our combined and consolidated financial statements have been presented as if we had been a separate business when RSG acquired IMVT-1401 on December 19, 2017, and accordingly, the assets, liabilities and expenses relating to our operations have been separated from RSL in the combined and consolidated financial statements for periods prior to and after our formation through December 31, 2019.

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 applies those principles. While our significant accounting policies are more fully described in Note 2 to our unaudited interim condensed combined and consolidated financial statements, we believe the following are the critical accounting policies used in the preparation of our combined and consolidated financial statements that require significant estimates and judgments.

Stock-Based Compensation

We recognize stock-based compensation expense related to stock options and restricted stock awards granted to employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. We account for forfeitures as they occur. The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

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

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

Risk-Free Interest Rate. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the stock options.

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

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

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

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

Research and Development Expense

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

Income Taxes

We account for income taxes in accordance with ASC 740,*Income Taxes.* Under the assets-and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2019, we did not have any significant uncertain tax positions.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASUNo. 2016-02, *Leases (Topic 842,* ASU No. 2016-02, a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 requires lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. We adopted this ASU as of April 1, 2019, with no impact on our unaudited interim condensed combined and consolidated financial statements and related disclosures. We elected the optional transition method to apply the standard as of the effective date and therefore did not apply the standard to the comparative periods presented in the condensed combined and

consolidated financial statements. We elected the transition package of three practical expedients permitted within the standard, which eliminates the requirements to reassess prior conclusions about lease identification, lease classification, and initial direct costs. We did not elect the hindsight practical expedient, which permits the use of hindsight when determining lease term and impairment of right-of-use assets. Further, we elected a short-term lease exception policy to not apply the recognition requirements of this standard to short-term leases with terms of 12 months or less and an accounting policy to account for lease and non-lease components as a single component for certain classes of assets.

JOBS Act

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency rates and changes in the market value of equity instruments. As of December 31, 2019, and March 31, 2019, we had cash of $123.5 million and $7.0 million, respectively, consisting of non-interest-bearing deposits denominated in the U.S. Dollar and Swiss franc. We do not believe we are currently exposed to any material market risk.

Item 4. Controls and Procedures

Upon the closing of the Business Combination on December 18, 2019, the sole business conducted by combined company is the business conducted by ISL. Also, as a result of the Business Combination, the internal control over financial reporting utilized by ISL prior to the Business Combination became the internal control over financial reporting of the combined company.

Evaluation of Disclosure Controls and Procedures.

We maintain “disclosure controls and procedures” (as defined in Rules13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019, the end of the period covered by this Quarterly Report on Form 10-Q. 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, 2019 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 Rules13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the fiscal quarter ended December 31, 2019 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 various legal proceedings that arise in the ordinary course of our business. We are not currently a party to any material legal proceedings, and are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

ITEM 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes. If any of the risks discussed in this Quarterly Report on Form 10-Q actually occur, they may harm our business, financial condition, results of operations and growth prospects. As a result, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also harm our business, financial condition, results of operations and growth prospects and could result in a complete loss of your investment.

Risks Related to Our Business, Financial Position and Capital Requirements

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

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

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, IMVT-1401 and any future product candidates. We have never been profitable, have no products approved for commercial sale, and have not generated any product revenue.

Even if we receive regulatory approval for IMVT-1401 or any future product candidate, we do not know when or if we will generate product revenue. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of IMVT-1401 or any future product candidate in the United States and in other jurisdictions;
- add operational, financial and management information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of IMVT-1401 or any future product candidate manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- attract and retain experienced management and advisory teams;
- raise additional funds when needed and on terms acceptable to us;
- commercially launch IMVT-1401 or any future product candidate, if approved, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- set an acceptable price for any approved product and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of any approved product in the medical community and with third-party payors and consumers;
- compete effectively with other biotechnology and pharmaceutical companies targeting autoimmune disease indications; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if IMVT-1401 or any future product candidate is approved for commercial sale, we anticipate incurring significant costs associated with its commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed and you may lose some or all of your investment.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

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 $34.2 million, $28.6 million and $45.8 million for the period from December 19, 2017 to March 31, 2018, the year ended March 31, 2019, and the nine months ended December 31, 2019, respectively. As of December 31, 2019, we had an accumulated deficit of $70.7 million.

We expect to continue to incur substantial and increasing losses through the commercialization of IMVT-1401 or any future product candidate, if approved. We currently have no products that are approved for commercial sale. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of IMVT-1401 or any future product candidate, obtain necessary regulatory approvals for such product candidate, and manufacture and successfully commercialize such product candidate alone or in collaboration with others. We cannot assure you that we will be profitable even if we successfully commercialize IMVT-1401 or any future product candidate. If we do successfully obtain regulatory approval to market a product candidate, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidate, the reimbursement environment for our product candidate and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities for IMVT-1401 or any future product candidate is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such product candidate, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of shares of our common stock and our ability to raise capital and continue operations.

We expect our research and development expenses in connection with our development program for IMVT-1401 to continue to be significant. In addition, if we obtain regulatory approval for IMVT-1401, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses had and will continue to have an adverse effect on our results of operations, financial position and working capital.

Our independent registered public accounting firm issued a going concern opinion on our combined and consolidated financial statements for the fiscal year ended March 31, 2019, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital for us to fund our operations. Our combined and consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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

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

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

We have not submitted a BLA for IMVT-1401 to the FDA or any comparable application to any other regulatory authority. Obtaining approval of a BLA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of IMVT-1401 for many reasons, including:

- we may not be able to demonstrate that our product candidate is safe and effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- 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 planned clinical trials of IMVT-1401 for the treatment of MG, GO and WAIHA;
- the contract research organizations, or 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 risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidate;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Even if we do receive regulatory approval to market IMVT-1401, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market IMVT-1401. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that our product candidate will be successfully developed or commercialized.

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

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

We expect to spend substantial capital to complete the development of, seek regulatory approvals for, and commercialize IMVT-1401. These expenditures will include costs associated with our license agreement with HanAll, or the HanAll Agreement, pursuant to which we are required to reimburse HanAll for half of budgeted research and development costs incurred by them with respect to IMVT-1401 (up to an aggregate reimbursement amount of $20.0 million), make payments in connection with the achievement of certain regulatory milestones prior to generating any product sales (including the initiation of certain clinical trials for IMVT-1401), make significant further payments upon the achievement of certain sales milestones and make tiered royalty payments in connection with the commercial sale of IMVT-1401, if approved.

We will require additional capital to complete the development and potential commercialization of IMVT-1401. Because the length of time and activities associated with successful development of our product candidate are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, timing, progress, costs and results of our clinical trials for IMVT-1401, including our planned clinical trials of IMVT-1401 for the treatment of MG, GO and WAIHA;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;
- the cost of future product candidates or technologies that we may acquire orin-license;
- the effect of competing market developments;
- the cost and timing of completion of commercial-scale and other manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for IMVT-1401 or any future product candidate in regions where we choose to commercialize such product candidate on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidate, if approved for commercial sale.

We do not have any committed external source of funds. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of IMVT-1401 and any future product candidates, or potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of IMVT-1401, we are unable to estimate the associated amounts of increased capital outlays, operating expenditures and capital requirements.

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

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or IMVT-1401 or any future product candidate, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We rely on the HanAll Agreement to provide rights to the core intellectual property relating to IMVT-1401. Any termination or loss of significant rights under the HanAll Agreement would adversely affect our development or commercialization of IMVT-1401.

We have licensed our core intellectual property relating to IMVT-1401 from HanAll under the HanAll Agreement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Our Key Agreements" If, for any reason, the HanAll Agreement is terminated or we otherwise lose those rights, it would adversely affect our business. The HanAll Agreement imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. We are also required to reimburse HanAll for half of budgeted research and development costs incurred by them with respect to IMVT-1401, up to an aggregate reimbursement amount of $20.0 million. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, under the HanAll Agreement, we may be required to pay damages to our collaborators and they may have the right to terminate the applicable licenses, which would result in us being unable to develop, manufacture and sell IMVT-1401, if approved.

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

We will be responsible for future contingent payments and royalties under the HanAll Agreement, including up to an aggregate of $452.5 million upon the achievement of certain development and regulatory milestone events, which events will occur prior to our planned commercialization of IMVT-1401. Accordingly, we will be required to make such payments prior to the time at which we are able to generate any revenue, if any, from commercial sales of IMVT-1401. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

We currently have a limited number of employees who are employed by our wholly owned subsidiary and we rely on RSI and RSG to provide various administrative, business development, clinical development and other services.

As of December 31, 2019, we had no employees, and our wholly owned subsidiary, IMVT Corporation, had 18 employees, including 11 who are engaged in research and development activities. We rely on the administrative support, business development, clinical development and other services provided by RSI and RSG, wholly owned subsidiaries of RSL, which provide services to us pursuant to services agreements, or the Services Agreements, as further described under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Our Key Agreements." For example, we currently rely and expect to continue to rely on RSI to support our nonclinical and clinical development programs. Personnel and support staff that provide services to us under the Services Agreements are not required to, and we do not expect that they will, have the management and administration of our business as their primary responsibility, or act exclusively for us. RSI and RSG have limited finance, accounting, clinical development and other resources. Furthermore, RSI and RSG engage in other business activities and provide support for other of our affiliates and subsidiaries of RSL. If their focus is diverted or their limited resources are otherwise employed, we could face potential delays or disruptions in the conduct of our ongoing clinical trial programs and the commercialization of our product candidate, if approved, which could harm our business.

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

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

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

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

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

We expect to hire, either directly, or through any current or future subsidiaries of ours, additional employees for our managerial, finance and accounting, legal, clinical, scientific and engineering, regulatory, operational, manufacturing, medical affairs, business development and sales and marketing teams. We may have difficulties identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial

resources from other projects, such as the development of IMVT-1401 and any future product candidate. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize IMVT-1401 or any future product candidate and compete effectively will partly depend on our ability to effectively manage any future growth.

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

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

We are exposed to the risk that our or our affiliates' employees and contractors, including principal investigators, CROs, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing and the FDA's Good Clinical Practice, or GCP, or current Good Manufacturing Practice, or cGMP, standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person, including any person who may have engaged in any fraud or misconduct, or government agency could allege such fraud or other misconduct, even if none occurred. Furthermore, we rely on our CROs and clinical trial sites to adequately report data from our ongoing clinical trials. For example, any failure by such parties to adequately report safety signals to us in a timely manner from any such trials may also affect the approvability of our product candidate or cause delays and disruptions for the approval of our product candidate, if at all. If our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors are alleged or found to be in violation of any such regulatory standards or requirements, or become subject to a corporate integrity agreement or similar agreement and curtailment of our operations, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and additional reporting requirements and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

We may not be successful in our efforts to identify and acquire orin-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 orin-license novel product candidates or technologies in the autoimmune disease field. The process by which we identify product candidates and technologies may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

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

- the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, or higher than expected acquisition or integration costs.

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

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

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

Part of our business strategy involves potentially expanding internationally with third-party collaborators to seek regulatory approval for IMVT-1401 and any future product candidates outside the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes orself-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, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the United States Foreign Corrupt Practices Act, or the FCPA, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, or 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.

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

Following the result of a referendum in 2016, the United Kingdom formally left the European Union, or E.U., on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the U.K. and E.U., the U.K. will be subject to a transition period until December 31, 2020, or the Transition Period, during which E.U. rules will continue to apply. Negotiations between the U.K. and the E.U. are expected to continue in relation to the customs and trading relationship between the U.K. and the E.U. following the expiry of the Transition Period.

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

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

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

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

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

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

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

We completed the implementation of a company-wide enterprise resource planning, or ERP, system to upgrade certain existing business, operational, and financial processes, upon which we rely. ERP implementations are complex and time-consuming projects that require transformations of business and finance processes to reap the benefits of the ERP system. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. Additionally, if the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess those controls adequately could be delayed. Significant delays in documenting, reviewing and testing our internal control over financial reporting could cause us to fail to comply with the SEC, reporting obligations related to our management's assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business during or following the implementation of the ERP system, our business and results of operations could be harmed.

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

The use of IMVT-1401 and any future product candidate in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with any approved products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;

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

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for IMVT-1401 or any future product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization any approved product.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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 to be reviewed and/or approved by necessary government agencies, which would harm 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could harm our business.

Risks Related to Development, Regulatory Approval and Commercialization

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

Our product candidate is still in clinical development and will require extensive clinical testing before we are prepared to submit a BLA or other similar application for regulatory approval. We cannot provide you any assurance that we will submit a BLA for regulatory approval for our product candidate within our projected timeframes or whether any such application will be approved by the relevant regulatory authorities. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other regulatory authorities may not agree with our proposed analysis plans or trial design for any clinical trials for IMVT-1401, including our planned ASCEND-MG, ACEND-GO and ASCEND-WAIHA trials; and during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of an BLA or similar application. The FDA may also find that the benefits of IMVT-1401 in any of our target indications do not outweigh its risks in a manner sufficient to grant regulatory approval. The clinical trial process is also time-consuming and costly and relies on the collaboration with many CROs and clinical trial sites.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of a BLA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit negative safety signals in later stage clinical trials that they did not exhibit in nonclinical or earlier-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in, or the discontinuation of, advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, the results of early nonclinical studies and clinical trials of IMVT-1401, some of which were not conducted by us, may not be predictive of the results of our planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

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

- failure to obtain regulatory authorization to commence a trial or reaching consensus with regulatory authorities regarding the design or implementation of our studies;
- unforeseen safety issues, or subjects experiencing severe or unexpected adverse events, or AEs;
- occurrence of serious AEs in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- resolving any dosing issues or limitations, including those raised by the FDA;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to add a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other regulatory authorities;
- 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;
- failure to manufacture or release sufficient quantities of our product candidate or placebo or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unmasking of trial results.

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 cGMP regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our IND or equivalent applications for other countries or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidate could be harmed, and our ability to generate product revenue from our product candidate, if approved, may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause or lead to a termination or suspension of, or delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidate. We may make formulation or manufacturing changes to our product candidate, in which case we may need to conduct additional nonclinical or clinical studies to bridge our modified product candidate to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidate and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidate could be significantly reduced.

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

In addition, we had no involvement with or control over the nonclinical or clinical development of IMVT-1401 prior to itsin-license from HanAll. We are dependent on our licensing partner having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all nonclinical studies and clinical trials and other research they conducted prior to our acquisition of the rights to our product candidate, having correctly

collected and interpreted the data from these studies, trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of this asset. Problems related to our predecessor could result in increased costs and delays in the development of our product candidate, which could adversely affect our ability to generate any future revenue from sales of our product candidate, if approved.

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

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior nonclinical testing and clinical trials. In particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our Phase 1 clinical trial of IMVT-1401, which did not include pre-specified endpoints for IgG reduction, will be observed in any future clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported AEs. The results of nonclinical studies and early clinical trials of our product candidate may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon our product candidate. Any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidate, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidate. The FDA has substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we propose. In addition, only a small percentage of biologics under development result in the submission of a BLA to the FDA and even fewer are approved for commercialization.

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize IMVT-1401 or any future product candidate, our business, operating results, prospects or financial condition may be harmed.

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

IMVT-1401 is a novel therapeutic antibody and its potential therapeutic benefit is unproven. While several FcRn inhibitor candidates are under development by other companies, there is currently no approved therapy inhibiting FcRn for the treatment of autoimmune diseases, and, as a result, the regulatory pathway for IMVT-1401 may present novel issues that could cause delays in development or approval. While results from early clinical trials of IMVT-1401 have shown meaningful reductions in IgG antibody levels in healthy volunteers, IMVT-1401 may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for IMVT-1401 in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although we and our licensing partner have evaluated IMVT-1401 in nonclinical studies and in early-stage clinical trials, we have not yet advanced IMVT-1401 into a large-scale, pivotal clinical trial for any indication. Positive results from our early-stage clinical trials are not necessarily predictive of the results of our planned clinical trials of IMVT-1401. If we cannot replicate the positive results from our Phase 1 clinical trial in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize IMVT-1401 for the treatment of MG, GO, WAIHA or any other autoimmune indication. As a result, our focus on exploring FcRn inhibition may fail to result in the identification of viable additional indications for IMVT-1401. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize IMVT-1401, raise capital, expand our business or continue our operations.

We have licensed the rights to IMVT-1401 in limited territories. Any adverse developments that occur during any clinical trials conducted by third parties, including HanAll, in other jurisdictions may affect our ability to obtain regulatory approval or commercialize IMVT-1401.

We have licensed the right to develop, manufacture and commercialize IMVT-1401 in the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America. HanAll or any of its sublicensees or collaborators, over which we have no control, has the right to develop and commercialize IMVT-1401 in geographies outside of our licensed territory. If serious AEs occur with patients using IMVT-1401 or during any clinical trials of IMVT-1401 conducted by HanAll or third parties in other jurisdictions outside of our licensed territory, the FDA may delay, limit or deny approval of IMVT-1401 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for IMVT-1401 and a new and serious safety issue is identified in connection with clinical trials of IMVT-1401 conducted by third parties in other jurisdictions outside of our licensed territory, the FDA may withdraw their approval of the product or otherwise restrict our ability to market and sell IMVT-1401. In addition, treating physicians may be less willing to administer our product candidate due to concerns over such AEs, which would limit our ability to commercialize IMVT-1401.

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

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials for MG, GO and WAIHA due to the existing alternative treatments available for the treatment of MG, GO 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, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, our ability to successfully complete prerequisite studies before enrolling certain patient populations. Our product candidate is focused in part on addressing rare autoimmune indications, including MG, GO and WAIHA with limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

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

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

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

We expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases, including multiple agents which are in the same class as IMVT-1401. We are aware of several FcRn inhibitors that are in clinical development. These include ABY-039 (Affibody AB/Alexion Pharmaceuticals), efgartigimod (argenx), nipocalimab, (Momenta Pharmaceuticals), rozanolixizumab (UCB) and ALXN1830 (Alexion Pharmaceuticals). Each of efgartigimod, nipocalimab, rozanolixizumab and ALXN1830 is currently under development for the treatment of MG. In addition, for WAIHA, Alexion has announced plans to begin a Phase 2 trial for ALXN1830 in early 2020 and Momenta has announced the launch of an adaptive Phase 2/3 clinical study for nipocalimab. Momenta also announced that the FDA has granted Fast Track Designation for nipocalimab in WAIHA.

We also expect to face competition from agents with different mechanisms of action. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of GO. The most commonly prescribed first-line agents for the treatment of MG are acetylcholinesterase inhibitors, such as pyridostigmine, which are marketed by several manufacturers of generic medicines. IVIg is also routinely used for patients with MG. Eculizumab (marketed by Alexion Pharmaceuticals), an antibody inhibitor of the C5 protein, was recently approved in 2017 for the treatment of generalized MG in patients who are positive for anti-AChR antibodies. The first line of treatment for patients with GO or WAIHA is generally immunosuppressive therapy, including high doses of corticosteroids. Other broad immunosuppressive drugs, such as cyclosporine, cyclophosphamide, mycophenolate mofetil and azathioprine, are used when patients do not respond adequately to corticosteroids. Rituximab, a monoclonal antibody that binds to an antigen specific to antibody-producing B cells, may also be used as a treatment for GO, WAIHA and other IgG-mediated autoimmune diseases. Momenta is developing its hypersialylated IVIg, M254, in a variety of autoimmune indications.

Other product candidates in development for the treatment of MG include: zilucoplan (UCB), a peptide inhibitor of C5, currently in a Phase 3 trial in a similar patient population; amifampridine (Catalyst Pharmaceuticals), a neuronal potassium channel blocker, for MG patients with the MuSK form of the disease, which is currently in Phase 3; and Myasterix (CuraVac), a therapeutic vaccine against B and T cells, which is being tested in early stage trials in MG patients. Moreover, Viela Bio has announced plans to initiate a pivotal trial in MG for inebilizumab, a CD19-targeted humanized monoclonal antibody, in 2020. Toleranzia has announced its intention to initiate Ph1/2a program in MG patients for its immunomodulating complex, TOL2, in 2020. Numerous product candidates are currently in development for the treatment of WAIHA. Fostamatinib (Rigel Pharmaceuticals), a syk inhibitor, is currently in Phase 3 development. A Phase 2 investigator-initiated study of ibrutinib (AbbVie), a BTK inhibitor, in steroid-refractory WAIHA is ongoing. Kezar Life Sciences is running a Phase 2 trial including WAIHA patients for its immunoproteasome inhibitor, KZR-616.

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

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

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

- develop and commercialize therapies in our target indications that are superior to other products in the market;
- demonstrate through our clinical trials that IMVT-1401 or any future product candidate is differentiated from existing and future therapies;
- attract qualified scientific, product development, manufacturing and commercial personnel;
- obtain patent or other proprietary protection for IMVT-1401 and any future product candidates;
- obtain required regulatory approvals, including approvals to market IMVT-1401 or any future product candidate we develop, in ways that are differentiated from existing and future products and treatments;
- have commercial quantities of any approved product manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- successfully commercialize IMVT-1401 or any future product candidate, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies.

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

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

IMVT-1401 and any future product candidate that we may develop, as well as the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by similar regulatory authorities outside the United States. Failure to obtain marketing approval for, and thus commercialize any product candidate, could negatively impact our ability to generate any revenue from product sales.

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

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

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

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

Adverse events associated with our product candidate in our clinical trials could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. The most commonly reported AE in our Phase 1 clinical trial was mild erythema and swelling at the injection site, which typically resolved within hours. If an unacceptable frequency or severity of AEs or new safety signals are reported in our clinical trials for our product candidate, our ability to obtain regulatory approval for such product candidate may be negatively impacted. Treatment-related side effects arising from, or those perceived to arise from, our product candidate or those from other companies targeting similar autoimmune indications, including incidence of headache from other product candidates targeting IgG antibody reductions, could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

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

- regulatory authorities may withdraw, suspend or limit their approval of the product or require a REMS (or equivalent outside the United States) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, require other labeling changes or require field alerts or other communications to physicians, pharmacies or the public;
- we may be required to change the way the product is administered or distributed, conduct additional clinical trials, change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we may be required to repeat a nonclinical study or clinical trial or terminate a program, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we may be sued and held liable for harm caused to patients;
- physicians may stop prescribing the product;
- reimbursement may not be available for the product;
- we may elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

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

IMVT-1401 is an antibody protein that could cause an immune response in patients, resulting in the creation of harmful or neutralizing antibodies against these therapeutic proteins, preventing or limiting regulatory approval or our ability to commercialize IMVT-1401.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidate, IMVT-1401, the administration of proteins such as monoclonal antibodies, even those that are fully human in nature including our product candidate, can cause an immune response, resulting in the creation of antibodies against the therapeutic protein. These anti-drug antibodies can have no effect or can neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. Whether anti-drug antibodies will be created and how they react can often not be predicted from nonclinical or even clinical studies, and their detection or appearance is often delayed. As a result, neutralizing antibodies may be detected at a later date or upon longer exposure of patients with our product candidates, such as following more chronic administration in longer lasting clinical trials. In some cases, detection of such neutralizing antibodies can even occur after pivotal clinical trials have been completed. Therefore, there can be no assurance that neutralizing antibodies will not be detected in future clinical trials or at a later date upon longer exposure (including after commercialization). If anti-drug antibodies reduce or neutralize the effectiveness of our product candidate, the continued clinical development or receipt of marketing approval for our product candidate could be delayed or prevented and, even if our product candidate is approved, its commercial success could be limited, any of which would impair our ability to generate revenue and continue operations.

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

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

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

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, AE reporting, storage, recordkeeping, conduct of potential post-market studies and post-market submission requirements, export, import, advertising and promotional activities for such product, among other things, by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions-including in some cases, a boxed warning be included in the product labeling, which could limit sales of the product.

Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action foroff-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable regulations in foreign jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other foreign regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, later discovery of previously unknown AEs or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements may yield various results, including:

- restrictions on the manufacture of such product;
- restrictions on the labeling or marketing of such product, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the United States);
- Warning or Untitled Letters;
- withdrawal of the product from the market;
- recall of a product;
- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such product;
- product seizure; or
- lawsuits, injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of IMVT-1401 or any future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

Even if we receive marketing approval for IMVT-1401 or any future product candidate, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

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

- the safety, efficacy, risk-benefit profile and potential advantages, including in the case of IMVT-1401 subcutaneous delivery method, compared to alternative, competing or existing treatments, which physicians may perceive to be adequately effective for some or all patients;
- 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 similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the cost, convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing or competing therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement at any given price level of our product candidate;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of our product candidate, if approved, together with other medications.

Market acceptance of IMVT-1401 for the treatment of MG, GO and WAIHA may also be affected by the perception that existing available treatments, such as pyridostigmine, corticosteroids and immunosuppressants, may be sufficient to treat the majority of these patients. In addition, IMVT-1401, if approved, may compete with other FcRn inhibitors under development that have demonstrated similar levels of IgG reductions as IMVT-1401 in completed clinical trials to date. In addition, the potential patient population for our initial indication and other autoimmune indications that we may target are relatively small. This could affect the rate of adoption and as a result, market acceptance of our product candidate, if approved, could be much slower than anticipated.

We cannot assure you that IMVT-1401 or any future product candidate, if approved, will achieve broad market acceptance among physicians, patients and third-party payors. The failure of any such product candidate that receives regulatory approval or clearance to achieve market acceptance or commercial success would adversely affect our business and results of operations.

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

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

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

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

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

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

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

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

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

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

We plan to seek orphan drug designation from the FDA for IMVT-1401 for the treatment of MG, GO and WAIHA and potentially in other orphan indications in which there is a medically plausible basis for its use, and we may seek orphan drug designation for IMVT-1401 in the E.U. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the E.U., the European Medicine Agency's Committee for Orphan Medicinal Products grants 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. Additionally, designation is granted for

products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or 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 or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. In addition, if a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective, or makes a major contribution to patient care. In the E.U., orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period 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 orphan drug designation for IMVT-1401 from the FDA, we may never receive such designation. Moreover, obtaining orphan drug designation for IMVT-1401 for the treatment of MG, GO or WAIHA does not mean we will be able to obtain such designation for any other indications. Even if we were to obtain orphan drug designation for IMVT-1401 from the FDA, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of IMVT-1401 could be blocked for seven years if another company obtains approval and orphan drug exclusivity for the same drug and same condition before us. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication, and different drugs for the same condition may already be approved and commercially available. Orphan drug designation does not convey any advantage in, or shorten the duration of, the development or FDA review and approval process.

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

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

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

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, 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 prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal false claims laws, including the False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and most providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the

relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; and state and local laws require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or 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 definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and 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 must agree to offer point-of-sale discounts (which through subsequent legislative amendments, will be increased to 70% from 50% starting in 2019) 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) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (7) 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; (8) created a licensure framework for follow-on biologic products; and (9) established a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or the TCJA, was enacted, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

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 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations. Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. In September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and on January 31, 2019, the HHS Office Inspector General proposed modifications to the U.S. federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Additionally, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list.

Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed

treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

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

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical supplies and commercial supplies of our product candidate. The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production that may delay or prevent our ability to obtain marketing approval or commercialize our product candidates, if approved.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. Third-party vendors may be difficult to identify for our product candidate process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. Any significant delay in the supply of a product candidate, or the raw material components thereof, or in placebo controls for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of IMVT-1401 or any future product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for any product candidate, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of such product candidate. In addition, IMVT-1401 is a biologic and requires processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims and insufficient inventory.

The facilities used by our contract manufacturers to manufacture our product candidate must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidate or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidate, if approved. Further, our reliance on third-party manufacturers entails risks, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;

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

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

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

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause IMVT-1401 or any future product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of IMVT-1401 or any future product candidate or jeopardize our ability to commence sales and generate revenue.

We are reliant on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements, it may harm our business.

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

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

We and our CROs are required to comply with GLP and GCP regulations and guidelines enforced by the FDA, and are also required by the competent authorities of the member states of the European Economic Area and other comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for any of our product candidates that are in nonclinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical trials before approving our marketing applications. Accordingly, if we or our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the relevant regulatory approval process. Failure by our CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as sponsors of those studies.

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

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

Risks Related to Our Intellectual Property

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

In the United States, the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. New biologics, such as IMVT-1401, may be entitled to regulatory exclusivity under the BPCIA. The BPCIA grants new biologics 12 years of FDA-granted exclusivity. Further, under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. During the period of exclusivity, however, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the Sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. After the expiration of the exclusivity period, the FDA can approve a biosimilar product through an abbreviated approval process. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that our product candidate, as a biological product, should qualify for the12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidate to be a reference product for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we are unable to obtain and maintain patent protection for IMVT-1401 or any future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our brand, current and future drug development programs and product candidate. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to IMVT-1401 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future drug development programs and product candidates, successfully defending our intellectual property rights against third-party challenges and successfully enforcing our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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

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

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

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

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

Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not until a patent issues. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect IMVT-1401 or any future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-partypre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize IMVT-1401 or any future product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize IMVT-1401 or any future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices, both in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products. Moreover, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S.non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Without patent protection for IMVT-1401 or any future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The validity, scope and enforceability of any patents that cover a biologic subject to approval by the FDA via a BLA, such as IMVT-1401, can be challenged by third parties.

For biologics subject to approval by the FDA via a BLA, such as IMVT-1401, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological products. Due to the large size and complexity of biological products, as compared to small molecules, a biosimilar must be “highly similar” to the reference product with “no clinically meaningful differences between the two.” The BPCIA does not require reference product sponsors to list patents in an Orange Book and does not include an automatic 30-month stay of FDA approval upon the timely filing of a lawsuit. The BPCIA, however, does require a formalpre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties’ basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims it could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or result in a finding of non-infringement. Such litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management’s attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with IMVT-1401 or any future product candidates.

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

Filing, prosecuting and defending patents on our product candidate in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection may be less extensive than that provided in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect patent rights to the same extent as federal laws in the United States.

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

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we may obtain patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. Additionally, such proceedings 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 United States, if all maintenance fees are timely paid, the naturalexpiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidate are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. The patent family directed to the composition of matter of IMVT-1401 has a natural projected expiration date in 2035 in the United States and in foreign jurisdictions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for IMVT-1401 or other product candidates that we may identify, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property rights in the United States and other countries with respect to our proprietary technology, product candidate and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidate might expire before or shortly after such candidates begin to be commercialized. Depending upon the timing, duration and specifics of FDA marketing approval of IMVT-1401 or other product candidates that we may identify, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA premarket regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries, including the E.U., upon regulatory approval of our product candidates, based on similar legislation. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

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

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering IMVT-1401 or other product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for patents we may later in-license or jointly own, we may not have the right to control patent prosecution, including filing with the USPTO a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of these patents was eligible for patent term extension under the Hatch-Waxman Act, we might not be able to control whether a petition to obtain a patent term extension would be filed, or obtained, from the USPTO.

We do not have rights to protect or enforce intellectual property rights in certain territories and jurisdictions.

We do not have rights to develop, manufacture, use or commercialize IMVT-1401 or file or enforce patents relating to these assets in territories other than the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America, as such rights in other jurisdictions have been retained by HanAll or licensed by HanAll to third parties. One or more third parties may challenge the current patents, or patents that may issue in the future, in such territories for which HanAll retains rights or has licensed out rights to defend and enforce such patents. HanAll may not coordinate the defense and enforcement of such patents with us, which could impair our ability to defend or enforce corresponding patents in other jurisdictions.

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

We have licensed certain intellectual property rights covering IMVT-1401 from HanAll. We are heavily dependent on the HanAll Agreement for the development, manufacture and commercialization of our product candidate. If, for any reason, our licenses under the HanAll Agreement are terminated or we otherwise lose those rights, it could adversely affect our business. The HanAll Agreement imposes, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and HanAll, as the licensor, may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

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

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

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

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

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

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidate. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize IMVT-1401 or any future product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that wein-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 United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidate. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing a product candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidate or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidate. Defending these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and

attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidate. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidate, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

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

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

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

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

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidate or any future product candidates, if approved. We may incorrectly determine that our product candidate is not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product 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 proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives, or could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For patents and patent applications that we may in-license, we may have a limited right or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on IMVT-1401 or any future product candidate. Such a loss of patent protection could harm our business.

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

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

Because the patents we own are owned by our wholly-owned subsidiary, ISG, we may not be in a position to obtain a permanent injunction against a third party that is found to infringe our patents.

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

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

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

Changes in United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidate.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our product candidate IMVT-1401 and any future product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or USPTO rules and regulations could increase the uncertainties and costs.

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

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

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

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

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

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

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

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, independent contractors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the

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

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

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

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

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

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

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

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

We expect to rely on trademarks and trade names as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties may have used

trademarks similar and identical to our trademarks in certain jurisdictions, and may have filed or may in the future file for registration of such trademarks. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we may not be able to use these trademarks to market our products in those countries and could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

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

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

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

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

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

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

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

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

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

- others may be able to make formulations or compositions that are the same as or similar to our product candidate, but that are not covered by the claims of the patents that we own;
- others may be able to make a product that is similar to our product candidate and not covered by the patents that we exclusively licensed and have the right to enforce;

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

Should any of these events occur, they could harm our business and results of operations.

Risks Related to Our Common Stock

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

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

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- results of clinical trials for IMVT-1401 or any future product candidate or those of our competitors;
- any delay in filing a BLA or similar application for IMVT-1401 or any future product candidate and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that BLA or similar application, as the case may be;
- failure to successfully develop and commercialize IMVT-1401 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States or other countries or jurisdictions applicable to IMVT-1401 or any future product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for IMVT-1401 or any future product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;
- significant lawsuits, including patent or stockholder litigation and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of shares of our common stock;

- sales of a substantial number of shares of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;
- sales or purchases of shares of our common stock by our directors or Section 16 officers;
- sales of shares of our common stock by us or sales or purchases of our common stock by our stockholders in the future, including RSL;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- the size of our public float;
- trading liquidity of shares of our common stock;
- investors' general perception of our company and our business;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and 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 below the initial public offering price, and you may lose some or all of your investment.

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

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

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

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

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

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

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

RSL has the ability to substantially influence us and exert significant control through this ownership position. For example, RSL may be able to control elections of directors, the issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL's interests may not always coincide with our corporate interests or the interests of other stockholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. Further, RSL is a privately held company whose ownership and governance structure is not transparent to our other stockholders. There may be

changes to the management or ownership of RSL, or to RSL's business model, that could impact RSL's interests in a way that may not coincide with our corporate interests or the interests of other stockholders. Any such changes may diminish, or eliminate entirely, any benefits we expect to derive from our membership in the Roivant family of companies. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

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

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

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

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

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

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

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

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

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

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

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings

against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

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

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the fiscal year ending March 31, 2021. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal controls procedures on a quarterly basis.

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

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal controls over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal controls over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of shares of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal controls over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets.

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

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the date (a) March 31, 2025, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of shares of our common stock that are held by non-affiliates exceeds $700.0 million as of the prior September 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

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

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

We may suffer adverse tax consequences because our wholly owned subsidiary, ISL, and itsnon-U.S. subsidiaries are expected to be characterized as a "controlled foreign corporation" or a CFC, under Section 957(a) of the Internal Revenue Code of 1986, as amended, or the Code.

A non-U.S. corporation is considered a CFC if more than 50% of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by U.S. stockholders (U.S. persons who own stock representing 10% or more of the vote or, for taxable years of non-U.S. corporations beginning after December 31, 2017 and for taxable years of stockholders with or within which such taxable years of non-U.S. corporations end, 10% or more of the value) on any day during the taxable year of such non-U.S. corporation. Certain U.S. stockholders of a CFC generally are required to include currently in gross income such stockholders' share of the CFC's "Subpart F income," a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC's "global intangible low-taxed income" (as defined under Section 951A of the Code). Such U.S. stockholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such stockholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. "Global intangible low-taxed income" may include most of the remainder of a CFC's income over a deemed return on its tangible assets.

As a result of certain changes in the U.S. tax law introduced by the TCJA, ISL believes that it and itsnon-U.S. subsidiaries are classified as CFCs in the current taxable year. Because we are a U.S. holder of 10% or more of the vote or value of common shares of ISL, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income and of amounts treated as global intangible low-taxed income under Section 951A of the Code, and being subject to certain reporting requirements with the U.S. Internal Revenue Service.

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 United Kingdom, 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 United Kingdom 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 shareholder, RSL, are incorporated under the laws of Bermuda. Further, we currently have subsidiaries that are domiciled in the United Kingdom, Switzerland and the United States. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between us, our parent company and our subsidiaries. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we

can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice or tax positions are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could harm our financial condition, results of operations and cash flows.

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

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

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

Item 2. Recent Sales of Unregistered Securities and Use of Proceeds

(a) Recent Sales of Unregistered Securities

In December 2019, we granted stock options to purchase an aggregate of 21,272 shares of our common stock at exercise prices of $15.97 per share to employees under our 2019 Equity Incentive Plan. We believe these issuances were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering.

(b) Use of Proceeds

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

Simultaneously with the closing of the IPO, HSAC consummated a private placement of 10,000,000 private warrants to its sponsor at a price of $0.50 per warrant, generating total proceeds of $5.0 million. The private warrants were issued pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act. Upon the closing of the Business Combination the private warrants were cancelled.

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

We intend to use these proceeds primarily to fund ourASCEND-MG trial, ASCEND-GO 1 trial, ASCEND-GO 2 trial, our planned ASCEND-WAIHA trial, and other clinical development activities.

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
4.1	Specimen Warrant Certificate.	S-1/A	333-230893	4.3	April 29, 2019
4.2	Form of Warrant Agreement by and between Continental Stock Transfer & Trust Company and Health Sciences Acquisitions Corporation.	S-1/A	333-230893	4.4	April 29, 2019
10.1	Amended and Restated Registration Rights Agreement, dated September 29, 2019, by and among Health Sciences Acquisitions Corporation and the Investors party thereto.	8-K	001-38906	10.1	December 20, 2019
10.2	Restricted Stock Agreement, dated September 29, 2019, by and between Health Sciences Acquisitions Corporation and Health Sciences Holdings, LLC.	8-K	001-38906	10.2	December 20, 2019
10.3†	2019 Equity Incentive Plan of Immunovant, Inc. and forms of award agreements thereunder.	8-K	001-38906	10.3	December 20, 2019
10.4†	2018 Equity Incentive Plan of Immunovant Sciences Ltd., and forms of award agreements thereunder.	8-K	001-38906	10.4	December 20, 2019
10.5†	Form of Indemnification Agreement.	8-K	001-38906	10.5	December 20, 2019
10.6^	License Agreement, dated December 19, 2017, by and between Roivant Sciences GmbH and HanAll BioPharma Co., Ltd.	8-K	001-38906	10.6	December 20, 2019
10.7	Assignment and Assumption Agreement, dated as of December 7, 2018, by and between Immunovant Sciences GmbH and Roivant Sciences GmbH, relating to the License Agreement by and between Roivant Sciences GmbH and HanAll BioPharma Co., Ltd.	8-K	001-38906	10.7	December 20, 2019
10.8	Services Agreement, effective as of August 20, 2018, by and between Roivant Sciences, Inc., Immunovant Sciences GmbH, IMVT Corporation (formerly Immunovant, Inc.) and Immunovant Sciences Ltd.	8-K	001-38906	10.8	December 20, 2019
10.9	Services Agreement, effective as of August 20, 2018, by and between Roivant Sciences GmbH and Immunovant Sciences GmbH.	8-K	001-38906	10.9	December 20, 2019
10.10	Amended and Restated Information Sharing and Cooperation Agreement, effective as of December 28, 2018, by and between Immunovant Sciences Ltd. and Roivant Sciences Ltd.	8-K	001-38906	10.10	December 20, 2019
10.11†	Employment Agreement with Peter Salzmann, dated as of May 30, 2019.	8-K	001-38906	10.11	December 20, 2019
10.12†	Employment Agreement with Pamela Connealy, dated as of October 22, 2019, as amended November 20, 2019.	8-K	001-38906	10.12	December 20, 2019
10.13†	Employment Agreement with Julia G. Butchko, dated as of October 9, 2019.	8-K	001-38906	10.13	December 20, 2019
10.14†	Employment Agreement with W. Bradford Middlekauff, dated as of April 15, 2019.	8-K	001-38906	10.14	December 20, 2019
10.15†	Employment Agreement with Robert K. Zeldin, dated as of July 8, 2019, as amended July 21, 2019.	8-K	001-38906	10.15	December 20, 2019
16.1	Letter from WithumSmith+Brown, PC.	8-K	001-38906	16.1	December 20, 2019

21.1	List of Subsidiaries.	8-K	001-38906	21.1	December 20, 2019
31.1*	Certification of Chief Executive Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934				
31.2*	Certification of Chief Financial Officer as required by Rule 13a-14(a) of the Securities Exchange Act of 1934				
32.1#*	Certification of Chief Executive Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934				
32.2#*	Certification of Chief Financial Officer as required by Rule 13a-14(b) of the Securities Exchange Act of 1934				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

\+ The annexes, schedules, and certain exhibits to the Share Exchange Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Immunovant, Inc. hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the Commission upon request.

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

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

\# In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this 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 14, 2020

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

By: /s/ Pamela Yanchik Connealy
Pamela Yanchik Connealy
Chief Financial Officer

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)) 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) [Reserved]

   (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 14, 2020

/S/ PETER SALZMANN, M.D.
Peter Salzmann, M.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Pamela Yanchik Connealy, certify that:

1. I have reviewed this Quarterly Report 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)) 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) [Reserved]

   (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 14, 2020

/S/ PAMELA YANCHIK CONNEALY
Pamela Yanchik Connealy
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, 2019, 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 14, 2020

/S/ PETER SALZMANN, M.D.
Peter Salzmann, M.D.
Chief Executive Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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 Securities Exchange Act of 1934, as amended (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), Pamela Yanchik Connealy, 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, 2019, 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 14, 2020

/S/ PAMELA YANCHIK CONNEALY
Pamela Yanchik Connealy
Chief Financial Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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 Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.