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

**FORM S-1
REGISTRATION STATEMENT**
*UNDER
THE SECURITIES ACT OF 1933*

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

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

83-2771572
(I.R.S. Employer
Identification Number)

**320 West 37th Street
New York, NY 10018
(917) 580-3099**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**W. Bradford Middlekauff
General Counsel
Immunovant, Inc.
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

TITLE OF SECURITIES BEING REGISTERED	AMOUNT TO BE REGISTERED ⁽¹⁾	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE PER SECURITY	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE	AMOUNT OF REGISTRATION FEE
Common stock, \$0.0001 par value per share	66,342,874	\$ 16.685 ⁽²⁾	\$ 1,106,930,853	\$ 143,680
Common stock, \$0.0001 par value per share, underlying warrants	5,750,000	\$ 14.080 ⁽³⁾	\$ 80,960,000	\$ 10,509
Total	72,092,874		\$ 1,187,890,853	\$ 154,189

- (1) In the event of a stock split, stock dividend or other similar transaction involving the registrant's common stock, in order to prevent dilution, the number of shares of common stock registered hereby shall be automatically increased to cover the additional shares of common stock in accordance with Rule 416(a) under the Securities Act.
- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act. The price per share and aggregate offering price are based on the average of the high and low prices of the Registrant's common stock on January 15, 2020, as reported on the Nasdaq Capital Market.
- (3) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(i) under the Securities Act. The price per share is based upon (a) the exercise price per warrant of \$11.50 per share plus (b) the average of the high and low prices of the Registrant's warrants on January 15, 2020, as reported on the Nasdaq Capital Market.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 17, 2020

PRELIMINARY PROSPECTUS



72,092,874 Shares of Common Stock

The selling stockholders named in this prospectus or their permitted transferees (the “selling stockholders”) may offer and sell from time to time up to 66,342,874 shares of our common stock, par value \$0.0001 per share, consisting of:

- up to 42,080,376 shares of common stock issued pursuant to that certain Share Exchange Agreement, dated as of September 29, 2019 (the “Share Exchange Agreement”), by and among Immunovant, Inc. (formerly Health Sciences Acquisitions Corporation (“HSAC”)), a Delaware corporation, Immunovant Sciences Ltd. (“ISL”), a Bermuda exempted limited company, the stockholders of ISL and Roivant Sciences Ltd., a Bermuda exempted limited company (“Roivant” or “RSL”), as representative of such stockholders;
- up to 20,000,000 additional shares of common stock that may be issued pursuant to the Share Exchange Agreement upon the satisfaction of certain conditions, as described under “Certain Relationships and Related Party Transactions—Earnout Payments;”
- up to 2,875,000 shares of common stock held by Health Sciences Holdings, LLC (the “Sponsor”); and
- up to 1,387,498 shares of common stock purchased by RTW Master Fund Ltd., RTW Innovation Master Fund, Ltd., RTW Venture Fund Limited (collectively, the “Selling RTW Entities”) and RSL in open market transactions.

In addition, this prospectus relates to the offer and sale of up to 5,750,000 shares of common stock that are issuable by us upon the exercise of outstanding warrants that were previously registered (the “warrants”).

The selling stockholders may offer, sell or distribute all or a portion of the securities hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. We will not receive any of the proceeds from such sales of the shares of common stock. We will bear all costs, expenses and fees in connection with the registration of these securities, including with regard to compliance with state securities or “blue sky” laws. The selling stockholders will bear all commissions and discounts, if any, attributable to their sale of shares of common stock. See the section titled “Plan of Distribution.”

Our common stock is listed on the Nasdaq Capital Market (“Nasdaq”) under the symbol “IMVT.” On January 16, 2020, the last reported sales price of our common stock was \$17.13 per share.

RSL is currently our majority stockholder, and we are a “controlled company” within the meaning of the listing rules of Nasdaq. In addition, 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. These directors currently hold a majority of the voting power on all matters presented to the board of directors. See “Description of Capital Stock—Series A Preferred Directors.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our securities involves risks. See “[Risk Factors](#)” beginning on page 5.

Neither the Securities and Exchange Commission in the United States nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus dated _____, 2020

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You should rely only on the information contained in this prospectus, any supplement to this prospectus or in any free writing prospectus, filed with the Securities and Exchange Commission. Neither we nor the selling stockholders have authorized anyone to provide you with additional information or information different from that contained in this prospectus filed with the Securities and Exchange Commission. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The selling stockholders are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the selling stockholders, have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside the United States.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference filed with the Securities and Exchange Commission before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our combined and consolidated financial statements and the related notes thereto and the information set forth in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Unless the context otherwise requires, we use the terms “Immunovant,” “company,” “we,” “us” and “our” in this prospectus to refer to Immunovant, Inc. and our wholly owned subsidiaries. Our fiscal year ends on March 31.

We are a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits the neonatal fragment crystallizable receptor (“FcRn”). IMVT-1401 is the product of a multi-step, multi-year research program 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 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 preclinical studies and in clinical trials conducted to date, IMVT-1401 has been observed to reduce immunoglobulin G (“IgG”) antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe IMVT-1401 has the potential for broad application in 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.

Autoimmune diseases are conditions where an immune response is inappropriately directed against the body’s own healthy cells and tissues. Approximately 50 million people in the United States suffer from one of more than 100 diagnosed autoimmune diseases according to the American Autoimmune Related Diseases Association, Inc. Predisposing factors may include genetic susceptibility, environmental triggers and other factors not yet known. Many of these diseases are associated with high levels of pathogenic IgG antibodies, which are the most abundant type of antibody produced by the human immune system, accounting for approximately 75% of antibodies in the plasma of healthy people. IgG antibodies are important in the defense against pathogens, such as viruses and bacteria. In many autoimmune diseases, IgG antibodies inappropriately develop against normal proteins found in the body, directing the immune system to attack specific organs or organ systems. Current treatment regimens for IgG-mediated autoimmune diseases include corticosteroids and immunosuppressants in early stage disease, followed by more invasive treatments, such as intravenous immunoglobulin (“IVIg”), and plasma exchange, as the disease progresses. Such treatments are often limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.

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 (“MG”), Graves’ ophthalmopathy (“GO”), warm autoimmune hemolytic anemia (“WAIHA”), idiopathic thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, bullous pemphigoid, neuromyelitis optica, pemphigus foliaceus, Guillain-Barré syndrome and PLA2R+ membranous nephropathy). In 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 its three target indications, and there is no certainty that we would obtain such designation, or maintain the benefits associated with such designation, if or when we do.

Our first target indication for IMVT-1401 is MG, an autoimmune disease associated with muscle weakness with an estimated prevalence of one in 5,000, with up to 65,000 cases in the United States. In MG, patients develop pathogenic IgG antibodies that attack critical signaling proteins at the junction between nerve and muscle cells. The majority of MG patients suffer from progressive muscle weakness, with maximum weakness occurring within six months of disease onset in most patients. In severe cases, MG patients can experience myasthenic crisis, in which respiratory function is weakened to the point where it becomes life-threatening, requiring intubation and mechanical ventilation.

In August 2019, we initiated dosing in our ASCEND-MG trial, a Phase 2a clinical trial in patients with MG. We plan to report top-line results from this trial in the first half of 2020.

Our second target indication for IMVT-1401 is GO, an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes, which can be sight-threatening. GO has an estimated annual incidence of 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe. Initial symptoms may include a dry and gritty ocular sensation, sensitivity to light, excessive tearing, double vision and a sensation of pressure behind the eyes.

In May 2019, we initiated dosing in our ASCEND-GO 1 trial, a Phase 2a clinical trial in Canada in patients with GO. We anticipate reporting initial results from this trial in the first quarter of 2020. In October 2019, we initiated dosing 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.

We are also developing IMVT-1401 for the treatment of WAIHA, a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of red blood cells ("RBCs"). Based on published estimates, we believe that there are approximately 42,000 patients in the United States and 66,000 patients in Europe living with WAIHA. The clinical presentation is variable and most commonly includes symptoms of anemia, such as fatigue, weakness, skin paleness and shortness of breath. In severe cases, hemoglobin levels are unable to meet the body's oxygen demand, which can lead to heart attacks, heart failure and even death.

In November 2019, we submitted our investigational new drug application ("IND") to the U.S. Food and Drug Administration ("FDA") for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020.

We obtained rights to IMVT-1401 pursuant to our license agreement (the "HanAll Agreement") with HanAll Biopharma Co., Ltd. ("HanAll"). Pursuant to the HanAll Agreement, 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.

Relationships with Roivant Sciences Ltd., Roivant Sciences, Inc. and Roivant Sciences GmbH

We are a Vant within the Roivant Family of Companies

We are a majority-owned subsidiary of Roivant and have benefited from our ability to leverage the Roivant model and the greater Roivant platform. The period of time between our formation and operational maturation was shortened based on the support from centralized Roivant functions available since its creation. This includes operational functions as well as access to Roivant's proprietary technology and digital innovation platforms. Consistent with its model, Roivant has also provided us with access to an embedded team of scientific experts, physicians and technologists to help optimize clinical development and commercial strategies. In the future, we may have the ability to benefit from Roivant's economies of scale and scope.

Our Controlling Stockholder

Roivant is currently our majority stockholder, and we are a “controlled company” within the meaning of the listing rules of Nasdaq. We will remain a “controlled company” so long as 50% of the voting power for the election of directors is held by Roivant. As such, we are availing ourselves of certain controlled company exemptions under the Nasdaq listing rules. We are not required to have a majority of “independent directors” on our board of directors, as defined under the Nasdaq listing rules, or to have a compensation committee or a committee performing the director nominating function composed entirely of independent directors. Roivant will be able to exercise control over all matters requiring stockholder approval, including the election of our directors and approval of significant corporate transactions. In addition, Roivant, as the holder of Series A Preferred Stock, has the right to elect a certain number of Series A Preferred Directors in accordance with the provisions of our amended and restated charter.

Services Agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH

We have received, and will continue to receive, various services provided by our affiliates, Roivant Sciences, Inc. (“RSI”) and Roivant Sciences GmbH (“RSG”), each an indirect wholly owned subsidiary of Roivant. These services include, but are not limited to, services related to development, administrative and financial activities. We expect that our reliance on RSI and RSG will decrease over time as we continue to hire the necessary personnel to manage the development and potential commercialization of IMVT-1401 and any future product candidate. For a description of the services agreements pursuant to which these services are provided, see “Certain Relationships and Related Party Transactions—Affiliate Services Agreements.”

Corporate Information

We were incorporated in Delaware in December 2018 as a blank check company under the name Health Sciences Acquisitions Corporation. On December 18, 2019, Immunovant Sciences Ltd. and HSAC consummated the transactions contemplated under the Share Exchange Agreement, following the approval at the special meeting of the stockholders of HSAC held on December 16, 2019 (the “Business Combination”). In connection with the closing of the Business Combination, we changed our name from HSAC to Immunovant, Inc.

Our principal executive offices are located at 320 West 37th Street, New York, New York, and our telephone number is (917)580-3099. Our corporate website address is www.immunovant.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We have four wholly owned subsidiaries: Immunovant Sciences Ltd., a Bermuda exempted limited company, Immunovant Sciences Holdings Limited, a limited company organized under the laws of the United Kingdom (the “U.K.”), IMVT Corporation, a Delaware corporation, and Immunovant Sciences GmbH (“ISG”), a company with limited liability formed under the laws of Switzerland. We also conduct business operations at 324 Blackwell Street, Suite 1220, Durham, North Carolina 27701. ISG maintains its headquarters at Viaduktstrasse 8, 4051 Basel, Switzerland. ISG holds our intellectual property rights in our product candidate.

“IMMUNOVANT” and our other registered and common law trade names, trademarks and service marks are property of Immunovant, Inc. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in this prospectus, our periodic reports and our proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of HSAC’s initial public offering, (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 our common shares that is held by non-affiliates exceeds \$700.0 million as of the end of our second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. 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 reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

The Offering	
Common stock offered by the selling stockholders	<p>We are registering 66,342,874 shares of common stock to be offered from time to time by the selling stockholders, consisting of:</p> <ul style="list-style-type: none">• up to 42,080,376 shares of common stock issued pursuant to the Share Exchange Agreement;• up to 20,000,000 additional shares of common stock that may be issued pursuant to the Share Exchange Agreement upon the satisfaction of certain conditions, as described under “Certain Relationships and Related Party Transactions—Earnout Payments;”• up to 2,875,000 shares of common stock held by the Sponsor; and• up to 1,387,498 shares of common stock purchased by the Selling RTW Entities and RSL in open market transactions. <p>In addition, we are registering 5,750,000 shares of common stock issuable upon exercise of the warrants.</p>
Terms of the offering	<p>The selling stockholders will determine when and how they will dispose of the shares of common stock registered for resale under this prospectus.</p>
Sponsor Restricted Stock Agreement	<p>An aggregate of 1,800,000 shares of common stock held by the Sponsor are subject to forfeiture in the event that certain Milestones are not achieved, and may not be sold until such time. See the section titled “Certain Relationships and Related Party Transactions—Sponsor Restricted Stock Agreement.”</p>
Lock-Up Agreements	<p>Each selling stockholder named in this prospectus has entered into a Lock-up Agreement with us with respect to the shares of common stock that may be sold by it from time to time pursuant to the registration statement of which this prospectus forms part. Such shares may not be sold for a period of six months from the date of the closing of the Business Combination, provided that 50% of such shares will be released on the date on which the last reported closing price of our common stock on the Nasdaq Capital Market equals or exceeds \$12.50 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days during any 30 trading-day period. See the section titled “Certain Relationships and Related Party Transactions—Lock-Up Agreements.”</p>
Controlled company	<p>RSL is currently our majority stockholder, and we are a “controlled company” within the meaning of Nasdaq listing rules. As a controlled company, we have elected to avail ourselves of the controlled company exemption under the corporate governance requirements of Nasdaq.</p>
Risk factors	<p>Before investing in our securities, you should carefully read and consider the information set forth in “Risk Factors” beginning on page 5.</p>
Use of proceeds	<p>We will not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders, except with respect to amounts received by us due to the exercise of the warrants. We expect to use the proceeds received from the exercise of the warrants, if any, for working capital and general corporate purposes.</p>
Nasdaq ticker symbol	<p>“IMVT”</p>
<p>For additional information concerning the offering, see “Plan of Distribution” beginning on page 140.</p>	

RISK FACTORS

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

Risks Related to Our Business, Financial Position and Capital Requirements

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;

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- 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 \$34.5 million for the period from December 19, 2017 to March 31, 2018, the year ended March 31, 2019, and the six months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of \$59.4 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.

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Our independent registered public accounting firm has issued a going concern opinion on our combined and consolidated financial statements included elsewhere in this prospectus, 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 (“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 (“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 preclinical 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 preclinical 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 preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

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- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy (“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 (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 or license;

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- the effect of competing market developments;
- the cost and timing of completion of commercial-scale and other manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for IMVT-1401 or any future product candidate in regions where we choose to commercialize such product candidate on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidate, if approved for commercial sale.

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

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

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

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

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

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

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 September 30, 2019, we had no employees, and our wholly owned subsidiary, IMVT Corporation, had 17 employees, including 13 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 (“Services Agreements”), as further described under the section titled “Certain Relationships and Related Party Transactions—Affiliate Services Agreements.” For example, we currently rely and expect to continue to rely on RSI to support our preclinical 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 ("GCP") or current Good Manufacturing Practice ("cGMP") standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct,

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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

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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 or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the United States Foreign Corrupt Practices Act ("FCPA"), including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010 ("U.K. Bribery Act"), and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

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

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

In June 2016, a majority of the eligible members of the electorate in the U.K. voted to withdraw from the European Union ("E.U.") in a national referendum, commonly referred to as "Brexit." The U.K. and the E.U. have agreed to a withdrawal agreement (the "Withdrawal Agreement") which may be approved by the U.K. Parliament in the very near future. If the Withdrawal Agreement is approved by the U.K. Parliament, it is expected that the U.K. will formally leave the E.U. on or before January 31, 2020. Under the Withdrawal Agreement, the U.K. would be subject to a transition period until December 31, 2020 (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.

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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 ("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, cash flows and 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 preclinical 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 are implementing a company-wide enterprise resource planning ("ERP") system to upgrade certain existing business, operational, and financial processes, upon which we rely. ERP implementations are complex and time-consuming projects that require transformations of business and finance processes to reap the benefits of the ERP system. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. Additionally, if the ERP system is not effectively implemented as planned, or the 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

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controls adequately could be delayed. Significant delays in documenting, reviewing and testing our internal control over financial reporting could cause us to fail to comply with the Securities and Exchange Commission (the "SEC") reporting obligations related to our management's assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business during or following the implementation of the ERP system, our business and results of operations could be harmed.

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

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

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

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

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 preclinical 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 preclinical 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 preclinical studies and clinical trials of IMVT-1401, some of which were not conducted by us, may not be predictive of the results of our planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

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

- failure to obtain regulatory authorization to commence a trial or reaching consensus with regulatory authorities regarding the design or implementation of our studies;
- unforeseen safety issues, or subjects experiencing severe or unexpected AEs;
- occurrence of serious AEs in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- resolving any dosing issues or limitations, including those raised by the FDA;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to add a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other regulatory authorities;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;

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- an institutional review board (“IRB”) refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- 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 preclinical 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 preclinical or clinical development of IMVT-1401 prior to its in-license from HanAll. We are dependent on our licensing partner having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all preclinical 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 preclinical 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 preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior preclinical testing and clinical trials. In particular, we cannot assure you that the reductions in IgG antibodies 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 preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported AEs. The results of preclinical 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 preclinical 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

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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 a very 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 preclinical 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.

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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.

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We also expect to face competition from agents with different mechanisms of action. The most commonly prescribed first-line agents for the treatment of MG are acetylcholinesterase inhibitors, such as pyridostigmine, which are marketed by several manufacturers of generic medicines. IVIg is also routinely used for patients with MG. 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.

In addition, other product candidates in development for the treatment of MG include: zilucoplan (Ra Pharma), 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. There are at least two agents in development for the treatment of GO, including: teprotumumab (Horizon Therapeutics), an anti-IGF-1R antibody, which is currently in Phase 3 development; and tocilizumab (Roche), an IL6 receptor antibody, which has been evaluated in a recent Phase 3 investigator-sponsored trial. In July 2019, Horizon Therapeutics announced it had submitted a BLA for teprotumumab and the availability of an expanded access program while the FDA reviews the BLA. Other product candidates in development for the treatment of WAIHA include: fostamatinib (Rigel Pharmaceuticals), a syk kinase inhibitor, which is in Phase 3 development, sutimlimab (Sanofi), an anti-C1s antibody, and APL-2 (Apellis Pharmaceuticals), a C3 inhibitor, each of which is currently in Phase 1/2 clinical development. Also ongoing is a Phase 2 investigator-initiated study of ibrutinib (AbbVie), a BTK inhibitor, in steroid refractory WAIHA.

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;

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

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

Adverse events 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 preclinical 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,

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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 preclinical 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 preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical 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 preclinical 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.

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Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable regulations in foreign jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, 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.

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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.

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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.

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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 (“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 (“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 (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.

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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 (“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 inseparable 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.

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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;

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

We rely upon CROs to monitor and manage data for our clinical programs, as well as for the execution of preclinical 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.

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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 preclinical 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 preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical 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 preclinical 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 (“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 preclinical 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.

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

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. The patent applications that we in-license may fail to result in issued patents with claims that cover our product candidate in the United States or in other foreign countries. 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 patents and patent applications that we in-license may fail to result in issued patents with claims that protect our product candidate in the United States or in other foreign countries. 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,

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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, or superior, 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 (the "USPTO") and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

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

Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. 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.

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

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

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

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

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

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

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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 natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidate are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. The patent family directed to the composition of matter of IMVT-1401 has a natural projected expiration date in 2035 in the United States and in foreign jurisdictions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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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 we 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

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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 products. 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 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 products.

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 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 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 the use of our product candidate, if approved.

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

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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 research programs and 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.

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

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

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

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

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

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

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, 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 foreign 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 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 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;

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- 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;

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- 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.

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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. See "Description of Capital Stock—Series A Preferred Directors."

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

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

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

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

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

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

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

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

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (the “Sarbanes Oxley Act”), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors’ and officers’ liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

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

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act (“Section 404”), to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the first fiscal year beginning after the effective date of the registration statement of which this prospectus forms a part. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the 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.

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

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the 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 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.

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

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

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

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Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will” and “would,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- future operating or financial results;
- future payments of dividends and the availability of cash for payment of dividends;
- future acquisitions, business strategy and expected capital spending;
- the initiation, timing, progress, costs and results of our clinical trials for IMVT-1401, including its ASCEND-MG, ASCEND-GO and ASCEND-WAIHA trials;
- the timing of meetings with and feedback from regulatory authorities as well as any submission of filings for regulatory approval of IMVT-1401;
- the potential advantages and differentiated profile of IMVT-1401 compared to existing therapies for the applicable indications;
- our ability to successfully manufacture or have manufactured drug product for clinical trials and commercialization;
- our ability to successfully commercialize IMVT-1401, if approved;
- the rate and degree of market acceptance of IMVT-1401, if approved;
- our expectations regarding the size of the patient populations for and opportunity for and clinical utility of IMVT-1401, if approved for commercial use;
- our estimates of its expenses, ongoing losses, future revenue, capital requirements and needs for or ability to obtain additional financing;
- our ability to maintain intellectual property protection for IMVT-1401;
- our ability to identify, acquire or in-license and develop new product candidates;
- our ability to identify, recruit and retain key personnel; and
- developments and projections relating to our competitors or industry.

You should refer to the section titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements.

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As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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 prospectus, 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 as predictions of future results.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

INDUSTRY AND MARKET DATA

Certain industry data and market data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of management's estimates presented herein are based upon management's review of independent third-party surveys and industry publications prepared by a number of sources and other publicly available information. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this prospectus is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

All the securities offered in this prospectus are being sold by the selling stockholders. We will not receive any proceeds from the sale of securities by the selling stockholders. We expect to use the proceeds received from the exercise of the warrants, if any, for working capital and general corporate purposes.

DIVIDEND POLICY

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

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 included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our fiscal year ends on March 31.

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

Overview

We are a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits 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 preclinical 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, it believes that IMVT-1401, if approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases, (e.g., MG, GO, 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 its three target indications, and there is no certainty that it would obtain such designation, or maintain the benefits associated with such designation, if or when it does.

In August 2019, we initiated dosing in its 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 its 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 an IND to 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. We were incorporated in July 2018 and its operations to date have been limited to organizing and staffing

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its company, 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 inception. As of March 31, 2019 and September 30, 2019, We had an accumulated deficit of \$24.8 million and \$59.4 million, respectively. For the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019, we recorded net losses of \$34.2 million and \$28.6 million, respectively, and \$10.7 million and \$34.5 million for the six months ended September 30, 2018 and 2019. These factors raise substantial doubt about our ability to continue as a going concern.

Our financial statements are derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with IMVT-1401 that have been contributed to us by RSL, from RSL's financial statements. Our financial statements have been presented as if we had been a separate business since the acquisition of IMVT-1401 by 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 its formation through March 31, 2019 and the six months ended September 30, 2019. The financial statements as of and for the period ended March 31, 2018, the six months ended September 30, 2018, the year ended March 31, 2019, and the six months ended September 30, 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 the accounts of us and our wholly owned subsidiaries.

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, RSG entered into the HanAll Agreement. Under the HanAll Agreement, RSG received (1) non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to develop, import and use the antibody referred to as IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, and to commercialize such products, in the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America ("the Licensed Territory") for all human and animal uses, during the term of the agreement.

In December 2018, we obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 from RSG in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and its wholly owned subsidiary, ISG, for an aggregate purchase price of \$37.8 million plus Swiss value-added tax of \$2.9 million.

Under the HanAll Agreement, the parties 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 its 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 and RSL have performed all the development associated with IMVT-1401 and no amounts were incurred by HanAll to research or develop the technology for the period from December 19, 2017 to March 31, 2018, the year ended March 31, 2019, or the six months ended September 30, 2019.

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. See "Business—License Agreement with HanAll Biopharma Co., Ltd." for further information. 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 it, or third parties acting on its behalf, incurs for us. 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.

Financial Operations Overview

Revenue

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

Research and Development Expenses

Since our incorporation, our operations have primarily been limited to organizing and staffing our company, acquiring rights to our product candidate, IMVT-1401, and preparing for and conducting clinical trials. Our research and development expenses for the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019 were \$33.8 million and \$25.7 million, respectively and \$28.8 million for the six months ended September 30, 2019. For the year ended March 31, 2019 and the six months ended September 30, 2019, research and development expenses primarily consisted 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. For the period from December 19, 2017 to March 31, 2018, research and development expenses consisted primarily of the upfront fee paid to HanAll under the HanAll Agreement. 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, share-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 preclinical studies designed to assist with the lead optimization of our product candidate;
- manufacturing costs in connection with conducting preclinical 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.

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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 planned Phase 2 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 share-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 its 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 for marketing, 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 Expense/(Income), Net

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

Results of Operations for the Six Months Ended September 30, 2018 and 2019

The following table sets forth our results of operations for the six months ended September 30, 2018 and 2019.

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	Six Months Ended September 30,	
	2018	2019
Operating expenses:		
Research and development	\$ 10,080,112	\$ 28,806,867
General and administrative	528,175	5,747,593
Total operating expenses	10,608,287	34,554,460
Interest expense	—	249,315
Other expense/(income), net	106,092	(318,806)
Loss before provision for income taxes	(10,714,379)	(34,484,969)
Income tax expense	3,985	56,005
Net loss	<u>\$ (10,718,364)</u>	<u>\$ (34,540,974)</u>

Research and Development Expenses

Research and development expenses increased by \$18.7 million, from \$10.1 million for the six months ended September 30, 2018 to \$28.8 million for the six months ended September 30, 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 CMO costs, CRO costs and other third-party costs of \$3.8 million, \$2.6 million and \$2.1 million, respectively, which were driven by advancement of clinical trials for the treatment of autoimmune disease, and personnel-related expenses and share-based compensation expense of \$1.5 million and \$1.6 million, respectively, which were due to our increased headcount to support our clinical operations. The overall increase was partially offset by decreases in non-clinical studies of \$1.3 million and costs billed to us under the Services Agreements of \$1.6 million.

General and Administrative Expenses

General and administrative expenses increased \$5.2 million, from \$0.5 million for the six months ended September 30, 2018 to \$5.7 million for the six months ended September 30, 2019. This increase was primarily due to higher legal and professional fees of \$2.9 million, higher personnel-related costs of \$0.6 million, an increase in other costs of \$0.2 million, an increase of \$0.2 million in allocations to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on its matters, and higher share-based compensation expense of \$1.3 million in relation to options issued by us.

Interest Expense

Interest expense of \$0.2 million for the six months ended September 30, 2019 is related to the convertible promissory notes entered into during the period.

Other Expense/(Income), Net

Other expense of \$0.1 million for the six months ended September 30, 2018 changed to other income of \$0.3 million for the six months ended September 30, 2019 primarily due to foreign exchange fluctuations.

Results of Operations from December 19, 2017 to March 31, 2018 and for the Year Ended March 31, 2019

The following table sets forth our results of operations for the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019.

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	Period from December 19, 2017 to March 31, 2018	Year Ended March 31, 2019
Operating expenses:		
Research and development	\$ 33,815,863	\$ 25,733,274
General and administrative	<u>369,279</u>	<u>2,691,946</u>
Total operating expenses	34,185,142	28,425,220
Other expense, net	<u>—</u>	<u>155,480</u>
Loss before provision for income taxes	(34,185,142)	(28,580,700)
Income tax expense	<u>—</u>	<u>18,724</u>
Net loss	<u>\$ (34,185,142)</u>	<u>\$ (28,599,424)</u>

Research and Development Expenses

Research and development expenses were \$25.7 million for the year ended March 31, 2019 and primarily consisted of program-specific research and development costs for the treatment of autoimmune disease, which include CMO costs of \$8.0 million, CRO costs of \$6.1 million, non-clinical studies of \$3.0 million, other third-party research and development costs of \$3.6 million and personnel related expenses of \$1.4 million. The remainder consisted primarily of costs billed to us under the Services Agreements of \$2.4 million, including personnel expenses and third-party costs associated with the preparation of its clinical and other research programs, and share-based compensation expense of \$1.2 million in relation to the RSL common share awards and options issued by RSL to employees of RSL, RSI, RSG and IMVT Corporation (formerly Immunovant, Inc.).

Research and development expenses were \$33.8 million for the period from December 19, 2017 to March 31, 2018 and consisted primarily of the upfront payment to HanAll of \$30.0 million and the remainder consisted primarily of manufacturing and CRO costs of \$3.0 million. The remainder consisted primarily of costs billed to us under the Services Agreement of \$0.6 million and share-based compensation expense \$0.2 million allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters.

General and Administrative Expenses

General and administrative expenses were \$2.7 million for the year ended March 31, 2019, which consisted primarily of legal and professional fees of \$1.0 million, other costs of \$0.2 million, personnel-related costs of \$0.3 million, \$1.1 million allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on its matters, and share-based compensation expense of \$0.1 million in relation to the RSL common share awards and options issued by RSL to employees of RSL, RSI, RSG and IMVT Corporation (formerly Immunovant, Inc.).

General and administrative expenses were \$0.4 million for the period from December 19, 2017 to March 31, 2018 and consisted primarily of share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters of approximately \$0.3 million, and costs of \$0.1 million billed to us under the Services Agreements, including personnel costs, overhead allocations and third-party costs.

Liquidity and Capital Resources

Overview

We had cash of \$7.0 million and \$19.0 million as of March 31, 2019 and September 30, 2019, respectively.

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For the period from December 19, 2017 to March 31, 2018 and for year ended March 31, 2019, we had net losses of \$34.2 million and \$28.6 million, respectively. For the six months ended September 30, 2018 and 2019, we had net losses of \$10.7 million and \$34.5 million, respectively. As of September 30, 2019, we have never generated revenue. As a result, there is substantial doubt about our ability to continue as a going concern.

We expect to continue to incur significant and increasing operating losses at least for the next several years. 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 our anticipated 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;
- 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
- begin and continue to operate as a public company.

We intend to use the proceeds of the Business Combination primarily to fund our ASCEND-MG trial, our ASCEND-GO 1 trial, our ASCEND-GO 2 trial, our planned ASCEND-WAIHA trial, and other clinical development activities. These 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. To continue as a going concern, we will need, among other things, additional capital resources. Accordingly, we may be required to obtain further funding through other public or private offerings of our capital stock, debt financing, collaboration and licensing arrangements or other sources. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we believe that we will continue to raise capital to fund our operations, ASC 240-40, *Going Concern*, does not allow us to consider future financing activities in our assessment of our future cash burn for the purpose of our liquidity assessment. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations.

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.

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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 itself or potentially discontinue operations.

Cash Flows

The following table sets forth a summary of our cash flows for the period from December 19, 2017 to March 31, 2018, for the year ended March 31, 2019 and for the six months ended September 30, 2018 and 2019:

	Period From December 19, 2017 to March 31, 2018	Year Ended March 31, 2019 Six Months	Ended September 30, 2018 Six Months	Ended September 30, 2019
Net cash used in operating activities\$	\$ (32,074,325)	\$ (28,547,577)\$	\$ (8,509,520)\$	\$ (25,889,520)
Net cash used in investing activities	—	(51,812)	—	(8,319)
Net cash provided by financing activities\$	\$ 32,074,325\$	\$ 35,584,478\$	\$ 13,556,436\$	\$ 37,904,399

Operating Activities

For the six months ended September 30, 2019, \$25.9 million of cash was used in operating activities. This was primarily attributable to a net loss for the period of \$34.5 million and unrealized foreign currency exchange translation adjustment of \$0.3 million, partially offset by a net change in operating assets and liabilities of \$3.9 million, share-based compensation of \$3.7 million and write-off of deferred offering costs of \$1.4 million. The change in our operating assets and liabilities was primarily due to an increase of \$1.6 million in accounts payable and accrued expenses, an increase of \$0.1 million in amounts due to RSL, partially offset by a decrease of \$2.1 million in prepaid expenses and a decrease of \$0.1 million in income tax receivable.

For the six months ended September 30, 2018, \$8.5 million of cash was used in operating activities. This was primarily attributable to a net loss for the period of \$10.7 million, partially offset by a net change in operating assets and liabilities of \$1.2 million, share-based compensation of \$0.8 million and unrealized foreign currency exchange translation adjustment of \$0.1 million. The change in our operating assets and liabilities was primarily due to a net increase of \$2.1 million in accounts payable and accrued expenses, partially offset by an increase of \$0.9 million in prepaid expenses.

For the year ended March 31, 2019, \$28.5 million of cash was used in operating activities. This was primarily attributable to a net loss for the period of \$28.6 million and a net change in operating assets and liabilities of \$1.4 million, which were partially offset by share-based compensation of \$1.3 million and unrealized foreign currency exchange translation adjustment of \$0.2 million. The change in our operating assets and liabilities was due to an increase of \$2.5 million in prepaid expenses and an increase of \$2.9 million in the Swiss value-added tax receivable related to the assignment of the HanAll License Agreement, partially offset by a net increase in accounts payable and accrued expenses of \$4.0 million due to a ramp up in our research and development efforts.

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For the period from December 19, 2017 to March 31, 2018, \$32.1 million of cash was used in operating activities. The net loss for the period of \$34.2 million was partially offset by share-based compensation \$0.5 million, unrealized foreign currency exchange translation adjustment of \$0.2 million, and a net change in operating assets and liabilities of \$1.5 million. The change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of \$1.6 million to support our research and development efforts, partially offset by an increase in prepaid expenses of \$0.1 million.

Investing Activities

For the six months ended September 30, 2019, \$8,319 of cash was used to purchase computer equipment.

For the six months ended September 30, 2018, no cash was used in investing activities.

For the year ended March 31, 2019, \$0.1 million of cash was used to purchase computer equipment.

For the period from December 19, 2017 to March 31, 2018, no cash was used in investing activities.

Financing Activities

For the six months ended September 30, 2019, \$37.9 million of cash provided by financing activities was due to \$35.0 million in proceeds from convertible promissory notes payable to RTW Entities and Biotechnology Value Fund ("BVF"), \$7.9 million in proceeds from promissory notes payable to RSL, and \$0.6 million in capital contributions by RSL, partially offset by \$5.0 million in repayments of convertible promissory notes payable to RTW Entities and RSL, and payment of deferred offering costs of \$0.6 million.

For the six months ended September 30, 2018, \$13.6 million of cash provided by financing activities was due to \$8.5 million in capital contributions by RSL and \$5.1 million of investments made by RSL.

For the year ended March 31, 2019, \$35.6 million of cash provided by financing activities was due to \$16.1 million in capital contributions by RSL, \$14.9 million of net proceeds from the issuance of common shares and \$5.1 million of investments made by RSL, partially offset by the payment of IPO costs of \$0.5 million.

For the period from December 19, 2017 to March 31, 2018, cash provided by financing activities was \$32.1 million, due to 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, 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 preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, subject to payment of its remaining obligations under binding purchase orders and, in certain cases, nominal early termination fees. These commitments are not deemed significant.

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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 March 31, 2019, the aggregate maximum amount of milestone payments we could be required to make under the HanAll Agreement is \$452.5 million upon the achievement of certain development, regulatory and sales milestone events. In May 2019, we achieved our first development and regulatory milestone under the HanAll Agreement resulting in a \$10.0 million milestone payment that was paid by us in August 2019. We are also required to reimburse HanAll for half of budgeted research and development costs incurred by them 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.

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 March 31, 2018, we did not have any cash. As of March 31, 2019 and September 30, 2019, We had cash of \$7.0 million and \$19.0 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of its financial condition and results of operations is based on ISL's combined and consolidated financial statements, which have been prepared in accordance with 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 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.

ISL's 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 ISL's formation were between entities under the common control of RSL and/or its wholly owned subsidiaries, ISL's combined and consolidated financial statements have been presented as if it 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 its formation through September 30, 2019.

We define our critical accounting policies as those under GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to ISL's combined and consolidated financial statements appearing elsewhere in this prospectus, we believe the following are the critical accounting policies used in the preparation of ISL's combined and consolidated financial statements that require significant estimates and judgments.

Share-Based Compensation

We recognize share-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 share-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the share-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. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. 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. Our expected term represents the period that its 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).

Common Stock Price. Our board of directors estimates the fair value of our common stock. In accordance with the American Institute of Certified Public Accountants' Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, our board of directors exercises reasonable judgment and considers a number of objective and subjective factors to determine our best estimate of the fair value of our common stock, as further described below.

Expected Volatility. Prior to the Business Combination, we were a privately-held company and did not have any trading history for our common stock and the expected volatility was estimated using weighted average measures of implied volatility and the historical volatility of its 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.

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 its matters. The fair value of the RSL common share awards are 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.

Prior to the Business Combination, the fair value of our common stock was estimated on each grant date by its board of directors. In order to determine the fair value of our common stock, our board of directors considered, among other things, timely valuations of its 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*. Our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including (1) our business, financial condition and results of operations, including related industry trends affecting our operations; (2) our forecasted operating performance and projected future cash flows; (3) the illiquid nature of our common stock; (4) the rights and privileges of our common stock; (5) market multiples of our most comparable public peers and (6) market conditions affecting our industry.

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After the closing of the Business Combination, our board of directors determines the fair value of each common stock underlying stock-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant and therefore it will not be necessary to determine the fair value of the new stock-based award pursuant to the methodology described above.

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 September 30, 2019, we did not have any significant uncertain tax positions.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. We are currently evaluating the new standard and its impact on the combined and consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU No. 2018-13”). ASU No. 2018-13 removes, modifies, and adds certain recurring and nonrecurring fair value measurement disclosures, including removing disclosures around the amount(s) of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation process for Level 3 fair value measurements, among other things. ASU No. 2018-13 adds disclosure requirements around changes in unrealized gains and losses included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period, the range and weighted average of significant unobservable inputs

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used to develop Level 3 fair value measurements, and a narrative description of measurement uncertainty. The amendments in ASU No. 2018-13 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty are to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption, with all other amendments applied retrospectively to all periods presented. Early adoption is permitted. We are currently evaluating the new standard and its impact on the combined and consolidated financial statements.

Recently Adopted Accounting Pronouncements

In January 2016, the FASB issued ASUNo. 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* (“ASU No. 2016-01”) which requires entities with financial liabilities measured using the fair value option in ASC 825 to recognize the changes in fair value of liabilities caused by a change in instrument-specific credit risk (own credit risk) in other comprehensive income. The ASU is effective for public business entities in fiscal years beginning after December 15, 2017. Entities can early adopt certain provisions of the new standard, including the provision related to financial liabilities measured under the fair value option. We adopted ASU No. 2016-01 as of April 1, 2018. The adoption of ASU No. 2016-01 did not have a material impact on our combined and consolidated financial statements and related disclosures.

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 its 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.

In November 2016, the FASB issued ASUNo. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force)* (“ASU No. 2016-18”). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU No. 2016-18 is effective for annual reporting periods beginning after December 15, 2017 and is required to be adopted using a retrospective approach, if applicable, with early adoption permitted. We adopted ASU No. 2016-18 on April 1, 2018. The adoption of ASUNo. 2016-18 did not have a material impact on our combined and consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASUNo. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU No. 2017-01”), which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU No. 2017-01 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. We adopted this ASU as of April 1, 2018, with no impact on our combined and consolidated financial statements.

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In February 2018, the FASB issued ASUNo. 2018-02, *Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU No. 2018-02"). ASU No. 2018-02 allows companies to reclassify stranded tax effects resulting from the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU No. 2018-02 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The adoption of ASU 2018-02 on April 1, 2018 did not have a material impact on our combined and consolidated financial statements.

In June 2018, the FASB issued ASUNo. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07"). ASU No. 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. 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.

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.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. We are developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits 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 preclinical 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.

Autoimmune diseases are conditions where an immune response is inappropriately directed against the body's own healthy cells and tissues. Approximately 50 million people in the United States suffer from one of more than 100 diagnosed autoimmune diseases according to the American Autoimmune Related Diseases Association, Inc. Predisposing factors may include genetic susceptibility, environmental triggers and other factors not yet known. Many of these diseases are associated with high levels of pathogenic IgG antibodies, which are the most abundant type of antibody produced by the human immune system, accounting for approximately 75% of antibodies in the plasma of healthy people. IgG antibodies are important in the defense against pathogens, such as viruses and bacteria. In many autoimmune diseases, IgG antibodies inappropriately develop against normal proteins found in the body, directing the immune system to attack specific organs or organ systems. Current treatment regimens for IgG-mediated autoimmune diseases include corticosteroids and immunosuppressants in early stage disease, followed by more invasive treatments, such as IVIg, and plasma exchange, as the disease progresses. Such treatments are often limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.

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

In several preclinical studies and Phase 1 clinical trials in healthy volunteers, intravenous and subcutaneous delivery of IMVT-1401 demonstrated dose-dependent IgG antibody reductions and was observed to be well tolerated. In the highest dose cohort from the multiple-ascending dose portion of the Phase 1 clinical trial, four weekly subcutaneous administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, and the standard deviation of the reduction was 2%. In addition, no headaches, an adverse event seen with some FcRn agents, have been noted to date in any of the subjects receiving IMVT-1401 in the 680 mg multiple-dose cohort.

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., MG, GO, 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

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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, and there is no certainty that we would obtain such designation, or maintain the benefits associated with such designation, if or when we do.

Our first target indication for IMVT-1401 is MG, an autoimmune disease associated with muscle weakness with an estimated prevalence of one in 5,000, with up to 65,000 cases in the United States. In MG, patients develop pathogenic IgG antibodies that attack critical signaling proteins at the junction between nerve and muscle cells. The majority of MG patients suffer from progressive muscle weakness, with maximum weakness occurring within six months of disease onset in most patients. In severe cases, MG patients can experience myasthenic crisis, in which respiratory function is weakened to the point where it becomes life-threatening, requiring intubation and mechanical ventilation.

In August 2019, we initiated dosing in our ASCEND-MG trial, a Phase 2a clinical trial in patients with MG. We plan to report top-line results from this trial in the first half of 2020.

Our second target indication for IMVT-1401 is GO, an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes, which can be sight-threatening. GO has an estimated annual incidence of 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe. Initial symptoms may include a dry and gritty ocular sensation, sensitivity to light, excessive tearing, double vision and a sensation of pressure behind the eyes.

In May 2019, we initiated dosing in its 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. In October 2019, we initiated dosing 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.

We are also developing IMVT-1401 for the treatment of WAIHA, a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of RBCs. Based on published estimates, we believe that there are approximately 42,000 patients in the United States and 66,000 patients in Europe living with WAIHA. The clinical presentation is variable and most commonly includes symptoms of anemia, such as fatigue, weakness, skin paleness and shortness of breath. In severe cases, hemoglobin levels are unable to meet the body's oxygen demand, which can lead to heart attacks, heart failure and even death.

In November 2019, we submitted our IND to 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.

We obtained rights to IMVT-1401 pursuant to the HanAll Agreement. Pursuant to the HanAll Agreement, 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.

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Our goal is to become a leading biopharmaceutical company in the development and commercialization of innovative therapies for autoimmune diseases with significant unmet need. To execute our strategy, we plan to:

- *Maximize the probability of success of IMVT-1401.* We plan to leverage IMVT-1401's differentiated profile in target indications where the anti-FcRn mechanism has already established clinical proof-of-concept. We intend to identify and target a variety of IgG-mediated autoimmune indications based on the following factors:
 - Inadequacy of the standard of care;
 - Disease severity that warrants novel therapies;
 - Ability to rapidly establish proof-of-concept through comparatively short duration clinical trials using validated clinical endpoints; and
 - Ability to rapidly initiate pivotal trial programs and potentially receive regulatory approval.
- *Strategically target indications for IMVT-1401.* We intend to be the first to study FcRn inhibition in target indications with clear biologic rationale and no known in-class competitors in clinical development.
- *Rapidly advance development of IMVT-1401 for the treatment of MG, GO and WAIHA.* We are currently developing IMVT-1401 for the treatment of MG, GO and WAIHA by leveraging the strong biologic rationale of targeting FcRn to reduce IgG antibody levels and the clinical and regulatory insights gained from other FcRn-targeted therapies in MG. In August 2019, we initiated our dose-confirmation ASCEND-MG trial of IMVT-1401 for the treatment of MG. We expect to report top-line data from this trial by the first half of 2020, following which we aim to commence a pivotal Phase 3 clinical trial of IMVT-1401 for the treatment of MG in 2020. In May 2019, we initiated dosing in its ASCEND-GO 1 trial in Canada in patients with GO. In October 2019, we initiated dosing in its ASCEND-GO 2 trial in the United States, Canada and Europe. We expect to report initial results of its ASCEND-GO 1 and ASCEND-GO 2 trials in the first quarter of 2020 and in early 2021, respectively. In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020.
- *Identify and acquire or in-license additional innovative therapies for autoimmune diseases.* Our parent company, RSL, and its subsidiaries have a track record of acquiring or in-licensing products in a range of therapeutic areas and we expect that RSL will continue to support us in identifying and evaluating potential acquisition and in-licensing opportunities in support of its goal to develop and commercialize innovative therapies for autoimmune diseases with significant unmet need.

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

INDICATION	ESTIMATED PREVALENCE (2017)	
	U.S.	EUROPE
Myasthenia Gravis	65,000	104,000
Warm Autoimmune Hemolytic Anemia	42,000	66,000
Graves' Ophthalmopathy	33,000	52,000
Idiopathic Thrombocytopenic Purpura	31,000	49,000
Pemphigus Vulgaris	28,000	45,000
Chronic Inflammatory Demyelinating Polyneuropathy	16,000	25,000
Bullous Pemphigoid	8,000	13,000
Neuromyelitis Optica	7,000	12,000
Pemphigus Foliaceus	7,000	11,000
Guillain-Barré Syndrome	3,000	5,000
PLA2R+ Membranous Nephropathy	2,000	4,000
Total	242,000	386,000

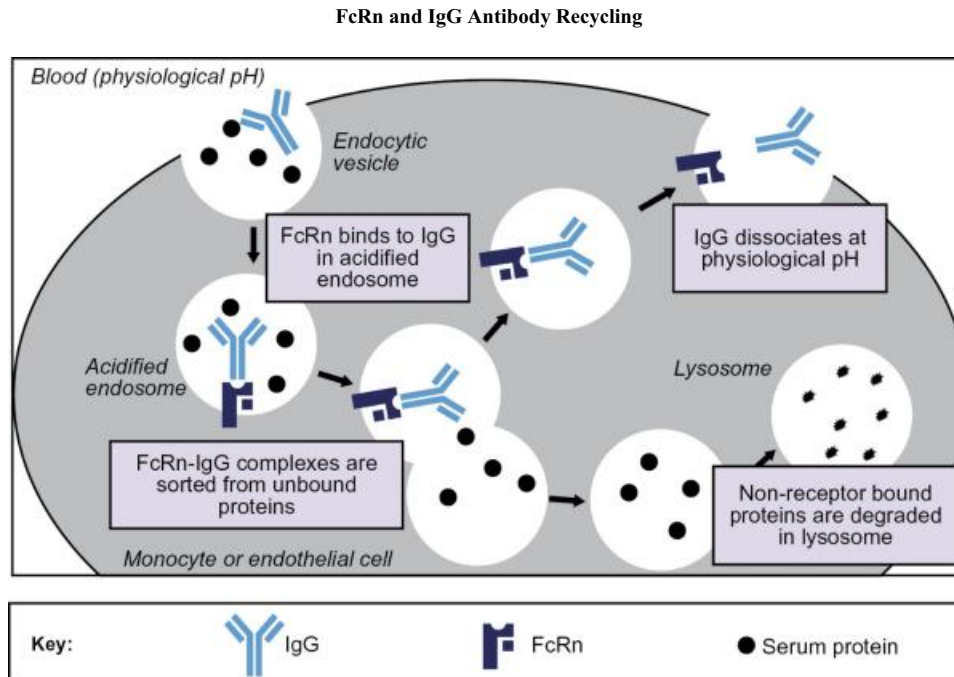
* Europe includes all E.U. countries, U.K. and Switzerland

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

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

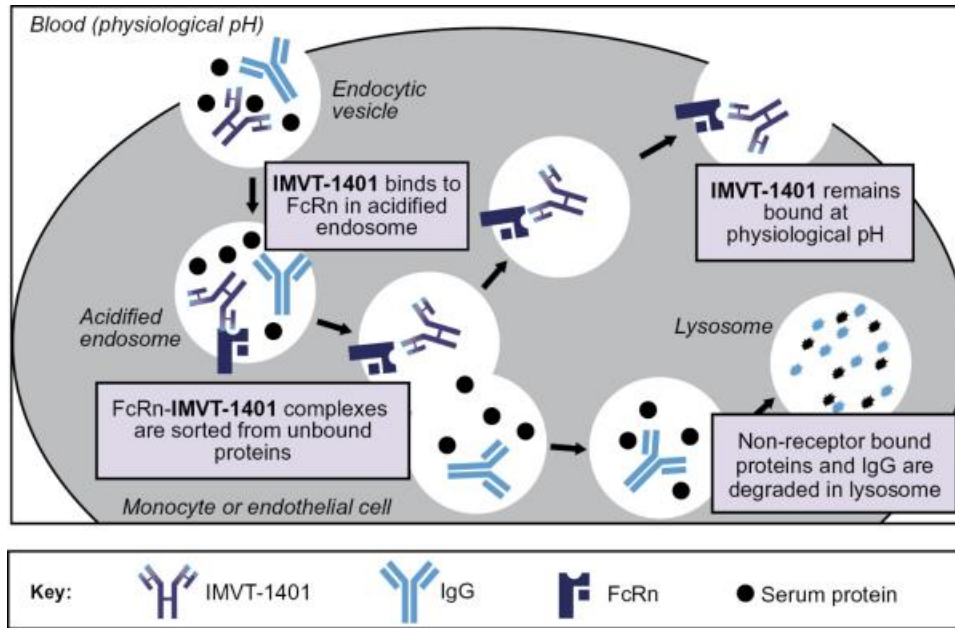
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In adults, FcRn is the primary protein responsible for preventing the degradation of IgG antibodies and albumin, the most abundant protein found in the blood. IgG antibodies are constantly being removed from circulation and internalized in cellular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



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

IMVT-1401's Mechanism of Action



IMVT-1401

Overview

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

Generation of IMVT-1401 and In Vitro Properties

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

- Potency and specificity for FcRn;
- Ability to block the IgG-FcRn interaction;
- Ability to remain bound to FcRn regardless of pH;

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- High production and stability in standard antibody production cell lines;
- Ability to achieve high concentrations appropriate for subcutaneous delivery; and
- Lack of immunogenicity.

IMVT-1401 was generated using the OmniAb transgenic rat platform from Open Monoclonal Technology (“OMT”). OMT was later acquired by Ligand Pharmaceuticals in 2015. As of May 2019, there are 12 OmniAb-derived clinical-stage antibody programs and greater than 300 active research programs.

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

Potential Benefits of IMVT-1401

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

- **Subcutaneous delivery.** Based on clinical data, we believe that we will be able to obtain therapeutically relevant levels of IgG reduction using one or two mL volume subcutaneous injections. Our current formulation is concentrated at 170 mg/mL.
- **Simple dosing schedule.** We are developing IMVT-1401 as a fixed-dose subcutaneous administered regimen without the need for preceding intravenous induction doses or lengthy subcutaneous infusions. If approved, we intend to market IMVT-1401 as a fixed-dose pre-filled syringe, which would allow for convenient self-administration, eliminating the need for frequent and costly clinic visits, and reduce complexity and errors associated with calculating individual doses.
- **Low immunogenicity risk.** IMVT-1401 is a fully human monoclonal antibody, and therefore contains only amino acid sequences native to humans. Preliminary data from the Phase 1 multiple ascending dose study showed no treatment emergent anti-drug antibodies.
- **Low effector function.** IMVT-1401 has been engineered to prevent activation of other components of the immune system, and, as a result, unintended immune response to IMVT-1401. Specifically, well-characterized and validated mutations introduced into the fragment crystallizable domain of IMVT-1401 have reduced its ability to cause ADCC and CDC. There have been no reports of severe systemic allergic reactions to study therapy.

Clinical Development for IMVT-1401

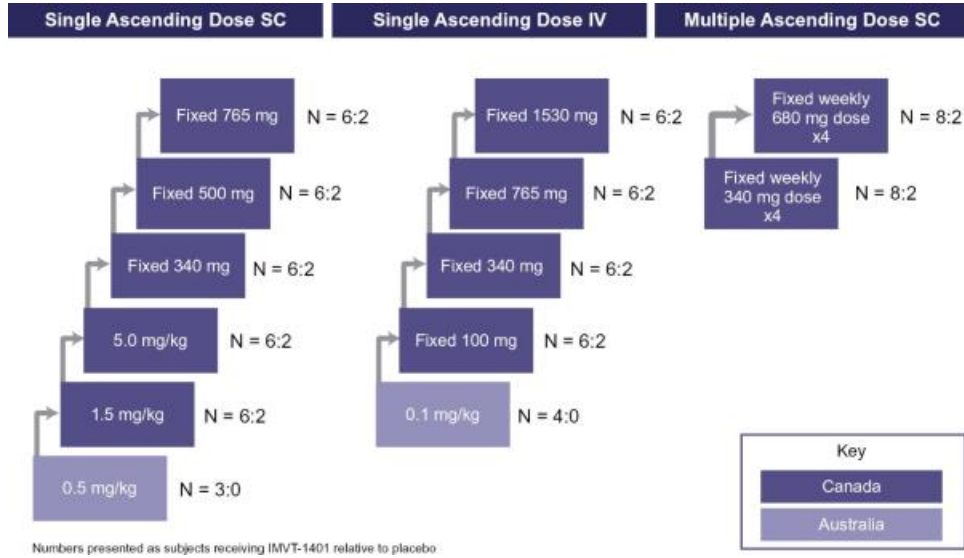
We are developing IMVT-1401 as a fixed-dose subcutaneous injection for a variety of IgG-mediated autoimmune diseases, with an initial focus on the treatment of MG, GO and WAIHA.

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Phase 1 Clinical Trials of IMVT-1401 in Healthy Volunteers

As of June 30, 2019, we have dosed 99 healthy volunteers in multi-part, placebo-controlled Phase 1 clinical trials conducted in Australia and Canada, both as an intravenous infusion and as a subcutaneous injection. In these trials, 77 subjects received at least one dose of IMVT-1401 and 22 subjects received placebo. We expect this multi-part, placebo-controlled Phase 1 clinical trial in healthy volunteers to continue to support its IND submissions to the FDA for IMVT-1401 in each of our current target indications, MG, GO and WAIHA. The preliminary results of this trial are presented below.

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



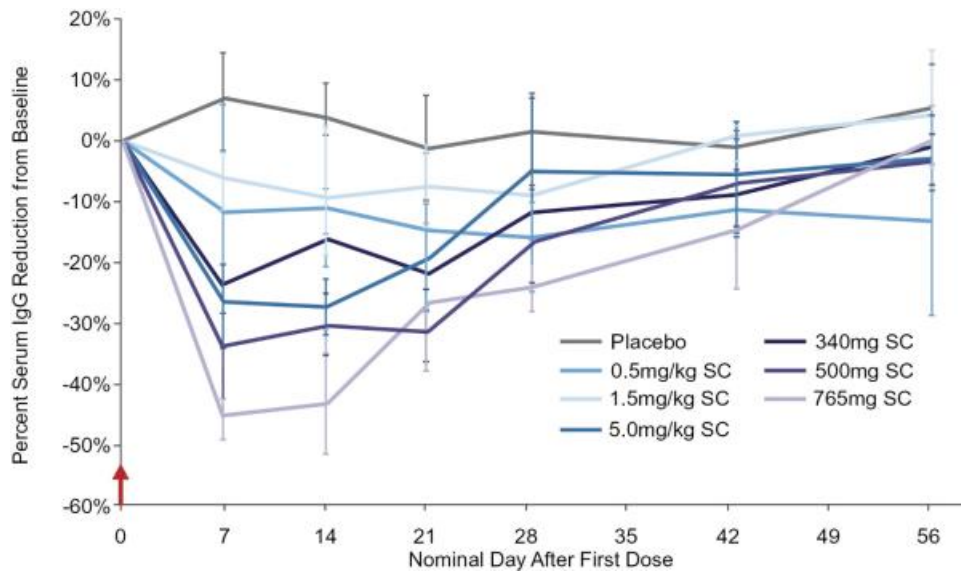
Pharmacokinetic Data

In the single-ascending dose portion of our Phase 1 clinical trial, IMVT-1401 demonstrated a PK profile that varies with increase in dose, consistent with the characteristics expected of a drug exhibiting target-mediated disposition. Following subcutaneous administration of IMVT-1401, the median time to peak concentrations ranged from less than a day for the lowest dose administered to approximately three days for the highest dose of 765 mg.

Pharmacodynamic Data

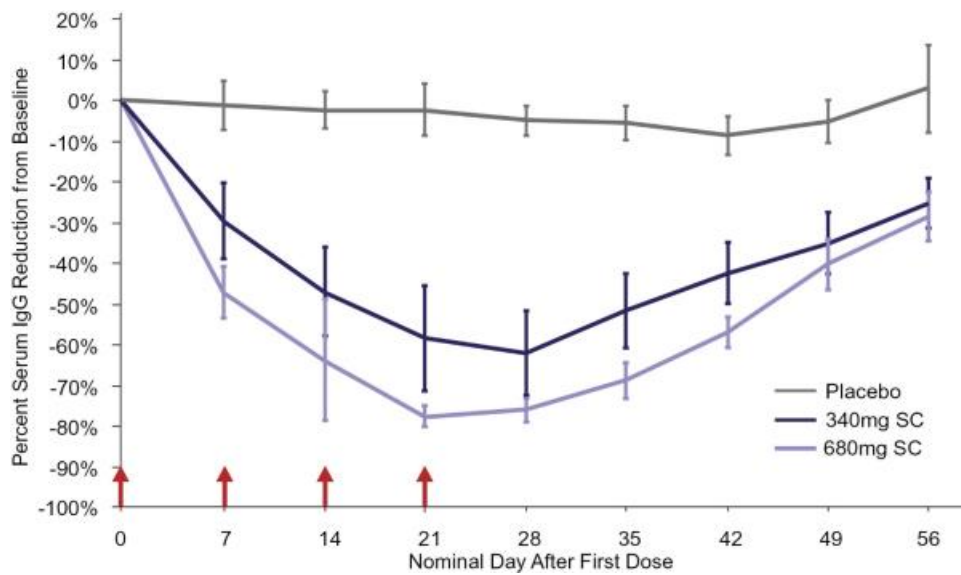
We tested single administrations of fixed intravenous doses of IMVT-1401, ranging from 0.1 mg/kg to 1530 mg as a fixed dose. The 1530 mg fixed intravenous dose resulted in mean maximum reduction of serum IgG antibody levels of 67%. Maximal reductions were observed between 10 and 14 days after dose administration. In addition, single administrations of per kilogram and fixed subcutaneous doses of IMVT-1401, ranging from 0.5 to 5 mg/kg and 340 mg to 765 mg, respectively, led to dose-dependent mean maximum reductions in serum IgG antibody levels of between 14% and 47%. Maximal reductions were observed between seven and 14 days after dose administration.

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

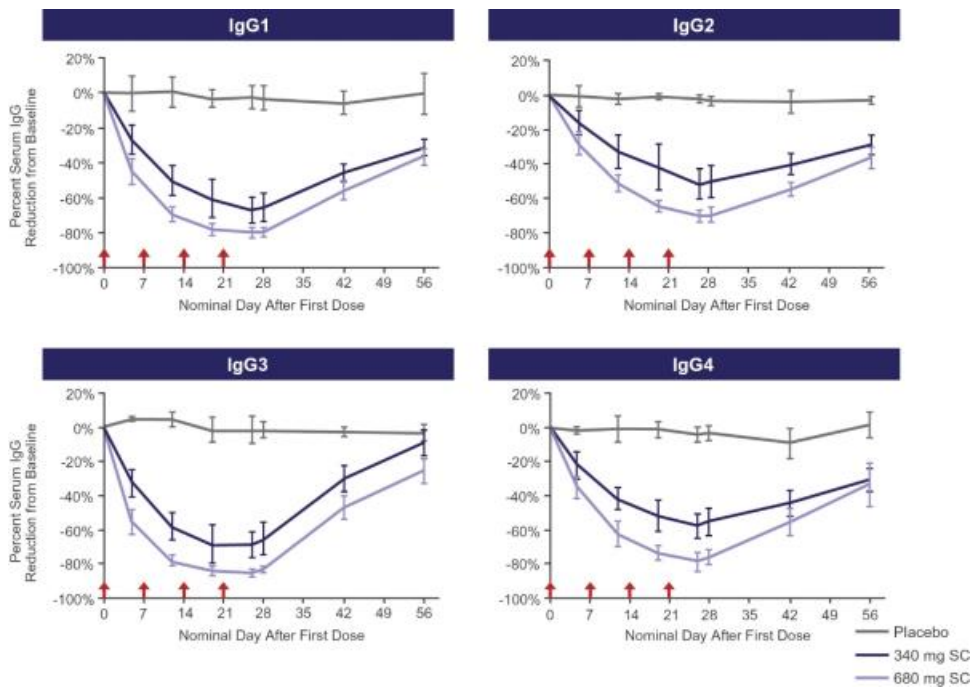


In the multiple-ascending dose portion of our Phase 1 clinical trial, two dose levels were tested. After four weekly subcutaneous administrations of 340 mg, a mean maximum reduction of serum IgG levels of 63% was observed during the treatment period, and the standard deviation of the reduction was 11%.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

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



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



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

Safety Data

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

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

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

NUMBER OF SUBJECTS	SINGLE ASCENDING DOSE											MULTIPLE ASCENDING DOSE							
	INTRAVENOUS INFUSION						SUBCUTANEOUS INJECTION					SUBCUTANEOUS INJECTION							
	0.1	100		340		765	1530	PLACEBO	0.5	1.5	5			340	680	PLACEBO			
	MG/	MG	MG	MG	MG	MG	MG	MG/	MG/	MG/	MG	MG	MG	MG	MG	MG	MG		
	N=4	N=6	N=6	N=6	N=6	N=8	N=3	N=6	N=6	N=6	N=6	N=6	N=6	N=6	N=6	N=10	N=8	N=8	N=4
MedDRA Preferred Term																			
Abdominal pain											1								1
Abdominal pain upper															2				1
Abnormal sensation in eye					1							1							
Back pain							2						1		1				1
Constipation							1												1
Cough													1						2
Diarrhea																			2
Dizziness							1									1			1
Dry skin																1			1
Erythema									1										1
Fatigue		1			1	1		1	1			1				1			
Headache		1	1	1	1	1				1	1	4	1		1	2			
Injection site erythema											5	1	5	6	7	8	7		4
Injection site pain													1			2			1
Injection site swelling											3	2	4		3	7	6		2
Insomnia											1					4			
Myalgia																	1		1
Nasal congestion											1		1		1	1			
Nausea											1	1			1				1
Ocular hyperaemia																			2
Oropharyngeal pain		1			1	2					1		1		1	2			
Pain in extremity							1									1			
Procedural complication										1		1							
Procedural dizziness					2								1						
Pyrexia				1	1							1							
Rash						2					2				2				1
Rhinorrhoea											1				2				
Sinusitis				1												1			
Somnolence			1									1							
Upper respiratory tract infection		1	1	1					3		1	1				1			
Vision blurred						1							1						

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

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

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

Immunogenicity Data

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

Preclinical Studies of IMVT-1401

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

<u>NAME OF STUDY</u>	<u>DURATION</u>	<u>ANIMALS TESTED</u>	<u>ROUTE OF ADMINISTRATION: DOSE (FREQUENCY)</u>
Evaluation of IgG Catabolism and PK of HL161 Candidates (HL161AN and HL161BKN) in Cynomolgus Monkey (Study TR-127-161)	4 weeks	N = 20 ^a	IV: 5, 20 mg/kg/dose (Days 0, 7, 14, 21)
Evaluation of IgG Catabolism and PK of HL161AN and HL161BKN Following IV and SC Administration (Study TR-140-161)	2 weeks	N = 36 ^a	IV: 5, 10 mg/kg/dose; SC: 5, 10 mg/kg/dose (Days 0, 3, 7, 10)

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NAME OF STUDY	DURATION	ANIMALS TESTED	ROUTE OF ADMINISTRATION: DOSE (FREQUENCY)
Evaluation of Low-dose PK-PD Cynomolgus Monkey for Selection of Maximum Recommended Start Dose (MRSD) of HL161BKN in Humans (Study TR-166-161)	2 weeks	N = 12	IV: 0.5, 1.5, 5 mg/kg/dose (Days 0, 3, 7, 10)
HL161BKN 1-Week Repeat-Dose Range-Finding Toxicity, PK, and PD Study in the Cynomolgus Monkey (Study 8348379)	1 week	N = 16 ^a	SC: 25, 100 mg/kg/dose IV: 100 mg/kg/dose (Days 1, 4, 8)
HL161BKN A Six-Week Subcutaneous and Intravenous Administration Toxicity Study in Cynomolgus Monkeys with a Nine-Week Treatment-Free Period (Study 8348381)	6 weeks	N = 48 ^a	SC: 25, 50, 100 mg/kg/dose; IV: 25, 100 mg/kg/dose (twice weekly)
12-Week Subcutaneous Injection and Intravenous Infusion Toxicity and Toxicokinetic Study with RVT-1401 in Cynomolgus Monkeys Followed by a 10-Week Recovery Period (Study 8386882)	12 weeks	N = 60 ^a	SC: 10, 25, 100 mg/kg/dose; IV: 10, 100 mg/kg/dose
26-Week Subcutaneous Injection and Intravenous Infusion Toxicity and Toxicokinetic Study with RVT-1401 in Cynomolgus Monkeys Followed by a 10-Week Recovery Phase (Study 8391434) ^b	26 weeks	N = 40 ^a	SC: 100 mg/kg/dose (twice weekly); IV: 50, 100 mg/kg/dose

- a: includes vehicle control group animals.
- b: final study report will be available in January 2020

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

PHARMACOLOGY STUDIES	TROUGH IgG % OF BASELINE (MEAN ± SD)
Evaluation of IgG Catabolism and PK of HL161 Candidates (HL161AN and HL161BKN) in Cynomolgus Monkey (Study TR-127-161)	IV 5 mg/kg: -57 ± 5
	IV 20 mg/kg: -74 ± 7
Evaluation of IgG Catabolism and PK of HL161AN and HL161BKN Following IV and SC Administration (Study TR-140-161)	IV 5 mg/kg: -78 ± 7
	IV 10 mg/kg: -73 ± 10
	SC 5 mg/kg: -74 ± 4
	SC 10 mg/kg: -77 ± 10
Evaluation of Low-dose PK-PD Cynomolgus Monkey for Selection of Maximum Recommended Start Dose (MRSD) of HL161BKN in Humans (Study TR-166-161)	IV 0.5 mg/kg: -53 ± 16
	IV 1.5 mg/kg: -58 ± 9
	IV 5 mg/kg: -75 ± 13

In the six-week and 12-week toxicology studies (Study 8348381, Study 8386882, respectively), exposure to IMVT-1401, a fully human monoclonal antibody, resulted in the development of an ADA response that led to immune complex formation in isolated animals. In the six-week study, at least one sampling point tested positive for ADA in 37 of the 38 animals that received IMVT-1401 twice weekly by subcutaneous or intravenous administration. Some animals with ADA had reduced PK and PD responses. However, the majority of animals still had measurable circulating levels of IMVT-1401 that translated to reduced IgG levels. In the 12-week toxicology study all animals developed ADA by Day 22 of the treatment phase of the study,

and IMVT-1401 exposures on Days 43 and 78 were generally lower compared to Day 1, particularly with low subcutaneous doses. An abrogation of the PD response was observed following development of ADA in the lower dose cohorts but was maintained in the higher dose cohorts. Overall, in these preclinical studies, there was a robust PK and PD correlation in cynomolgus monkeys after removing the confounding element of ADA.

The immunogenicity response to human proteins generated in nonclinical species is generally not predictive of that in the human. This was confirmed in the multiple dose cohorts of the on-going Phase 1 clinical trial, where after 4 weeks of IMVT-1401 treatment, no subject in either dose cohort developed a confirmed ADA response. Nevertheless, subjects in clinical trials with IMVT-1401 will be carefully monitored for any AEs, including those related to immunogenicity.

IMVT-1401 for the Treatment of Myasthenia Gravis

Myasthenia Gravis Overview

MG is an autoimmune disorder associated with muscle weakness. MG patients develop antibodies that lead to an immunological attack on critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. This leads to muscle weakness, which can be localized to the ocular muscles or which can be more generalized throughout the body. Patients with localized disease suffer from the mildest symptoms, including droopy eyelids and blurred or double vision due to partial paralysis of eye movements. The majority of MG patients demonstrate elevated serum levels of acetylcholine receptor (“AChR”), antibodies, which disrupt signal transmission between neurons and muscle fibers, ultimately leading to muscle weakness and fatigue.

The prevalence of MG is estimated to be one in 5,000, with up to 65,000 cases in the United States. MG can occur at any age; however, the age of onset tends to follow a bimodal distribution. Early onset disease usually occurs in individuals between 10 to 30 years old and predominantly affects females. Later onset disease usually occurs in individuals over 50 years old and predominantly affects males. As with many autoimmune diseases, there are no known genetic alterations that specifically cause MG, and in most patients, it arises spontaneously. Approximately 3% of patients have a primary relative with MG, suggesting that there are genetic factors that may predispose development of the disease, but these genes have yet to be identified.

The symptoms of the disease can be transient and in the early stages of the disease can remit spontaneously. However, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months. After 15 to 20 years, weakness often becomes fixed, with the most severely affected muscles frequently becoming atrophic. Many patients find it difficult to perform daily activities due to both insufficient improvement in symptoms even after treatment and the long-term side effects of oral corticosteroids, a common treatment for MG. Approximately 15% to 20% of MG patients will experience at least one myasthenic crisis over their lifetimes. During myasthenic crisis, the impairment of muscles required to breathe can become life-threatening, leading to death in approximately 2% to 5% of cases. Up to 90% of patients in myasthenic crisis require intubation and mechanical ventilation, leading to hospital stays lasting a median of 17 days. Over half of patients who survive such a crisis are functionally dependent upon discharge from the hospital.

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

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

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

Previously completed clinical trials of anti-FcRn antibodies have generated promising results. In a completed Phase 2 clinical trial conducted by argenx to evaluate efgartigimod, an anti-FcRn antibody fragment, for the treatment of MG, patients dosed with intravenous drug product showed clinically meaningful and statistically significant improvement in MG-ADL scores compared to placebo after four weeks of treatment.

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

Current Treatment Paradigm

Very early stage MG is symptomatically treated with acetylcholinesterase inhibitors such as pyridostigmine, which block the breakdown of acetylcholine, thereby increasing its concentration in the neuromuscular junction. As the disease progresses, patients are typically treated with immunomodulating agents such as glucocorticoids, mycophenolate mofetil and cyclosporine, each of which is associated with significant side effects and can lead to disease exacerbation. Thymectomy may be indicated for treatment in patients with evidence of a thymoma and can be considered for treatment in some patients who do not have thymoma. As MG becomes more advanced, patients can be treated with IVIg, which provides therapeutic benefit through multiple potential mechanisms including the saturation of FcRn. However, IVIg requires burdensome infusions to obtain significant reductions in symptoms, and the large volumes of intravenous fluid associated with the administration of IVIg can lead to significant side effects, including pulmonary edema and renal complications.

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Physicians direct patients with more advanced disease and patients in crisis to therapies that reduce levels of circulating IgG antibodies. One method of reducing IgG levels is to take blood from a patient and physically remove IgG antibodies from the plasma before returning it to the patient in a process called plasma exchange. This is a slow process that typically takes two hours. Furthermore, this process often needs to be repeated several times over a number of days to achieve a significant initial reduction in IgG antibody levels. A variant of this procedure is immunoadsorption, in which bacterial proteins are used to selectively remove IgG antibodies from serum. The table below sets forth an overview of these treatments for MG. The most recent agent approved for MG is eculizumab, a complement C5 inhibitor, the use of which is limited to patients with anti-AChR-positive MG. Anti-MuSK antibodies have a low propensity to activate complement proteins, thus C5 inhibition may not be therapeutically relevant in anti-MuSK-positive patients. Studies indicating that patients with MuSK-positive disease are more likely to become treatment refractory thus present a need unaddressed by this latest treatment option. Approximately 10% of MG patients are refractory to current treatments, while up to 80% fail to achieve complete stable remission.

Overview of Current Treatment Options for Advanced Myasthenia Gravis

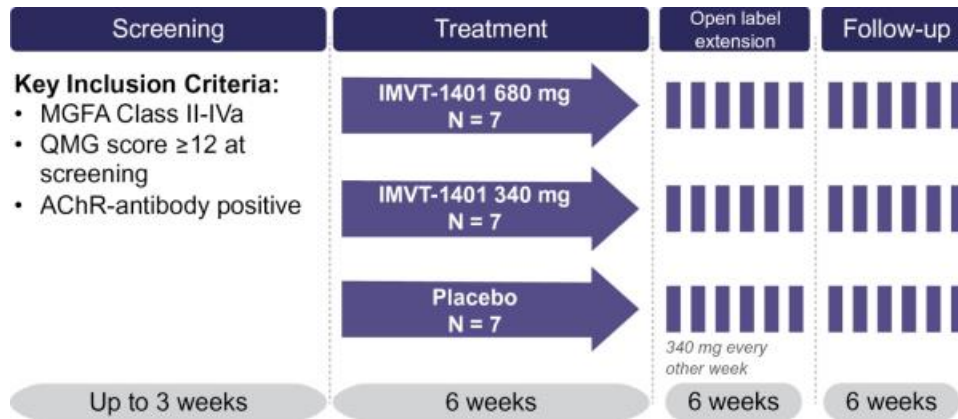
Mechanism of Action	IVIg	IMMUNOADSORPTION	PLASMA EXCHANGE	ECULIZUMAB
	Not fully known	Removal of autoantibodies	Removal of autoantibodies	Complement inhibition (only approved in anti-AChR MG)
Pathogenic IgG Reduction*	~30% to 70%	~55% to 90%	~65% to 75%	N/A
Mode of Administration	Intravenous or subcutaneous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

* Company estimates based on literature review across autoimmune indications.

ASCEND-MG Trial

In August 2019, we initiated dosing in a randomized, blinded, placebo-controlled Phase 2a clinical trial of IMVT-1401 for the treatment of MG. The ASCEND-MG trial assesses safety and efficacy of IMVT-1401 in an anticipated 21 patients with MG symptoms, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12. In the ASCEND-MG trial, patients with MG who have confirmed anti-AChR antibodies will receive one of two dose levels of IMVT-1401 (680 mg or 340 mg) or placebo delivered by subcutaneous injection on a weekly schedule for six weeks followed by a six-week open-label extension period, in which patients will be able to receive up to three further injections of IMVT-1401 administered every other week. There are then three follow-up visits during a six-week post-dosing period. The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401 and identification of optimal dosing for Phase 3 administration through measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG. Secondary endpoints include PK and changes from baseline in various clinical scores such as QMG, MG-ADL and quality of life measures. Exploratory endpoints include assessment of multiple biomarkers including gene expression profiles, pro-inflammatory markers and receptor occupancy. We anticipate reporting top-line results from this trial in the first half of 2020.

Trial Design of ASCEND-MG Trial



IMVT-1401 for the Treatment of Graves’ Ophthalmopathy

Graves’ Ophthalmopathy Overview

GO is an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes, which can be sight-threatening. Initial symptoms may include a dry and gritty ocular sensation, sensitivity to light, excessive tearing, double vision and a sensation of pressure behind the eyes. By the time that GO is clinically diagnosed, many patients have retraction of their upper eyelids, swelling and redness surrounding the eyes and protrusion of the eyes. In some cases, swelling and stiffness of the muscles that move the eyes cause the eyes to no longer line up with each other or for the eyelids to no longer be able to close. Approximately 3% to 5% of GO patients have a severe manifestation of the disease, with intense pain, inflammation and sight-threatening corneal ulcers or optic neuropathy that requires surgical intervention. Decompression surgery to improve ocular function or rehabilitative surgery to improve quality of life is required in up to 20% of GO patients.

GO, also known as thyroid eye disease, is most commonly caused by IgG autoantibodies that form against the thyroid-stimulating hormone receptor (“TSHR”). These antibodies activate certain cell types, such as fibroblasts and adipocytes, present in the extraocular space, which are known to highly express TSHR. The activation of these fibroblasts causes them to proliferate and to produce hyaluronan, a substance that contributes directly to the swelling associated with GO. Hyaluronan also serves as an inflammatory signal leading to the synthesis of cytokines that cause recruitment of lymphocytes and extensive tissue inflammation and remodeling. Exposure to other inflammatory agents, such as cigarette smoke, lead to exacerbation of the disease resulting in more severe symptoms. Anti-TSHR antibodies also increase the proliferation of adipose or fat cells as well as myofibroblasts, smooth muscle-like cells. Levels of anti-TSHR autoantibodies correlate positively with clinical features of GO and influence its prognosis.

In addition to anti-TSHR autoantibodies, antibodies that activate the insulin-like growth factor 1 receptor (“IGF1R”) have been described in the literature. TSHR and IGF1R have functional overlaps and stimulation of either receptor may lead to activation of similar biochemical pathways in certain cell types, including the ones implicated in GO. Published studies investing this pathway have led to the discovery that the IGF1R and TSHR form a receptor complex where IGF1R can augment the signaling of TSHR. The exact nature of the interaction between IGF1R and TSHR continues to be investigated; however, experimental evidence suggest that the effects of TSHR stimulating antibodies are only partially blocked by an IGF1R antagonist while they may be completely blocked with a TSHR antagonist.

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GO has an estimated annual incidence of 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe. The natural history of GO begins with an inflammatory phase lasting between six and 24 months that is characterized by lymphocyte infiltration, fibroblast proliferation and increases in adipose tissue. Treatment of patients with immunosuppressive therapies during this active inflammatory phase can lead to reduction in symptoms and can alter the course of the disease. However, once the initial inflammatory phase is over, immunosuppressive therapies are ineffective and levels of fibrosis that have developed as the result of acute inflammation are only reversible by surgery. We estimate that 15,000 to 20,000 patients in the United States have active inflammatory GO disease and are eligible for treatment.

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

Relationship between GO and Graves’ Disease

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

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

Current Treatment Paradigm

There are no FDA-approved therapies for GO, and we believe there is a significant unmet medical need for an effective and safe treatment. As a first option, patients with active GO are treated with immunosuppressive therapy such as high-doses of corticosteroids, typically administered intravenously or orally. Corticosteroids are not effective in all patients, and approximately one-third of patients will relapse. This therapy is associated with an increased risk of acute and severe organ damage, bone thinning, weight gain, diabetes, hypertension, osteoporosis and depression.

Orbital radiation therapy is used as a means of reducing the infiltration of lymphocytes and can be used in conjunction with corticosteroids or immunosuppressive therapy. Similar to these anti-inflammatory and immunosuppressive drugs, radiation therapy is most effective in the active stage of GO.

Patients with moderate-to-severe active GO which is still in the active stage and who do not respond adequately to corticosteroids can be treated with cyclosporine or mycophenolate mofetil, two broad immunosuppressive drugs. These powerful drugs are associated with numerous side effects related both to their general immunosuppressive effects as well as to inherent toxicities, such as hypertension, kidney disease and gastrointestinal toxicity.

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Small case studies have identified rituximab as an alternate way of inducing immunosuppression in patients with GO. Rituximab (Roche) is a monoclonal antibody that binds to an antigen specific to B cells, leading to their destruction. However, rituximab is associated with the potential for serious side effects, such as infusion-related reactions. Rare cases of progressive multifocal encephalopathy and other viral infections have also been reported.

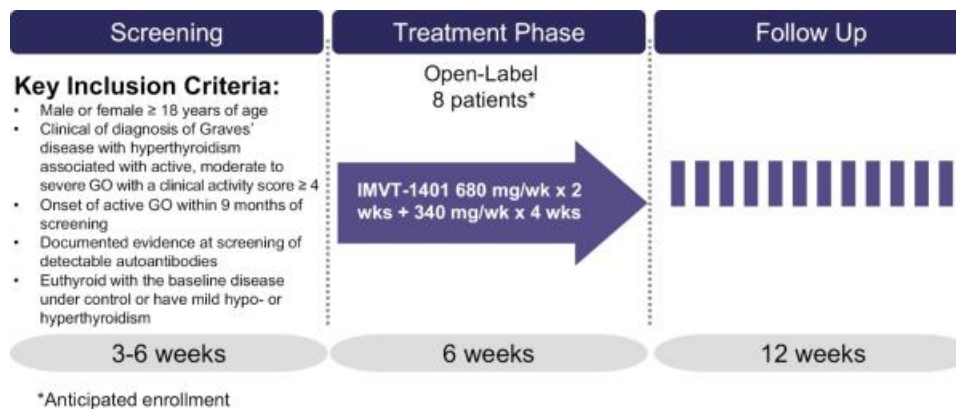
Surgery is considered to be a treatment option in patients with a high CAS who have been treated with corticosteroids or immunosuppressive therapy but continue to have progressive disease. The goal of surgery is to reduce the pressure causing proptosis, reduced eye movement and loss of visual acuity. Because of its invasive nature, surgery is typically reserved for inactive disease.

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

ASCEND-GO 1 Trial

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

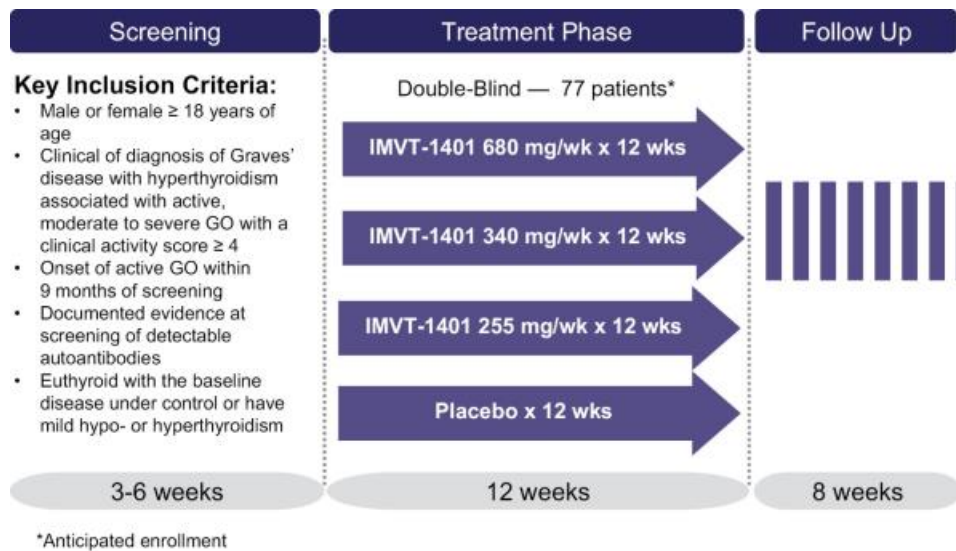
Trial Design of ASCEND-GO 1 Trial



ASCEND-GO 2 Trial

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

Trial Design of ASCEND-GO 2 Trial



IMVT-1401 for the Treatment of Warm Autoimmune Hemolytic Anemia

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020.

Warm Autoimmune Hemolytic Anemia Overview

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

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

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

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

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

Current Treatment Paradigm

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

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

Patients with persistent disease despite use of corticosteroids and rituximab may be offered a course of other immunosuppressive drugs, such as cyclophosphamide, mycophenolate mofetil or azathioprine sirolimus. These powerful drugs are associated with numerous side effects related both to their general immunosuppressive effects as well as to inherent toxicities, such as hypertension and are associated with an increased risk of developing malignancy, especially lymphoma.

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

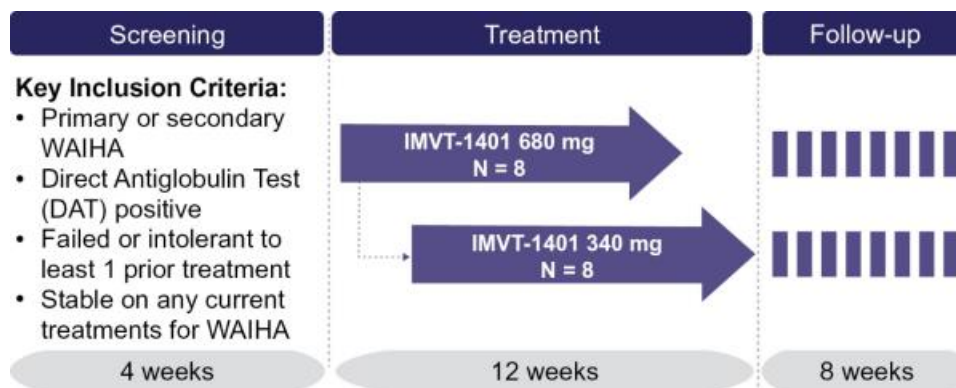
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RBC transfusions are indicated in patients who require immediate stabilization. Such patients are monitored closely for evidence of a transfusion reaction. In contrast to other treatment modalities that lead to nonspecific suppression of the immune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

ASCEND-WAIHA Trial

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020. The ASCEND-WAIHA trial will explore the potential of IMVT-1401 to increase hemoglobin levels and assess the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of two doses of IMVT-1401 (680 mg or 340 mg) administered weekly by subcutaneous injection for 12 weeks. The primary endpoint of this trial is the proportion of responders, defined as patients achieving a hemoglobin level of at least 10 g/dL and at least a 2 g/dL increase from baseline. Secondary endpoints include change from baseline in other hematologic and chemistry parameters, time to response, patient reported outcome measures, total IgG antibodies and IgG antibodies by subclasses. We plan to report initial results from the first treatment cohort of this trial in the fourth quarter of 2020.

Trial Design of ASCEND-WAIHA Trial



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 (“the Licensed Territory”) for all human and animal uses, during the term of the agreement. With respect to these licenses, RSG also received the right to grant a sublicense, with prior written notice to HanAll of such sublicense, to: (1) a third party in any country in the Licensed Territory outside of the United States and E.U.; (2) an affiliate of RSG in any country in the Licensed Territory; and (3) a third party in the United States and E.U. only after submission of a BLA in the United States or an MAA in the E.U. Pursuant to the HanAll Agreement, RSG granted to HanAll an exclusive, royalty-free license under certain RSG patents, know-how and other intellectual property controlled by RSG relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the Licensed Territory. HanAll also reserves the right to conduct discovery or research activities with the IMVT-1401 antibody, and certain back-up and next-generation antibodies, with or through a contract research organization or service provider in the Licensed Territory.

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In December 2018, we obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 from RSG in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and our wholly owned subsidiary, 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 it pursuant to this research program will be included in HanAll's license. In May 2019, we achieved its first development and regulatory milestone, which resulted in the payment of a \$10.0 million milestone payment in August 2019.

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.

Except for cost-sharing in connection with the research program, we are solely responsible, at our expense, for all other activities related to the research, development and commercialization of licensed products for the Licensed Territory. We may use a third party for manufacturing activities necessary for the research, development and commercialization of licensed products for the Licensed Territory. In addition, under the HanAll Agreement, we have agreed to use commercially reasonable efforts to develop and commercialize licensed products in the Licensed Territory. Each party has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory.

Under the HanAll Agreement, we have the sole right, but not the obligation, to control the prosecution, defense and enforcement of the licensed patents, and HanAll has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which we elect not to exercise such rights.

The HanAll Agreement will expire on a product-by-product basis on the expiration of the last royalty term with respect to a given licensed product, unless earlier terminated. We may terminate the HanAll Agreement in its entirety without cause upon 180 days' written notice following 30 days of discussion. Either party may terminate the HanAll Agreement upon 60 days' written notice for uncured material breach (or 30 days in the case of non-payment), or immediately upon written notice if the other party files a voluntary petition, is subject to a substantiated involuntary petition or for certain other solvency events. HanAll may terminate the HanAll Agreement if we or our affiliates challenge the validity or enforceability of any of the licensed patents.

We are a Vant within the Roivant Family of Companies

We are a majority-owned subsidiary of Roivant and have benefited from our ability to leverage the Roivant model and the greater Roivant platform. The period of time between our formation and its operational maturation was shortened based on the support from centralized Roivant functions available since its creation. This includes operational functions as well as access to Roivant's proprietary technology and digital innovation platforms. Consistent with its model, Roivant has also provided us with access to an embedded team of scientific experts, physicians and technologists to help optimize clinical development and commercial strategies. In the future, we may have the ability to benefit from Roivant's economies of scale and scope, including but not limited to the opportunity to:

- leverage business development engine and vast network of industry relationships of Roivant's business unit Roivant Pharma for the identification of, and access to, new assets and synergistic partnerships;
- enter channel partnerships with other Vants in the Roivant family of companies (including but not limited to technology-focused Vants built by Roivant's business unit Roivant Health), with the goal of delivering efficiencies in the development and commercialization process;
- access Roivant's human capital engine to recruit new employees from within and beyond the biopharmaceutical industry;
- enable its employees to participate in Roivant's career development program which facilitates employee mobility across Vants in the Roivant family of companies;
- benefit from shared learnings, best practices, and external industry relationships across the Roivant family of companies; and
- derive certain benefits of scale upon becoming a commercial-stage company.

Sales and Marketing

We do not currently have our own marketing, sales or distribution capabilities. In order to commercialize IMVT-1401 or any future product candidate, if approved for commercial sale, we would have to develop a sales and marketing infrastructure. We intend to build a small, targeted sales organization in the United States, targeting specialist physicians that treat high numbers of patients with autoimmune conditions. We believe these physicians treat a majority of patients with the autoimmune indications that we intend to target and most often serve as the diagnosing and treating physicians for such indications. We may opportunistically seek strategic collaborations to maximize the commercial opportunities for IMVT-1401 or any future product candidates inside and outside the United States.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of IMVT-1401, and there are a limited number of manufacturers that operate under the cGMP requirements (particularly for the development of antibodies) of the FDA that might be capable of manufacturing for us. We currently rely and intend to continue to rely on contract manufacturing organizations ("CMOs"), for both drug substance and drug product. Currently, we contract with two well-established third-party manufacturers, one for the manufacture of our drug substance and another for the manufacture of our drug product. We expect to engage additional third party manufacturers to support any pivotal clinical trials for IMVT-1401 as well as commercialization of IMVT-1401, if approved, in the United States or other jurisdictions. In addition, we intend to recruit personnel with experience to manage the CMOs producing our product candidate and other product candidates or products that we may develop in the future.

Our outsourced approach to manufacturing relies on CMOs to first develop cell lines and manufacturing processes that are compliant with cGMP then produce material for preclinical studies and clinical trials. Our agreements with CMOs may obligate them to develop a production cell line, establish master and working cell banks, develop and qualify upstream and downstream processes, develop drug product process, validate (and in some cases develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for preclinical testing, produce cGMP-compliant drug substance, or produce cGMP-compliant drug product. We conduct audits of CMOs prior to initiation of activities under these agreements and monitor operations to ensure compliance with the mutually agreed process descriptions and cGMP regulations.

Competition

We expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases, including multiple agents which are in the same class as IMVT-1401. We are aware of several FcRn inhibitors that are in clinical development. These include ABY-039 (Affibody AB/Alexion Pharmaceuticals), efgartigimod (argenx), nipocalimab (Momenta Pharmaceuticals), rozanolixizumab (UCB) and ALXN1830 (Alexion Pharmaceuticals). Each of efgartigimod, nipocalimab, and rozanolixizumab is currently under development for the treatment of MG. In addition, nipocalimab and ALXN1830 are being developed for the treatment of WAIHA.

In a Phase 1 trial conducted by argenx, efgartigimod was observed to reduce mean IgG levels by approximately 50% after two 20 mg/kg intravenous induction doses followed by eight weekly 300 mg subcutaneous doses. In a Phase 2 trial conducted in MG, UCB's rozanolixizumab was infused subcutaneously, over 30 minutes, and was observed to reduce mean IgG levels by approximately 56% and approximately 68% after three and six weekly 7 mg/kg infusions, respectively. In a Phase 1 trial conducted by Affibody AB/Alexion Pharmaceuticals, ABY-039 was observed to reduce mean IgG levels by approximately 45% after a single subcutaneous 200 mg dose. Momenta's nipocalimab and Alexion's ALXN1830 are not yet in clinical development with a subcutaneous formulation.

IMVT-1401, if approved, may also face competition from agents with different mechanisms of action. The most commonly prescribed first-line agents for the treatment of MG are acetylcholinesterase inhibitors, such as pyridostigmine, which are marketed by several manufacturers of generic medicines. IVIg is also routinely used for patients with MG. Eculizumab (marketed by Alexion), an antibody inhibitor of the C5 protein, was approved in 2017 for the treatment of generalized MG in patients who are positive for anti-AChR antibodies. The first line of treatment for GO and WAIHA patients is generally immunosuppressive therapy, including high doses of corticosteroids. Other broad immunosuppressive drugs, such as cyclosporine, cyclophosphamide, mycophenolate mofetil and azathioprine, are used when patients do not respond adequately to corticosteroids. Rituximab (Roche), a monoclonal antibody that binds to an antigen specific to antibody-producing B cells, may also be used as a treatment for GO, WAIHA and other IgG-mediated autoimmune diseases.

In addition, other product candidates in development for the treatment of MG include: zilucoplan (Ra Pharma), a peptide inhibitor of C5, which has finished a Phase 2 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 late-stage development; and Myasterix (CuraVac), a therapeutic vaccine against B and T cells, which is being tested in early stage trials in MG patients. There are at least two agents in development for the treatment of GO, including: teprotumumab (Horizon Therapeutics), an anti-IGF-1R antibody, whose BLA is currently under review by the FDA; and tocilizumab (Roche), an IL6 receptor antibody, which has been evaluated in an investigator-sponsored trial. Other product candidates in development for the treatment of WAIHA include: fostamatinib (Rigel Pharmaceuticals), a syk kinase inhibitor, which is in Phase 3 development; and sutimlimab (Sanofi), an anti-C1s antibody, and APL-2 (Apellis Pharmaceuticals), a C3 inhibitor, each of which is currently in Phase 1/2 clinical development. Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon its ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that it may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries could result in even more resources being concentrated among a small number of our competitors.

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

Intellectual Property

our commercial success depends in part on its ability to obtain and maintain proprietary protection for IMVT-1401 and any of its future product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to any products we develop or processes we use may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates.

Following our assumption of all rights, title, interest and obligations under the HanAll Agreement from RSG in December 2018, by virtue of the license of patent rights under the HanAll Agreement, we are the exclusive licensee of a patent family directed to IMVT-1401, and certain back-up and next-generation antibodies, and products containing such antibodies, in the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America. As of September 30, 2019, this patent family includes patent applications pending in the United States, Argentina, Brazil, Canada, European Patent Office, Egypt, Israel, Mexico and Saudi Arabia. These patent applications disclose the antibody, pharmaceutical composition thereof, methods of treating autoimmune disease using the same, polynucleotide encoding the antibody, expression vector including such polynucleotide, host cell transfected with such recombinant expression vector, methods of manufacturing the antibody and methods of detecting FcRn in vivo or in vitro using the antibody. Generally, the term of any patent granted from a patent application in the in-licensed HanAll patent family directed to the IMVT-1401 composition of matter and methods of use has a projected natural expiration and will expire on April 30, 2035 in the United States and in other jurisdictions, subject to such terms as may be modified by, for example, terminal disclaimer or any adjustment or extension of patent term that may be available in a particular jurisdiction. Notably, in this patent family, a U.S. patent in the patent family was issued on July 2, 2019, with claims directed to an isolated anti-FcRn antibody or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof. Furthermore, in this patent family, a Notice of Allowance was received on September 24, 2019 in a U.S. patent application with claims directed to an isolated anti-FcRn antibody or antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof as well as methods of treating various autoimmune diseases using the antibody, polynucleotides and expression vectors encoding the antibody, host cells capable of expressing the antibody and methods of producing the antibody. Additionally, we have filed provisional patent applications in the U.S. directed to methods of treating autoimmune disease using IMVT-1401 in November 2018, January 2019 and May 2019. Assuming patents issue from the corresponding non-provisional filings of these provisionally filed patent applications, the projected natural expiry for each of these patent families is November 2039, January 2040 and May 2040, respectively.

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In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date, as the term of a patent granted on a utility patent application filed after June 8, 1995 expires 20 years after the non-provisional U.S. filing date (or any earlier filing date relied upon under 35 U.S.C. 120, 121, or 365(c)), with the timely payment of maintenance fees. In certain instances, the patent term may be adjusted to add additional days to compensate for certain delays incurred by the USPTO in the examination process, issuing the patent and/or the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the patent extension granted for FDA regulatory review is only applied to a single patent that covers either the product candidate or a method of using or manufacturing the same which has not expired at the time of FDA approval. Additionally, the period of time the patent is extended may not exceed five years, and the total patent term, including the period of time the patent is extended, must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years after from the earliest effective non-provisional filing date. The protection afforded by a patent with respect to a particular product varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, its coverage, the availability of regulatory-related extensions, the availability of legal remedies in the particular country and the validity and enforceability of the patent under the local laws. Immunovant Sciences GmbH owns a trademark for IMMUNOVANT, the corporate logo, and a composite trademark for its corporate logo with the IMMUNOVANT mark. As of October 9, 2019, this trademark portfolio included registration of the Immunovant trademark in the United States, Australia, Brazil, Israel, the International Register, Mexico, Norway, Russian Federation, Saudi Arabia, Singapore and Switzerland, plus registration of the Immunovant logo trademark in Switzerland, and registration of the composite trademark in the International Register and Switzerland. Additionally, trademark applications are pending for the Immunovant trademark in the United States and 33 foreign jurisdictions, and for the composite trademark in the United States and 23 foreign jurisdictions. Under the HanAll Agreement, we have the right to market IMVT-1401 in the territory defined as the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America under the trademark(s) of our choice, subject to regulatory approval. However, upon termination of the HanAll Agreement, we must assign to HanAll all right, title and interest in and to any and all trademarks we use in the development, manufacture or commercialization of the licensed products.

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

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

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of IMVT-1401 or any future product candidate.

FDA Drug Approval Process

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA’s current Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials; satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product’s continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold until the IND sponsor and the FDA resolve the outstanding concerns or questions. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

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Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. For new indications, a separate new IND may be required. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries. For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

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

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing (60-day process), or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process can be significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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

Expedited Development and Review Programs

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

A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA. The review clock does not begin until the final section of the BLA is submitted.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act ("FDASIA") passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

Orphan Drug Designation

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

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

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "the ACA") signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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

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

Other U.S. Healthcare Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. 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 and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (“Affordable Care Act”), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the Anti-Kickback Statute can result in significant civil and criminal fines and penalties, imprisonment, and exclusion from federal healthcare programs. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (“FCA”) (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare

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companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus significant mandatory civil penalties, and exclusion from participation in federal healthcare programs.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act") within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, to the extent that we have business operations in foreign countries or sell any of our products in foreign countries and jurisdictions, including Canada or the E.U., we may be subject to additional regulation.

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We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

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

Coverage, Pricing and Reimbursement

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

our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, which decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

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

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

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develops.

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

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

Healthcare Reform

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

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (“AMP”);
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which through subsequent legislative amendments, has been increased to 70%, starting in 2019, off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers’ outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;

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- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow on biologic products.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018 (the "BBA"), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, TCJA included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable 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.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the 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. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical 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.

The Foreign Corrupt Practices Act

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

Additional Regulation

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

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Other Regulations

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

Employees

As of September 30, 2019, we had no employees, and our wholly owned subsidiary, IMVT Corporation had 17 employees, including 13 who are engaged in research and development activities. The employees of IMVT Corporation provide services to us and our subsidiaries pursuant to an intercompany services agreement by and among ISL, IMVT Corporation (formerly Immunovant, Inc.) and ISG.

Facilities

We maintain our headquarters at 320 West 37th Street, New York, New York 10018 and also conduct business operations at 324 Blackwell Street, Suite 1220, Durham, North Carolina 27701. ISL's registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda and ISL's principal office is located at Suite 1, 3rd Floor, 11-12 St. James's Square, London, SW1Y 4LB, United Kingdom. ISG maintains its headquarters at Viaduktstrasse 8, 4051 Basel, Switzerland. We intend to add new facilities or expand our existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

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.

MANAGEMENT

Directors and Executive Officers

As used in this section, “Immunovant” refers collectively to ISL prior to the closing of the Business Combination, its wholly owned subsidiary, IMVT Corporation (formerly Immunovant, Inc.), and Immunovant, Inc. after the closing of the Business Combination. Upon the closing of the Business Combination, the executive officers of IMVT Corporation became executive officers of Immunovant, Inc.

Immunovant’s executive officers and directors as of December 31, 2019:

Name	Age	Position
Peter Salzmann, M.D., M.B.A.	52	Chief Executive Officer and Director
Pamela Yanchik Connealy, M.B.A.	58	Chief Financial Officer
Julia G. Butchko, Ph.D.	48	Chief Development and Technology Officer
W. Bradford Middlekauff, J.D.	58	General Counsel
Robert K. Zeldin, M.D., FAAAAI	56	Chief Medical Officer
Frank M. Torti, M.D.(2) (3)	41	Chairperson of the Board of Directors
Andrew Fromkin(1) (2)	53	Director
Douglas Hughes(1) (2)	58	Director
George Migausky(1)	64	Director
Atul Pande, M.D.(3)	65	Director
Myrtle S. Potter(3)	61	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Peter Salzmann, M.D., M.B.A. has served as Immunovant’s Chief Executive Officer since June 2019, and as a member of its board of directors since October 2019. From November 2018 to June 2019, he served as Global Brand Development Leader in Immunology at Eli Lilly and Company, where he designed and executed a comprehensive indication development strategy and oversaw Phase 2 and 3 clinical trial execution. From March 2013 to October 2018, Dr. Salzmann was Head of U.S. Immunology at Eli Lilly, and Managing Director of Lilly Alps from January 2011 to April 2013. From January 2008 to December 2010, Dr. Salzmann was the Head of Marketing for Eli Lilly China. Dr. Salzmann earned a B.A. in Chemistry from Northwestern University, an M.D. from University of Chicago’s Pritzker School of Medicine, and an M.B.A. from Stanford University’s Graduate School of Business. Our board of directors believes that Dr. Salzmann’s position as our Chief Executive Officer and his extensive prior experience in the biopharmaceutical industry qualify him to serve as a member of our board of directors.

Pamela Yanchik Connealy, M.B.A. has served as Immunovant’s Chief Financial Officer since November 2019. From August 2018 to November 2019, Ms. Connealy served as the Chief Financial Officer, Chief Operating Officer and Chief Human Resources Officer of Kiva Microfunds, a San Francisco based nonprofit organization. From April 2014 to June 2018, Ms. Connealy served as Global Head of Talent at The Bill & Melinda Gates Foundation focused on talent management, compensation, benefits, and global mobility. From March 2012 to November 2013, she served as Vice President of Business Operations at Salesforce, a software company, and from March 2002 to April 2010, Ms. Connealy served as Vice President and Corporate Officer at Genentech, a biotechnology company, with roles including Chief Financial Officer of Research & Development, Global Head of Procurement and other Commercial and Technology roles. Ms. Connealy earned a B.S. in Chemistry from Gannon University and an M.B.A in Finance from the University of St. Thomas in Houston, Texas.

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Julia G. Butchko, Ph.D. has served as Immunovant's Chief Development and Technology Officer since November 2019. From March 2018 to June 2019, she served as the Chief of Staff for the BioMedicine's Business Unit at Eli Lilly and Company, a pharmaceutical company, where she was responsible for Immunology and Neurology Strategy and Operations. From June 2014 to May 2016, Dr. Butchko was the Vice President of Oncology Portfolio Management and Clinical Development, and from September 2012 to May 2014, she participated in a rotational program completing assignments in Autoimmune Market Research and Men's Health Marketing. She also served as Senior Director of Biologics and Device Project Management in Lilly's Research and Development organization from July 2009 to September 2012. Dr. Butchko earned a B.S. in Chemistry from the State University of New York, College at Fredonia, a Ph.D. in Chemistry from Pennsylvania State University and a Business Certificate from the Kelley School of Business at Indiana University.

W. Bradford Middlekauff, J.D. has served as Immunovant's General Counsel since April 2019. From October 2015 to April 2019, he served as Senior Vice President, General Counsel and Secretary of PDS Biotechnology Corporation (formerly known as Edge Therapeutics, Inc.), a publicly traded biotechnology company. From October 2014 to October 2015, Mr. Middlekauff was Executive-in-Residence at Princeton University. From December 2008 to August 2013, Mr. Middlekauff was Chief Legal Officer, General Counsel and Secretary at Kolltan Pharmaceuticals, Inc., where he also ran the business development function. From March 2000 to April 2008, he was Senior Vice President, General Counsel and Secretary of Medarex, Inc., a publicly traded biotechnology company. Mr. Middlekauff serves on the Board of Directors of ProteoDesign, S.L., a privately-held biotechnology company based in Barcelona, Spain. Mr. Middlekauff earned a B.A. in Political Science from Brown University and a J.D. from Yale Law School.

Robert K. Zeldin, M.D., FAAAAI has served as Immunovant's Chief Medical Officer since July 2019. From June 2018 to April 2019, he served as Chief Medical Officer of Acceleron Pharma. From December 2015 to June 2018, Dr. Zeldin was Chief Medical Officer of Belgium-based Ablynx NV, where he directed the Phase 3 development program and regulatory filings for caplacizumab, which has been approved for the treatment of thrombotic thrombocytopenic purpura in the U.S. and Europe. From January 2011 to November 2015, he was Senior Vice President and Head of Global Clinical Development at Stallergenes SA. From 2005 to 2010, Dr. Zeldin worked at Novartis, first as Executive Medical Director and later as Vice President and U.S. Medical Franchise Head of Respiratory and Dermatology. Dr. Zeldin earned a B.A. from the Johns Hopkins University and an M.D. from Tufts University School of Medicine.

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Frank M. Torti, M.D. has served as Chairperson of Immunovant's board of directors since June 2019. Dr. Torti has served as the Vant Chair of Roivant Sciences, Inc. ("RSI") since January 2020. In this capacity he serves as Chairperson of the boards of directors of the biopharmaceutical companies in the Roivant family and is responsible for the operations and management of those companies. He previously served as Vant Investment Chair of RSI, from August 2018 to December 2019. Prior to joining RSI, from August 2007 to August 2018, Dr. Torti served as a Partner of New Enterprise Associates ("NEA"), specializing in investments in healthcare. Prior to joining NEA, Dr. Torti worked for the Duke University Center for Clinical & Genetic Economics from 2002 to 2005 in various capacities, where he was involved in clinical trials research and economic evaluations of multinational clinical trials. Dr. Torti presently serves as Chairperson of the board of directors of Arbutus Biopharma Corp., Axovant Sciences Ltd. and several private biopharmaceutical companies. He has previously served on the boards of directors of numerous development and commercial stage public and private healthcare companies, including Myovant Sciences Ltd., Urovant Sciences Ltd., Annexon Biosciences, Inc., Eargo Inc., Galera Therapeutics, Inc., NeoTract, Inc., Novast Pharmaceuticals Ltd., OrphoMed, Inc., Tarveda Therapeutics, Inc. and XOC Pharmaceuticals, Inc. Dr. Torti earned an M.D. from the University of North Carolina School of Medicine, an M.B.A. from Harvard Business School and a B.A. from the University of North Carolina. Our board of directors believes that Dr. Torti's extensive experience in healthcare investing, as well as his clinical trial background, qualifies him to serve on its board of directors.

Andrew Fromkin has served as a member of Immunovant's board of directors since October 2019. Since March 2015, Mr. Fromkin has served as Chief Executive Officer of Tarveda Therapeutics, Inc. (formerly Blend Therapeutics, Inc.). From 2005 until 2011, Mr. Fromkin served in various roles for Clinical Data, Inc., including Executive Vice President (October 2005 until May 2006), President, Chief Executive Officer and Director (May 2016 until May 2011). Prior to Clinical Data, Mr. Fromkin served as President and Chief Executive Officer of DoctorQuality, Inc., President, Chief Executive Officer and Director of Endo Surgical Devices, Inc. and Corporate Vice President, Business Development, for Merck-Medco, a wholly-owned subsidiary of Merck & Co. Mr. Fromkin began his career at Health Information Technologies, Inc. as General Manager of its subsidiary, MCA, and Director of Marketing and Payer Alliances for the parent company. From 2014 until 2016, Mr. Fromkin served on the board of Regado Biosciences, Inc. which became Tobira Therapeutics, Inc. in 2015. Mr. Fromkin received a B.A. from Brandeis University. Our board of directors believes that Mr. Fromkin's significant experience in the biopharmaceutical industry and his knowledge of healthcare ventures qualifies him to serve as a member of its board of directors.

Douglas Hughes has served as a member of Immunovant's board of directors since October 2019. Since 2018, Mr. Hughes has served as Chief Financial Officer of Kalera Medical, an early stage medical device company. From 2011 until 2018, Mr. Hughes was Chief Financial Officer for NeoTract, Inc., a Urology company. Prior to that time, he served as Chief Financial Officer and Chief Operating Officer for Nellix, Inc., an endovascular graft biotechnology company. Before joining Nellix, Inc., Mr. Hughes served as Chief Financial officer for Evalve Inc., a medical device company, from 2009 until 2010. Prior to 2010, Mr. Hughes held a variety of senior finance management positions at Boston Scientific, Guidant Corporation and The Clorox Company. Mr. Hughes is currently a director at Kalera Medical, Inc., a position held since 2018. Mr. Hughes received a B.S. in Finance from San Francisco State University and an M.B.A. from University of Chicago. Our board of directors believes that Mr. Hughes' expertise in successfully leading high-growth companies, his experience in strategic planning and his knowledge of mergers and acquisitions qualifies him to serve as a member of its board of directors.

George Migausky has served as a member of Immunovant's board of directors since the closing of the Business Combination in December 2019. From March 2019 until the closing of the Business Combination he served as a member of HSAC's board of directors. Mr. Migausky has more than 30 years of experience in the life sciences industry, having served as Chief Financial Officer for several public biopharmaceutical and clinical diagnostic companies. In 2017, Mr. Migausky served as interim Chief Financial Officer for Ocular Therapeutix, Inc. Prior to that, he served as Executive Vice President and Chief Financial Officer of Dyax Corp. a position he held from 2008 through the company's acquisition by Shire for \$6.4 billion in 2016. Before joining Dyax, Mr. Migausky served as Chief Financial Officer of Wellstat Management Company from 2007 to 2008; and Chief Financial Officer of IGEN International and BioVeris Corporation from 1986 through their acquisitions by F. Hoffman LaRoche in 2004 and 2007, respectively. Current directorships include Hyperion Catalysis International, a position he has held since 2008, and the Massachusetts Eye and Ear Institute, where he has served as a trustee since 2015. Mr. Migausky has previously served on the board of directors as Chair of the audit committee at Dimension Therapeutics, a position he held from 2015 until the company was acquired in 2017. Mr. Migausky received his BS from Boston College and his MBA from Babson College. Our board of directors believes that Mr. Migausky's qualifications to sit on its board include his experience both in the capacity of an executive as well as a director, along with his expertise in strategic planning, corporate financing and financial reporting, business development and human resources.

Atul Pande, M.D. has served as a member of Immunovant's board of directors since October 2019. Dr. Pande has extensive experience in treatment development across multiple disease areas. He is currently an independent board member of Axovant Gene Therapies, Karuna Therapeutics, Autifony Therapeutics, and Perception Neurosciences. He previously served as the Chief Medical Officer of PureTech Health, Chief Medical Officer of Tal Medical, and medical advisor to PureTech Health. Since April 2014, he has also served as President of Verity BioConsulting, a drug development consulting firm that provides services to clients in the biopharmaceutical business. From 2007 to April 2014, Dr. Pande was Senior Vice President and Senior Advisor, Pharmaceutical R&D at GlaxoSmithKline. He has also held senior roles at Pfizer R&D, Parke-Davis/Warner-Lambert and Lilly Research

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Laboratories. He has been on the Scientific Advisory Boards of Cennerv Pharma and Centrexion Corporation. Dr. Pande is a physician who completed his research fellowship training in psychiatry at the University of Michigan Medical School and his postgraduate specialty training and psychiatry residency program at Western University. Our board of directors believes that Dr. Pande's medical background and his significant knowledge of the biopharmaceutical industry qualifies him to serve as a member of its board of directors.

Myrtle S. Potter has served as a member of Immunovant's board of directors since June 2019. Ms. Potter is currently the Chief Executive Officer of Sumitovant Biopharma, Inc., a wholly owned subsidiary of Sumitovant Biopharma Ltd. ("SBL"), which is in turn a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. SBL is the parent of Myovant Sciences Ltd., Urovant Sciences Ltd., Altavant Sciences Ltd., Enzyvant Therapeutics Ltd. and Spirovant Sciences Ltd. Mr. Potter previously served as Vant Operating Chair of Roivant Sciences, Inc. from July 2018 to December 2019. Ms. Potter founded Myrtle Potter & Company, LLC, a private healthcare and life sciences consulting firm, in September 2005, and served as the Chief Executive Officer until July 2018. From August 2009 until December 2014, Ms. Potter served as Founder and Chief Executive Officer of Myrtle Potter Media, Inc., a consumer healthcare company. From 2000 to 2004, Ms. Potter served as Chief Operating Officer at Genentech, Inc., a biopharmaceutical company, and from 2004 to 2005, she served as the President, Commercial Operations and Executive Vice President of Genentech. Prior to that, Ms. Potter held various positions, including President, Cardiovascular/Metabolics at Bristol-Myers Squibb and a vice president at Merck & Co. Ms. Potter currently serves as chairperson of the board of directors of Myovant Sciences Ltd. and Urovant Sciences Ltd. and on the boards of directors of Arbutus Biopharma Corp., Axovant Sciences Ltd., Immunovant Sciences Ltd., Liberty Mutual Holding Company Inc., a diversified global insurance company, and Axsome Therapeutics, Inc., a biopharmaceutical company. Ms. Potter previously served on the boards of directors of Rite Aid Corporation, a leading drug store chain, from December 2013 to October 2018, INSMED Inc., a biopharmaceutical company, from December 2014 to November 2018, Everyday Health, Inc., a leading provider of digital health and wellness solutions, from October 2010 until its acquisition in December 2016, and Amazon.com, Inc., a leading e-commerce company, from 2004 to 2009. She also served on the boards of directors of Medco Health Solutions Inc. and Express Scripts Holding Co., subsequent to its acquisition of Medco Health Solutions, as well as other privately held companies. Ms. Potter earned a B.A. from the University of Chicago. Our board of directors believes that Ms. Potter's extensive operational experience leading biopharmaceutical companies and her expertise in commercializing prescription drugs qualifies her to serve as a member of its board of directors.

Family Relationships

There are no family relationships between our board of directors and any of our executive officers.

Board of Directors

Our business and affairs are managed under the direction of the board of directors. Each member of the board of directors serves a one-year term expiring at the next annual meeting of stockholders, subject to his or her office being vacated sooner pursuant to our amended and restated bylaws. Pursuant to our amended and restated charter, the authorized number of directors will be no less than seven directors, and may be changed only by resolution approved by a majority of its board of directors, including the directors appointed by the holder(s) of the Series A Preferred Stock.

Pursuant to our amended and restated charter, the holder(s) of the Series A Preferred Stock are entitled to elect four directors, which individuals shall initially be Mr. Hughes, Dr. Pande, Ms. Potter and Dr. Torti.

Director Independence and Controlled Company Exemptions

We are a "controlled company" within the meaning of the listing rules of Nasdaq. We will remain a "controlled company" so long as either more than 50% of the voting power for the election of directors is held by RSL or the RSL designated directors control all matters presented to its board of directors for a vote. As such, we intend to avail itself of the controlled company exemptions under the Nasdaq listing rules. As a controlled company, we will not be required to have a majority of "independent directors" on its board of directors, as defined under the Nasdaq listing rules, or to have a compensation committee or a committee of our board of directors performing the director nominating function composed entirely of independent directors. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq. We may continue to rely on these exemptions so long as we are allowed to as a "controlled company."

The "controlled company" exemption does not modify the independence requirements for the audit committee, and the Combined Company intends to comply with the requirements of Rule 10A-3 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Nasdaq listing rules, which rules require that our audit committee be composed of at least three members. Under Rule 10A-3 of the Exchange Act, we are permitted to phase in its compliance with the independent audit committee requirements set forth in Rule 10A-3 of the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing.

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Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, the board of directors has determined that, other than Drs. Salzmann and Torti and Ms. Potter, each member of our board of directors, are independent, as that term is defined under the applicable rules and regulations of the SEC, and the Nasdaq listing rules. The Board has determined that Ms. Potter and Dr. Torti are not independent under applicable SEC and the Nasdaq listing rules. We plan to comply with the corporate governance requirements of the SEC and the Nasdaq listing rules.

Audit Committee

The audit committee consists of Mr. Migausky, Mr. Fromkin and Mr. Hughes, with Mr. Migausky as the chairperson of the audit committee. The audit committee consists solely of directors who are independent under Nasdaq's listing standards and meet the independence standards set forth in Rule 10A-3 of the Exchange Act. Our board of directors has further determined that each of the members of the audit committee satisfies the financial literacy and sophistication requirements of the SEC and Nasdaq listing rules. In addition, our board of directors has determined that Mr. Migausky qualifies as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act. The charter for the audit committee is available at www.immunovant.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Compensation Committee

The compensation committee consists of Mr. Fromkin, Mr. Hughes and Dr. Torti, with Mr. Fromkin as the chairperson of the compensation committee. The charter for the compensation committee is available at www.immunovant.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee consists of Dr. Pande, Ms. Potter and Dr. Torti, with Dr. Pande as the chairperson of the nominating and corporate governance committee. The charter for the nominating and corporate governance committee is available at www.immunovant.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Code of Business Conduct and Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics (the "Code of Conduct") applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.immunovant.com. We will disclose any amendments to the Code of Conduct, or any waivers of our requirements, on our website to the extent required by the applicable rules and exchange requirements.

Compensation Committee Interlocks and Insider Participation

None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

EXECUTIVE COMPENSATION

HSAC

Employment Agreements

Prior to the closing of the Business Combination, HSAC did not enter into any employment agreements with its executive officers, and did not make any agreements to provide benefits upon termination of employment.

Executive Officers and Director Compensation

No executive officer has received any cash compensation for services rendered to HSAC. No compensation of any kind, including finders, consulting or other similar fees, will be paid to any of its existing stockholders, including HSAC directors, or any of their respective affiliates, prior to, or for any services they rendered in order to effectuate, the consummation of a business combination. However, such individuals were reimbursed for any out-of-pocket expenses incurred in connection with activities on HSAC's behalf such as identifying potential target businesses and performing due diligence on suitable business combinations. There was no limit on the amount of these out-of-pocket expenses and there was no review of the reasonableness of the expenses by anyone other than HSAC board of directors and audit committee, which includes persons who may seek reimbursement, or a court of competent jurisdiction if such reimbursement is challenged.

Immunovant Sciences Ltd.

Summary Compensation Table for Year Ended March 31, 2019

During the year ended March 31, 2019, Sandeep C. Kulkarni, M.D. was IMVT Corporation's only executive officer. The following table summarizes the total compensation awarded or paid to or earned by or Mr. Kulkarni for the year ended March 31, 2019.

<u>Name and Principal Position</u>	<u>SALARY(1)</u>	<u>NON-EQUITY INCENTIVE PLAN COMPENSATION(2)</u>	<u>TOTAL</u>
Sandeep C. Kulkarni, M.D.(1) <i>Chief Operating Officer of IMVT Corporation</i>	\$ 137,500	\$ 127,664	\$265,164

- (1) Dr. Kulkarni was an officer of IMVT Corporation. He provided services to ISL pursuant to the Services Agreement with RSI. See the section titled "Certain Relationships and Related Party Transactions—Affiliate Services Agreements" for further information. Dr. Kulkarni was named an executive officer of IMVT Corporation in October 2018. Dr. Kulkarni resigned as Chief Operating Officer of IMVT Corporation, but continues to provide services to us in a non-executive officer capacity as an employee of RSI.
- (2) Represents the pro-rated salary and non-equity incentive bonus amounts earned by Dr. Kulkarni, and allocated to IMVT Corporation pursuant to the Services Agreement with RSI, for the year ended March 31, 2019. The non-equity incentive bonus amount was based on an assessment of Dr. Kulkarni's performance as an executive officer of IMVT Corporation.

Outstanding Equity Awards at March 31, 2019

At March 31, 2019, Dr. Kulkarni did not hold any ISL equity awards.

2019 Equity Incentive Plan

Our board of directors and stockholders approved our 2019 Equity Incentive Plan (the “2019 Plan”) in December 2019. The 2019 Plan became effective upon the closing of the Business Combination. The 2019 Plan is designed to secure and retain the services of our employees, directors and consultants, provide incentives for such employees, directors and consultants to exert maximum efforts for our success, and provide a means by which the our employees, directors and consultants may be given an opportunity to benefit from increases in the value of our common stock. No additional awards have been or will be granted under the 2018 Plan (as defined below) following the effective date of the 2019 Plan. The 2019 Plan has the following principal features:

- *Types of Awards.* The 2019 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards that may be settled in cash, stock, or other property. All of our and our affiliates’ employees (including officers), directors and consultants may receive all types of awards other than incentive stock options. Incentive stock options may be granted under the 2019 Plan only to our and our affiliates’ employees (including officers).
- *Shares Available for Awards.* Initially, the aggregate number of shares of common stock that may be issued under the 2019 Plan (the “Share Reserve”), will not exceed 5,500,000 shares. The Share Reserve will automatically increase on April 1st of each year, for a period of not more than ten years, commencing on April 1, 2020 and ending on (and including) April 1, 2029, in an amount equal to 4% of the shares of common stock outstanding on March 31st of the preceding calendar year; however our board of directors or compensation committee may act prior to April 1st of a given year to provide that there will be no April 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares than would otherwise occur pursuant to the automatic increase.
- *Non-Employee Director Compensation Limit.* Under the 2019 Plan, the maximum number of shares of common stock subject to stock awards granted under the 2019 Plan or otherwise during any one calendar year to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such calendar year for services on our board of directors, will not exceed \$1,000,000 in total value (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes).
- *Performance Awards.* The 2019 Plan allows us to grant performance stock and cash awards. The plan administrator can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain performance goals during a designated performance period.

2018 Equity Incentive Plan

In September 2018, ISL’s board of directors and its stockholder adopted its 2018 Equity Incentive Plan (the “2018 Plan”). The 2018 Plan provided for the grant of incentive options within the meaning of Section 422 of the Code to ISL employees and its parent and subsidiary corporations’ employees, and for the grant of nonstatutory options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. The 2018 Plan also provided for the grant of performance cash awards to ISL’s employees, consultants and directors. Upon closing of the Business Combination, all option awards under the 2018 Plan automatically and without any required action on the part of any holder or beneficiary thereof, were assumed by HSAC and converted into an option to purchase HSAC Shares.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Sponsor Shares

In December 2018, the Sponsor purchased an aggregate of 2,875,000 shares for an aggregate purchase price of \$25,000.

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 \$5,000,000), 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 2018. Pursuant to the Share Exchange Agreement, all of the private warrants were canceled upon the closing of the Business Combination.

Sponsor Restricted Stock Agreement

In accordance with the restricted stock agreement, dated September 29, 2019, by and between HSAC and the Sponsor, the Sponsor subjected 1,800,000 shares of its common stock to potential forfeiture in the event that the Milestones (as defined below) are not achieved. In the event of an Acceleration Event (as defined below), 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. See “—Earnout Payments” below for a further description of the Milestones and Acceleration Events.

Lock-Up Agreements

Each selling stockholder named in this prospectus has entered into a Lock-up Agreement with us with respect to the shares of common stock that may be sold by it from time to time pursuant to the registration statement of which this prospectus forms part. Each such stockholder has agreed that during the Lock-up Period (as defined below), it will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any such shares), enter into a transaction that would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of such shares, whether any of these transactions are to be settled by delivery of any such shares, in cash or otherwise, publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement, or engage in any short sales with respect to any security of ours.

The “Lock-up Period” means: (i) with respect to 50% of the shares subject to the lock-up agreement, the shorter of (A) the period commencing on the date of closing of the Business Combination and ending on the date that is six months thereafter; and (B) the period commencing on the date of the closing of the Business Combination and ending on the date on which the last reported closing price of our common stock on the Nasdaq Capital Market equals or exceeds \$12.50 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days during any 30 trading day period thereafter; and (ii) with respect to the remaining 50% of the shares subject to the lock-up agreement, the period commencing on the date of the closing of the Business Combination and ending on the date that is six months thereafter. In addition, if within six months after the date of the closing of the Business Combination, there is a Change of Control (as defined in the Share Exchange Agreement), then upon the consummation of such Change of Control, all such shares shall be released from the foregoing restrictions.

Notwithstanding these restrictions, the selling stockholders will be permitted to make transfers or distributions to current or former general or limited partners, managers or members, stockholders, other equity holders or direct or indirect affiliates or to the estates of any of the foregoing; by bona fide gift to a member of such stockholder’s immediate family or to a trust, the beneficiary of which is the stockholder or a member of the stockholder’s immediate family for estate planning purposes; by virtue of the laws of descent and distribution upon death of the holder; or pursuant to a qualified domestic relations order, in each case where such transferee agrees to be bound by the terms of a lock-up agreement.

Registration Rights

We have entered into an amended and restated registration rights agreement which provides certain holders of our securities registration rights with respect to such securities. See the section titled “Description of Capital Stock—Registration Rights.”

Earnout Payments

The former stockholders of ISL (the “Sellers”) are entitled to receive up to an additional 20,000,000 shares of common stock (the “Earnout Shares”) after the closing of the Business Combination, if the volume-weighted average price of our common stock equals or exceeds the following prices for any 20 trading days within any 30 trading-day period (the “Trading Period”) following the closing of the Business Combination: (1) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon achievement of a volume-weighted average price of at least \$17.50 per share; and (2) during any Trading Period prior to March 31, 2025, 10,000,000 Earnout Shares upon achievement of a volume-weighted average price of at least \$31.50 per share (each, a “Milestone”). In the event that after closing of the Business Combination and prior to March 31, 2025, (i) we experience a change of control, (ii) any liquidation, dissolution or winding up is initiated with respect to us, (iii) any bankruptcy, dissolution or liquidation proceeding is instituted by or against us, or (iv) we make 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 us (whether or not previously earned) shall be deemed earned and due by to the Sellers, unless in a change of control, the value of the consideration to be received in exchange for a share is lower than the applicable Milestone share price thresholds described above.

ISL Financing Transactions

On December 28, 2018, RTW Master Fund, Ltd. and RTW Innovation Master Fund, Ltd. (the “RTW Entities”), entities controlled by officers and directors of HSAC, purchased 2,604,166 shares of ISL, which represented at the time of investment approximately 3% interest in ISL, in exchange for approximately \$10.0 million. On August 1, 2019, the RTW Entities made an additional \$25.0 million investment in ISL in exchange for two promissory notes (the “Promissory Notes”). On September 26, 2019, \$2.5 million aggregate principal amount of the Promissory Notes issued to the RTW Entities was repaid, and the accrued interest on such principal amount was forgiven. The remaining aggregate principal amount of the Promissory Notes automatically converted immediately prior to the consummation of the Business Combination into shares of ISL exchangeable for an aggregate of 2,250,000 shares of our common stock upon the closing of the Business Combination. All interest under the Promissory Notes was waived and cancelled immediately prior to the closing of the Business Combination.

On June 11, 2019, ISL issued an interest-free promissory note to RSL in the amount of \$5.0 million, which was due and payable at the earlier of December 12, 2019 or upon demand by RSL. Subsequently, on August 7, 2019, ISL cancelled this note and entered into a promissory note with RSL in the amount of \$5.0 million under the same terms as the Promissory Notes. On September 26, 2019, ISL repaid \$2.5 million of the principal amount of the Promissory Note issued to RSL, and the accrued interest on such amount was forgiven. The remaining aggregate principal amount of the Promissory Note issued to RSL automatically converted immediately prior to the consummation of the Business Combination into shares of ISL exchangeable for an aggregate of 250,000 shares of our common stock upon the closing of the Business Combination. All interest under this Promissory Note was waived and cancelled immediately prior to the closing of the Business Combination.

In July 2019, ISG issued a promissory note to RSL in the amount of \$2.9 million with a 180-day term. The promissory note does not have a stated interest rate and is payable on demand upon the expiration of the term.

HanAll Agreement Assignment and Sublicense

In December 2018, ISL obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 from RSG in the Licensed Territory, pursuant to an assignment and assumption agreement between RSG and our wholly owned subsidiary, ISG, for an aggregate purchase price of \$37.8 million plus value-added tax of \$2.9 million.

Affiliate Services Agreements

ISL has entered into services agreements with each of Roivant Sciences, Inc. (“RSI”) and Roivant Sciences GmbH (“RSG”), wholly owned subsidiaries of our controlling stockholder RSL, each as further described below. Pursuant to these services agreements, for the period from ISL’s formation through March 31, 2019, ISL incurred expenses of \$2.3 million, inclusive of the mark-up under these agreements.

Roivant Sciences, Inc. Services Agreement

Effective as of August 20, 2018, ISL and its wholly owned subsidiaries, IMVT Corporation (formerly Immunovant, Inc.) and ISG, entered into a services agreement with RSI, a wholly owned subsidiary of RSL (the “RSI Services Agreement”) pursuant to which RSI provides ISL with various services, including, but not limited to, services related to development, administrative and financial activities. We expect that our reliance on RSI will decrease over time as we and our subsidiaries continue to hire the necessary personnel to manage the development and potential commercialization of IMVT-1401 or any future product candidates.

Under the terms of the RSI Services Agreement, we are obligated to pay or reimburse RSI for the costs we, or third parties acting on our behalf, incur in providing services to us. In addition, we are obligated to pay to RSI a pre-determined mark-up on costs incurred by us in connection with any general and administrative and support services as well as research and development services.

Administrative and support services include, but are not limited to, payroll, general administrative, corporate and public relations, investor relations, financial marketing, activities in connection with raising capital, accounting, tax, health, safety, environmental and regulatory affairs, staffing and recruiting, benefits, information and technology services, purchasing and legal services. Research and development services include, but are not limited to, drug discovery and development from target identification through regulatory approval.

Under the RSI Services Agreement, RSI has agreed to indemnify ISL, IMVT Corporation and ISG, and each our respective officers, employees and directors against all losses arising out of, due to or in connection with the provision of services (or the failure to provide services) under the RSI Services Agreement, subject to certain limitations set forth in the RSI Services Agreement. In addition, ISL, IMVT Corporation and ISG have agreed to indemnify RSI and its affiliates and their respective officers, employees and directors against all losses arising out of, due to or in connection with the receipt of services under the RSI Services Agreement, subject to certain limitations set forth in the RSI Services Agreement. Such indemnification obligations will not exceed the payments made by ISL, by IMVT Corporation and by ISG under the RSI Services Agreement for the specific service that allegedly caused or was related to the losses during the period in which such alleged losses were incurred. The term of the RSI Services Agreement will continue until terminated upon 90 days’ written notice by RSI or by either IMVT Corporation or ISG with respect to the services either such party receives thereunder.

Roivant Sciences GmbH Services Agreement

Effective as of August 20, 2018, ISG entered into a services agreement with RSG, a wholly owned subsidiary of RSL (the “RSG Services Agreement”) pursuant to which RSG provides ISG with various services, including, but not limited to, services related to development, administrative and financial activities. Following the closing of this Business Combination, we expect that reliance on RSG by ISG will decrease over time as ISG hires the necessary personnel to manage the development and potential commercialization of IMVT-1401 or any future product candidates.

Under the terms of the RSG Services Agreement, ISG is obligated to pay or reimburse RSG for the costs it, or third parties acting on its behalf, incur(s) in providing services to ISL. In addition, ISG is obligated to pay to RSG a pre-determined mark-up on costs incurred by it in connection with any general and administrative and support services as well as research and development services.

Administrative and support services include, but are not limited to, payroll, general administrative, corporate and public relations, investor relations, financial marketing, activities in connection with raising capital, accounting and auditing, tax, health, safety, environmental and regulatory affairs, staffing and recruiting, benefits, information and technology services, purchasing and legal services. Research and development services include, but are not limited to drug discovery and development from target identification through regulatory approval.

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Under the RSG Services Agreement, RSG has agreed to indemnify ISG, and each of its officers, employees and directors against all losses arising out of, due to or in connection with the provision of services (or the failure to provide services) under the RSG Services Agreement, subject to certain limitations set forth in the RSG Services Agreement. ISG has also agreed to indemnify RSG and its affiliates and their respective officers, employees and directors against all losses arising out of, due to or in connection with the receipt of services under the RSG Services Agreement, subject to certain limitations set forth in the RSG Services Agreement. Such indemnification obligations will not exceed the payments made by ISG under the RSG Services Agreement for the specific service that allegedly caused or was related to the losses during the period in which such alleged losses were incurred. The term of the RSG Services Agreement will continue until terminated by RSG or ISG upon 90 days' written notice.

RSL Information Sharing and Cooperation Agreement

In December 2018, ISL entered into an amended and restated information sharing and cooperation agreement (the "Cooperation Agreement") with RSL. The Cooperation Agreement, among other things: (1) obligates ISL to deliver to RSL periodic financial statements and other information upon reasonable request and to comply with other specified financial reporting requirements; (2) requires ISL to supply certain material information to RSL to assist it in preparing any future SEC filings; and (3) requires ISL to implement and observe certain policies and procedures related to applicable laws and regulations. ISL has agreed to indemnify RSL and its affiliates and their respective officers, employees and directors against all losses arising out of, due to or in connection with RSL's status as a stockholder under the Cooperation Agreement and the operations of or services provided by RSL or its affiliates or their respective officers, employees or directors to ISL 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, ISL believes 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 is no longer (a) required by GAAP to consolidate our results of operations and financial position, account for its investment in ISL 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.

Employment Arrangements

Prior to the Business Combination, each of our executive officers was employed by our wholly owned subsidiary, IMVT Corporation (formerly Immunovant, Inc.), and provides services to ISL pursuant to an inter-company services agreement between ISL and IMVT Corporation and ISG. Each of our executive officers has an employment agreement or offer letter with us that sets forth the initial terms and conditions of employment.

Indemnification Agreements

In connection with the Business Combination, we entered into indemnification agreements with each of our directors and executive officers. These indemnification agreements provide the directors and executive officers with contractual rights to indemnification and expense advancement.

Related Person Transaction Policy

We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. A related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to the Combined Company as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including RSL, and any of their respective immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of the board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under the Code of Conduct our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, the audit committee, or other independent body of the board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, the audit committee, or other independent body of the board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as the audit committee, or other independent body of the board of directors, determines in the good faith exercise of its discretion.

BENEFICIAL OWNERSHIP OF SECURITIES

The following table sets forth information regarding the beneficial ownership of shares of our common stock as of December 18, 2019 by:

- each person known by us to be the beneficial owner of more than 5% of our common stock;
- each of our executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days.

This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that all persons named in the table have sole voting and investment power with respect to all shares of our common stock beneficially owned by them. Applicable percentages are based on 56,455,376 shares of common stock outstanding on December 18, 2019, adjusted as required by rules promulgated by the SEC.

<u>Name and Address of Beneficial Owner(1)</u>	<u>Number of Shares</u>	<u>% of Class</u>
Roivant Sciences Ltd.(2)	37,404,967	66.3%
Entities affiliated with RTW(3)	4,426,106	7.8
Health Sciences Holdings, LLC (Sponsor)(4)	2,875,000	4.9
Peter Salzmann, M.D., M.B.A.	—	—
Pamela Yanchik Connealy, M.B.A.	—	—
Julia G. Butchko, Ph.D.	—	—
W. Bradford Middlekauff, J.D.	—	—
Robert K. Zeldin, M.D., FAAAAI	—	—
Frank M. Torti, M.D.	—	—
Myrtle S. Potter	—	—
Atul Pande, M.D.	—	—
Andrew Fromkin	—	—
Douglas Hughes	—	—
George Migausky(5)	20,000	*
All directors and executive officers (11 individuals) as a group	20,000	*

* Less than 1%.

(1) Unless otherwise indicated, the business address of each of the individuals is 320 West 37th Street, New York, New York 10018.

(2) Excludes 10,000 shares of Series A Preferred Stock issued to Roivant upon closing of the Business Combination. Each share of Series A Preferred Stock is convertible at any time at the option of the holder into one share of common stock. Roivant owns all of the authorized and outstanding shares of Series A Preferred Stock and is entitled to elect a specified number of directors to our board of directors. Sakshi Chhabra, Andrew Lo, Patrick Machado, Keith Manchester, M.D., Ilan Oren, Masayo Tada and Vivek Ramaswamy are the members of the board of directors of Roivant and may be deemed to have shared voting, investment and dispositive power with respect to the shares held by this entity. These individuals disclaim beneficial ownership with respect to such shares except to the extent of their pecuniary interest therein. The principal business address of Roivant is Suite 1, 3rd Floor, 11-12 St. James's Square, London SW1Y 4LB, United Kingdom.

(3) Consists of shares owned by RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd. and RTW Venture Fund Limited. Roderick Wong, M.D. has voting and dispositive power over the shares owned by the RTW Entities.

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- (4) Includes 100,000 shares of common stock beneficially owned by Pedro Granadillo, Gotham Makker, George Migausky, Sukumar Nagendran and Mark Schoenebaum, which shares are held of record by the Sponsor. Sponsor is governed by a board of directors consisting of three directors: Roderick Wong, M.D., Naveen Yalamanchi, M.D., and Alice Lee. Each director has one vote, and the approval of a majority of the directors is required to approve an action of Sponsor. Under the so-called “rule of three,” if voting and dispositive decisions regarding an entity’s securities are made by three or more individuals, and a voting or dispositive decision requires the approval of a majority of those individuals, then none of the individuals is deemed a beneficial owner of the entity’s securities. Based upon the foregoing analysis, no director of Sponsor exercises voting or dispositive control over any of the securities held by Sponsor, even those in which he or she directly holds a pecuniary interest. Accordingly, none of them will be deemed to have or share beneficial ownership of such shares.
- (5) Includes 20,000 shares of common stock that are held of record by the Sponsor.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights of our common stock and preferred stock. This summary is qualified by reference to the complete text of our amended and restated charter and bylaws filed as exhibits to the registration statement of which this prospectus forms a part.

General

Our authorized capital stock consists of 500,000,000 shares of common stock, par value \$0.0001 per share, 10,000 shares of Series A Preferred Stock, par value \$0.0001 per share, and 10,000,000 shares of blank check preferred stock, par value \$0.0001 per share.

Common Stock

Holders of the common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than the directors that holders of Series A Preferred Stock are entitled to elect or any directors that the holders of any undesignated preferred stock that may be issued in the future may be entitled to elect. Subject to preferences of the Series A Preferred Stock and any preferences that may be applicable to any then outstanding blank check preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds.

Series A Preferred Stock

Holders 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: (1) 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, (2) 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 (3) 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 Series A Preferred Holders, given either at a special meeting of the Series A Preferred Holders duly called for that purpose or pursuant to a written consent of the Series A Preferred Holder(s).

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 Charter.

Each share of Series A Preferred Stock will automatically convert into one share of common stock at such time as the holders of Series A Preferred Stock hold less than 25% of the total voting power of our outstanding shares.

Blank Check Preferred Stock

Under the terms of the Amended Charter, the board of directors has the authority, without further action by its stockholders, to issue up to 10,000,000 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, to fix the dividend, voting, and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations, or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

The board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in control of us and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock.

Liquidation Rights

In the event of our liquidation, dissolution, or winding up, the holders 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 our debts and other liabilities, subject any blank check preferred stock then outstanding.

No Preemptive or Similar Rights

Holders of our Series A Preferred Stock and common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the Series A Preferred Stock and common stock.

Warrants

Each warrant entitles the registered holder to purchase one-half (1/2) of a share of common stock at a price of \$11.50 per whole share, subject to adjustment as discussed below, at any time commencing on May 14, 2020. Pursuant to the warrant agreement, a warrant holder may exercise its warrants only for a whole number of shares. This means that only an even number of warrants may be exercised at any given time by a warrant holder. However, no warrants will be exercisable for cash unless has an effective and current registration statement covering the shares of common stock issuable upon exercise of the warrants and a current prospectus relating to such shares of common stock. Notwithstanding the foregoing, if a registration statement covering the shares of common stock issuable upon exercise of the warrants is not effective within 120 days from the closing of the Business Combination, warrant holders may, until such time as there is an effective registration statement and during any period when we shall have failed to maintain an effective registration statement, exercise the warrants on a cashless basis pursuant to an available exemption from registration under the Securities Act of 1933, as amended. The warrants will expire five years from the closing of the Business Combination at 5:00 p.m., New York City time.

We may call the outstanding warrants for redemption, in whole and not in part, at a price of \$0.01 per warrant:

- at any time while the warrants are exercisable,
- upon not less than 30 days' prior written notice of redemption to each warrant holder,

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- if, and only if, the reported last sale price of a share of common stock equals or exceeds \$16.50 per share,
- for any 20 trading days within a 30-day trading period ending on the third business day prior to the notice of redemption to warrant holders, and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

The right to exercise will be forfeited unless the warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of a Warrant will have no further rights except to receive the redemption price for such holder's warrant upon surrender of such warrant.

The redemption criteria for the warrants have been established at a price which is intended to provide warrant holders a reasonable premium to the initial exercise price and provide a sufficient differential between the then-prevailing share price and the warrant exercise price so that if the our share price declines as a result of a redemption call, the redemption will not cause the share price to drop below the exercise price of the warrants.

If we call the warrants for redemption as described above, our management will have the option to require all holders that wish to exercise the warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares underlying the HSAC Warrants, multiplied by the difference between the exercise price of the Warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of a share of commons stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants. Whether we will exercise our option to require all holders to exercise their warrants on a "cashless basis" will depend on a variety of factors including the price of our common stock at the time the warrants are called for redemption, our cash needs at such time and concerns regarding dilutive share issuances.

The warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval, by written consent or vote, of the holders of a majority of the then outstanding warrants in order to make any change that adversely affects the interests of the registered holders.

The exercise price and number of shares of common stock issuable on exercise of the warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary dividend or a recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuances of shares of common stock at a price below their respective exercise prices.

The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the Warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of shares of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

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Except as described above, no warrants will be exercisable for cash and we will not be obligated to issue shares of common stock unless at the time a holder seeks to exercise such warrant, a prospectus relating to the shares of common stock issuable upon exercise of the warrants is current and the shares of common stock have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the warrant agreement, we have agreed to use our best efforts to meet these conditions and to maintain a current prospectus relating to the shares of common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that we will be able to do so and, if we do not maintain a current prospectus relating to the shares of common stock issuable upon exercise of the warrants, holders will be unable to exercise their Warrants and it will not be required to settle any such warrant exercise. If the prospectus relating to the shares of common stock issuable upon the exercise of the Warrants is not current or if the shares of common stock are not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside, we will not be required to net cash settle or cash settle the warrant exercise, the warrants may have no value, the market for the warrants may be limited and the warrants may expire worthless.

The warrant holders may elect to be subject to a restriction on the exercise of their warrants such that an electing warrant holder would not be able to exercise their warrants to the extent that, after giving effect to such exercise, such holder would beneficially own in excess of 9.9% of our outstanding shares of common stock.

No fractional shares will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number of shares of common stock to be issued to the warrant holder.

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 us to register for resale under 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 the lock-up agreements described above. Subject to certain exceptions, if we propose 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 we 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.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- authorize the issuance of up to 10,000,000 shares of “blank check” preferred stock, the rights, preferences and privileges of which may be designated from time to time by the our board of directors to increase the number of outstanding shares and discourage a takeover attempt;
- provide that the authorized number of directors will be fixed at no less than seven and may be changed only by resolution of our board of directors, including the Series A Preferred Directors;
- authorize the issuance of Series A Preferred Stock and the appointment of Series A Preferred Directors;
- provide that directors may be removed with or without cause by the affirmative vote of the holders of at least 66 2/3% of the voting power of all then-outstanding shares of our capital stock entitled to vote generally at an election of directors; provided that the Series A Preferred Directors may be removed without cause only by the holder(s) of Series A Preferred Stock;
- provide that, as long as we are a “controlled company,” as such term is defined under the rules of the exchange on which our securities are listed, the chairperson of the board of directors will be entitled to a casting vote and be entitled to two votes on any matter or resolution presented to the full board of directors or any committee on which he or she then serves for which a majority vote cannot be obtained; and
- provide that from and after such time as we are no longer a “controlled company,” as such term is defined under the rules of the exchange on which our securities are listed:
 - any amendment to our bylaws will require the approval of the holders of at least 66 2/3% of our then-outstanding shares of capital stock entitled to vote generally at an election of directors; and
 - any amendment to certain provisions of our amended and restated charter will require the approval of the holders of at least 66 2/3% of our then-outstanding shares of capital stock entitled to vote generally at an election of directors; provided that we shall not amend any provision of our amended and restated charter in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock without the approval of the holder(s) of a majority of the Series A Preferred Stock.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and our policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock.

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Choice of Forum

Our amended and restated certificate provides that the Court of Chancery of the State of Delaware be the exclusive forum for actions or proceedings brought under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of fiduciary duty; (3) any action asserting a claim against us arising under the Delaware General Corporation Law; (4) any action regarding our amended and restated certificate of incorporation or our amended and restated bylaws; (5) any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or (6) any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Transfer Agent

The transfer agent for our securities is Continental Stock Transfer & Trust Company. The transfer agent's address is 1 State Street, 30^h Floor, New York, New York 10004.

SELLING STOCKHOLDERS

The selling stockholders may offer and sell, from time to time, any or all of the shares of common stock being offered for resale by this prospectus, which consists of:

- up to 42,080,376 shares of common stock issued pursuant to the Share Exchange Agreement;
- up to 20,000,000 additional shares of common stock that may be issued pursuant to the Share Exchange Agreement upon the satisfaction of certain conditions, as described under “Certain Relationships and Related Party Transactions—Earnout Payments”;
- up to 2,875,000 shares of common stock held by the Sponsor; and
- up to 1,387,498 shares of common stock purchased by the Selling RTW Entities and RSL in open market transactions.

An aggregate of 1,800,000 shares of common stock held by the Sponsor are subject to forfeiture in the event that the Milestones are not achieved and may not be sold until such time. See the section titled “Certain Relationships and Related Party Transactions—Sponsor Restricted Stock Agreement.”

Each selling stockholder listed below has entered into a Lock-up Agreement with us with respect to certain of the shares of common stock that may be sold by it from time to time pursuant to the registration statement of which this prospectus forms part. Such shares may not be sold for a period of six months from the date of the closing of the Business Combination, provided that 50% of such shares will be released on the date on which the last reported closing price of our common stock on the Nasdaq Capital Market equals or exceeds \$12.50 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days during any 30 trading-day period. See the section titled “Certain Relationships and Related Party Transactions—Lock-Up Agreements.”

As used in this prospectus, the term “selling stockholders” includes the selling stockholders listed in the table below, together with any additional selling stockholders listed in a subsequent amendment to this prospectus, and their donees, pledgees, assignees, transferees, distributees and successors-in-interest that receive shares in any non-sale transfer after the date of this prospectus.

The following table provides, as of the date of this prospectus, information regarding the beneficial ownership of our common stock of each selling stockholder, the number of shares of common stock that may be sold by each selling stockholder under this prospectus and that each selling stockholder will beneficially own after this offering. Because each selling stockholder may dispose of all, none or some portion of their securities, no estimate can be given as to the number of securities that will be beneficially owned by a selling stockholder upon termination of this offering. For purposes of the table below, however, we have assumed that after termination of this offering none of the securities covered by this prospectus will be beneficially owned by the selling stockholders and further assumed that the selling stockholders will not acquire beneficial ownership of any additional securities during the offering. In addition, the selling stockholders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, our securities in transactions exempt from the registration requirements of the Securities Act after the date on which the information in the table is presented.

Please see the section titled “Plan of Distribution” for further information regarding the stockholders’ method of distributing these shares.

Name	Shares of Common Stock			Percent Owned After Offering
	Number Beneficially Owned Prior to Offering(1)	Number Registered for Sale Hereby(2)	Number Beneficially Owned After Offering	
Roivant Sciences Ltd.(3)	37,404,967	37,404,967	—	—
RTW Master Fund, Ltd.(4)	3,235,952	3,235,952	—	—
RTW Innovation Master Fund, Ltd.(4)	1,037,580	1,037,580	—	—
RTW Venture Fund Limited(4)	152,574	152,574	—	—
HanAll BioPharma Co., Ltd.(5)	636,805	636,805	—	—
Biotechnology Value Fund, L.P.	493,952	493,952	—	—
Biotechnology Value Fund II, L.P.	401,724	401,724	—	—
Biotechnology Value Trading Fund OS, L.P.	71,925	71,925	—	—
MSI BVF SPV L.L.C.	32,395	32,395	—	—
Health Sciences Holdings, LLC (Sponsor)(6)	2,875,000	2,875,000	—	—

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- (1) Based upon 56,455,376 shares of common stock outstanding as of December 18, 2019, assuming the exercise of all currently outstanding warrants.
- (2) Excludes 20,000,000 shares of common stock registered for sale hereby that may be issued to certain of the selling stockholders as described under “Certain Relationships and Related Party Transactions—Earnout Payments.”
- (3) Excludes 10,000 shares of Series A Preferred Stock issued to Roivant upon closing of the Business Combination. Roivant, as the holder of our Series A preferred stock, is entitled to elect a specified number of Series A Preferred Directors to our board of directors, in accordance with our amended and restated certificate of incorporation.
- (4) Roderick Wong, M.D., the former President and Chief Executive Officer and Chairman of HSAC, has voting and dispositive power over the shares owned by the entities affiliated with RTW.
- (5) We have licensed our core intellectual property relating to IMVT-1401 from HanAll under the HanAll Agreement. See “Business—License Agreement with HanAll Biopharma Co., Ltd.”
- (6) Includes an aggregate of 100,000 shares of common stock held of record by the Sponsor, 20,000 of which are beneficially owned by each of Pedro Granadillo, Gotham Makker, George Migausky, Sukumar Nagendran and Mark Schoenebaum.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling warrants, shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their warrants, shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the warrants or shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of warrants, shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for our account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the warrants or shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the warrants or shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our warrants, shares of common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the warrants or shares of common stock in the course of hedging the positions they assume. The selling stockholders may also sell warrants or shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the warrants or common stock to broker-dealers that in turn may sell these securities. The selling

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stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of warrants or shares offered by this prospectus, which warrants or shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the warrants or common stock offered by them will be the purchase price of the warrants or common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of warrants or common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the warrants or shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the warrants or shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the warrants or common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the warrants or common stock may not be sold unless they have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of warrants or shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the warrants or shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or such securities have been withdrawn.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Cooley LLP.

EXPERTS

The combined and consolidated financial statements of Immunovant Sciences Ltd. at March 31, 2019 and 2018, and for the year ended March 31, 2019 and for the period from December 19, 2017 to March 31, 2018, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about Immunovant Sciences Ltd.'s ability to continue as a going concern as described in Note 1[B] to the combined and consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The financial statements of Health Sciences Acquisitions Corporation as of December 31, 2018 and for the period from December 6, 2018 (inception) through December 31, 2018 appearing in this prospectus have been audited by WithumSmith+Brown, PC, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere in this prospectus and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the shares of common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov.

We are subject to the information reporting requirements of the Exchange Act, and we file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website at www.sec.gov. We also maintain a website at www.immunovant.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Introduction

On December 18, 2019, Immunovant Sciences Ltd. (“ISL”) and Health Sciences Acquisitions Corporation (“HSAC”) consummated the transactions contemplated by the Share Exchange Agreement (the “Business Combination”). In connection with the closing of the Business Combination, the registrant changed its name from Health Sciences Acquisitions Corporation to Immunovant, Inc.

The following unaudited pro forma condensed combined balance sheet as of September 30, 2019 combines the unaudited historical condensed consolidated balance sheet of ISL as of September 30, 2019, with the unaudited historical condensed balance sheet of HSAC as of September 30, 2019, giving effect to the Business Combination, the conversion of the Promissory Notes and the issuance of shares arising from the Business Combination as if these events had occurred as of that date.

In August 2019, ISL issued \$30.0 million of Promissory Notes, consisting of \$25.0 million to the RTW Entities, and \$5.0 million to RSL as a replacement of an existing \$5.0 million promissory note payable to RSL in June 2019. In September 2019, ISL repaid \$2.5 million aggregate principal amount of the Promissory Notes issued to the RTW Entities and \$2.5 million principal amount of the Promissory Note issued to RSL, and the accrued interest on such principal amounts was forgiven. Subsequently, ISL issued four additional Promissory Notes having an aggregate principal amount of \$10.0 million to entities affiliated with BVF. The Promissory Notes automatically converted immediately prior to the consummation of the Business Combination into common shares of ISL exchangeable for an aggregate of 3,500,000 shares of HSAC common stock (“HSAC Shares”) upon the closing of the Business Combination. All interest on the Promissory Notes was waived and cancelled immediately prior to the closing of the Business Combination. As the Business Combination triggered the automatic conversion of the Promissory Notes into common stock, the subsequent conversion of the Promissory Notes have been reflected as a pro forma adjustment in the unaudited pro forma condensed combined balance sheet.

The following unaudited pro forma condensed combined statements of operations for the six months ended September 30, 2019 and the year ended March 31, 2019 combined the unaudited and audited historical combined and consolidated statements of operations of ISL for the six months ended September 30, 2019 and the year ended March 31, 2019, respectively, with the unaudited and audited historical condensed statements of operations of HSAC for the six months ended September 30, 2019 and year ended March 31, 2019, respectively, giving effect to the Business Combination, the conversion of the Promissory Notes and the issuance of shares arising from the Business Combination as if these events had occurred on April 1, 2018.

The historical financial information of ISL was derived from the combined and consolidated financial statements of ISL for the six months ended September 30, 2019 and the audited combined and consolidated financial statements of ISL for the year ended March 31, 2019, included elsewhere in this prospectus. The historical financial information of HSAC as of and for the six months ended September 30, 2019 was derived from the unaudited financial statements of HSAC for the three months ended September 30, 2019 and the unaudited financial statements of HSAC for the three months ended September 30, 2019, included elsewhere in this prospectus. The historical statement of operations of HSAC for the year ended March 31, 2019 was derived from the audited financial statements of HSAC for the period from December 6, 2018 (Inception) through December 31, 2018 and the unaudited financial statements of HSAC for the three months ended March 31, 2019, included elsewhere in this prospectus. This information should be read together with ISL’s and HSAC’s audited and unaudited financial statements and related notes, the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and other financial information included elsewhere in this prospectus.

Description of the Share Exchange

Pursuant to the Share Exchange Agreement, HSAC acquired 100% of the issued and outstanding securities of ISL, in exchange for 42,080,376 HSAC Shares and 10,000 shares of Series A preferred stock of HSAC, calculated in accordance with the terms of the Share Exchange Agreement. At closing, all vested or unvested outstanding options in ISL under its equity incentive plan were automatically assumed by HSAC and converted into options to purchase shares of HSAC Shares with no substantial changes to their vesting conditions.

The Sellers are entitled to receive up to an additional 20,000,000 Earnout Shares after the closing of the Business Combination if the volume-weighted average price of the HSAC Shares equals or exceeds the following prices for any 20 trading days within any 30 trading-day period (the “Trading Period”) following the closing: (1) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon achievement of a volume-weighted average price of at least \$17.50 per share; and (2) during any Trading Period prior to March 31, 2025, 10,000,000 Earnout Shares upon achievement of a volume-weighted average price of at least \$31.50 per share (each, a “Milestone”). In the event that after closing of the Business Combination and prior to March 31, 2025, (i) there is a change of control of HSAC, (ii) any liquidation, dissolution or winding up of HSAC is initiated, (iii) any bankruptcy, dissolution or liquidation proceeding is instituted by or against HSAC, or (iv) HSAC 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 HSAC (whether or not previously earned) shall be deemed earned and due by HSAC to the Sellers, unless in a change of control, the value of the consideration to be received in exchange for a HSAC Share is lower than the applicable Milestone share price thresholds described above.

Accounting for the Share Exchange

The Business Combination will be accounted for as a “reverse recapitalization” in accordance with GAAP. Under this method of accounting HSAC will be treated as the “acquired” company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Business Combination, the Sellers are expected to have a majority of the voting power of the combined company, ISL will comprise all of the ongoing operations of the combined entity, ISL will comprise 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 will be treated as the equivalent of ISL issuing shares for the net assets of HSAC, accompanied by a recapitalization. The net assets of HSAC will be stated at historical costs. No goodwill or other intangible assets will be recorded. Operations prior to the Business Combination will be those of ISL.

Basis of Pro Forma Presentation

The historical financial information has been adjusted to give pro forma effect to events that are related and directly attributable to the Business Combination, the conversion of the Promissory Notes and the issuance of shares arising from the Business Combination, are factually supportable and are expected to have a continuing impact on the results of the combined company. The adjustments presented on the unaudited pro forma condensed combined financial statements are based on currently available information and certain assumptions that both HSAC and ISL believe are reasonable under the circumstances. The unaudited condensed pro forma adjustments may be revised as additional information becomes available.

The unaudited pro forma condensed combined financial information is for illustrative purposes only. The financial results may have been different had the companies always been combined. You should not rely on the unaudited pro forma condensed combined financial information as being indicative of the historical results that would have been achieved had the companies always been combined or the future results that the combined company will experience. ISL and HSAC have not had any historical relationship prior to the Business Combination. Accordingly, no pro forma adjustments were required to eliminate activities between the companies.

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Shares outstanding and weighted average shares outstanding as presented in the pro forma condensed combined financial statements include the 42,080,376 HSAC Shares and 10,000 shares of Series A preferred stock of HSAC issued to the Sellers and exclude the 20,000,000 Earnout Shares. Because the terms of replacement share-based awards are not finalized yet, their accounting impact is not included in the unaudited pro forma condensed combined financial statements.

As a result of the Business Combination, the Sellers own approximately 77.0% of the non-redeemable shares of common stock of the Combined Company, the Sponsor owns approximately 2.0% of the non-redeemable shares of the Combined Company and HSAC public stockholders own approximately 21.0% of the non-redeemable shares of the Combined Company, based on the number of HSAC Shares outstanding as of September 30, 2019 (in each case, not giving effect to any shares issuable upon exercise of HSAC Warrants and HSAC Unit purchase option, or Earnout Shares). The Private Warrants were forfeited and cancelled at the closing of the Business Combination.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET

	As of September 30, 2019		Pro Forma Adjustments	Debt Financing Adjustments	As of
	ISL (Historical)	HSAC (Historical)			September 30, 2019
Assets					
Current assets:					
Cash	\$ 18,991,649	\$ 1,610,350	\$ 116,024,698(A) (4,025,000)(D) (3,174,058)(E)	\$ —	\$ 129,427,639
Prepaid expenses	512,850	152,103			664,953
Income tax receivable	4,827	—			4,827
Value-added tax receivable	2,920,940	—			2,920,940
Total current assets	22,430,266	1,762,453	108,825,640	—	133,018,359
Property and equipment, net	45,327	—			45,327
Deferred offering costs	1,677,929	—	(1,677,929)(E)		—
Cash and marketable securities held in Trust Account	—	116,024,698	(116,024,698)(A)		—
Total assets	\$ 24,153,522	\$ 117,787,151	\$ (8,876,987)	\$ —	\$ 133,063,686
Liabilities and Stockholders' (Deficit)/Equity					
Current liabilities:					
Accounts payable	\$ 1,176,236	\$ —	\$ —	\$ —	\$ 1,176,236
Accrued expenses	8,195,749	306,115		(190,411)(H)	8,311,453
Due to Roivant Sciences Ltd.	3,057,298	—		(20,548)(H)	3,036,750
Convertible promissory note payable to Roivant Sciences Ltd.	2,500,000	—		(2,500,000)(G)	—
Convertible promissory notes payable	32,500,000	—		(32,500,000)(G)	—
Income tax payable	10,786	31,510			42,296
Total current liabilities	47,440,069	337,625	—	(35,210,959)	12,566,735
Deferred underwriting fee payable	—	4,025,000	(4,025,000)(D)		—
Total liabilities	47,440,069	4,362,625	(4,025,000)	(35,210,959)	12,566,735
Commitments and Contingencies:					
Common stock subject to possible redemption, 10,842,452 shares at redemption value	—	108,424,520	(108,424,520)(C)		—
Stockholders' Equity/(Deficit):					
Series A preferred shares	—	—	1(B)	—	1
Preferred shares	—	—			—
Common shares	789	353	(251)(B)	3,500(G)	5,475
Additional paid-in capital	36,090,133	4,692,712	250(B) 1,084(C) 108,423,436(C) (4,851,987)(E) 306,941(F)	34,996,500(G)	179,657,985
Accumulated other comprehensive income	1,378	—			1,378
(Accumulated deficit)/retained earnings	(59,378,847)	306,941	(306,941)(F)	210,959(H)	(59,167,888)
Total stockholders' (deficit)/equity	(23,286,547)	5,000,006	103,572,533	35,210,959	120,496,951
Total liabilities and stockholders' (deficit)/equity	\$ 24,153,522	\$ 117,787,151	\$ (8,876,987)	\$ —	\$ 133,063,686

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

	Six Months Ended September 30, 2019				Six Months Ended September 30, 2019
	ISL (Historical)	HSAC (Historical)	Pro Forma Adjustments	Debt Financing Adjustments	Pro Forma Combined
Operating expenses:					
Research and development	\$ 28,806,867	\$ —			\$ 28,806,867
General and administrative	5,747,593	512,099	(438,620)(BB)		5,821,072
Total operating expenses	34,554,460	512,099	(438,620)	—	34,627,939
Loss from operations	(34,554,460)	(512,099)	438,620		(34,627,939)
Interest expense	249,315	—	—	(249,315)(CC)	—
Interest income	—	(1,024,698)	1,024,698(AA)		—
Other (income)/expense, net	(318,806)	—	—	38,356(CC)	(280,450)
(Loss)/income before provision for income taxes	(34,484,969)	512,599	(586,078)	210,959	(34,347,489)
Income tax expense	56,005	204,760	(204,760)(AA)		56,005
Net (loss)/income	<u>\$ (34,540,974)</u>	<u>\$ 307,839</u>	<u>\$ (381,318)</u>	<u>\$ 210,959</u>	<u>\$ (34,403,494)</u>
<u>(Net Loss)/Income per Share</u>					
Net loss per non-redeemable common share – basic and diluted	\$ (0.44)	\$ (0.16)			\$ (0.63)
Weighted average non-redeemable common shares outstanding – basic and diluted	78,906,250	2,875,000			54,655,376
Net income per redeemable common share – basic and diluted		\$ 0.07			
Weighted average redeemable common shares outstanding – basic and diluted		11,500,000			

See accompanying notes to unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

	Year Ended March 31, 2019	Period from December 6, 2018 (Inception) to March 31, 2019	Pro Forma Adjustments	Year Ended March 31, 2019
	ISL (Historical)	HSAC (Historical)		Pro Forma Combined
Operating expenses:				
Research and development	\$ 25,733,274	\$ —		\$ 25,733,274
General and administrative	2,691,946	898		2,692,844
Total operating expenses	28,425,220	898	—	28,426,118
Loss from operations	(28,425,220)	(898)		(28,426,118)
Other expense, net	155,480	—		155,480
Loss before provision for income taxes	(28,580,700)	(898)	—	(28,581,598)
Income tax expense	18,724	—		18,724
Net loss	<u>\$(28,599,424)</u>	<u>\$ (898)</u>	<u>\$ —</u>	<u>\$(28,600,322)</u>
Net Loss per Share				
Net loss per non-redeemable common share – basic and diluted	\$ (0.63)	\$ (0.00)		\$ (0.52)
Weighted average non-redeemable common shares outstanding – basic and diluted	45,333,048	2,500,000		54,655,376

See accompanying notes to unaudited pro forma condensed combined financial information.

**NOTES TO UNAUDITED PRO FORMA
CONDENSED COMBINED FINANCIAL INFORMATION**

1. Accounting Policies

Upon consummation of the Business Combination, management will perform a comprehensive review of the two entities' accounting policies. As a result of the review, management may identify differences between the accounting policies of the two entities which, when conformed, could have a material impact on the financial statements of the post-combination company. Based on its initial analysis, management did not identify any differences that would have a material impact on the unaudited pro forma condensed combined financial information. As a result, the unaudited pro forma condensed combined financial information does not assume any differences in accounting policies.

2. Adjustments to Unaudited Pro Forma Condensed Combined Financial Information

The unaudited pro forma condensed combined financial information has been prepared to illustrate the effect of the Business Combination and has been prepared for informational purposes only.

The historical financial statements have been adjusted in the unaudited pro forma condensed combined financial information to give pro forma effect to events that are (1) directly attributable to the Business Combination, (2) factually supportable, and (3) with respect to the statements of operations, expected to have a continuing impact on the results of the post-combination company. ISL and HSAC did not have any historical relationship prior to the Business Combination. Accordingly, no pro forma adjustments were required to eliminate activities between the companies.

The pro forma basic and diluted earnings per share amounts presented in the unaudited pro forma condensed combined statements of operations are based upon the number of ISL's shares outstanding as of September 30, 2019, assuming the Business Combination occurred on April 1, 2018. As the unaudited pro forma condensed statements of operations are in a loss position, anti-dilutive instruments were not included in the calculation of diluted weighted average number of common shares outstanding.

Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet

The adjustments included in the unaudited pro forma condensed combined balance sheet as of September 30, 2019 are as follows:

- (A) Reflects the reclassification of \$116.0 million of cash and cash equivalents held in the Trust Account that becomes available following the Business Combination.
- (B) Reflects the adjustment to present the non-redeemable outstanding shares of common stock and Series A preferred stock upon consummation of the Business Combination of 54,655,376 and 10,000 shares, respectively, at a par value \$0.0001 per share.
- (C) Reflects the reclassification of \$108.4 million of common shares (10,842,452 shares at redemption value) subject to possible redemption to permanent equity.
- (D) Reflects the settlement of \$4.0 million of deferred underwriters' fees incurred during the IPO that were due upon completion of the Business Combination.
- (E) Reflects the adjustment of \$4.9 million to additional paid-in capital for transaction costs expected to be incurred in relation to the Business Combination (of which \$1.7 million was already incurred by ISL and capitalized as deferred financing costs).
- (F) Reflects the reclassification of HSAC's historical retained earnings.
- (G) Reflects the conversion of the outstanding principal balance of Promissory Notes due to the RTW Entities, RSL and entities affiliated with BVF in the aggregate amount of \$35.0 million to common shares and additional paid in capital.

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- (H) Reflects the adjustment for the forgiveness of accrued interest of \$0.2 million upon the conversion of the Promissory Notes due to RTW Entities, RSL and entities affiliated with BVF.

Adjustments to Unaudited Pro Forma Condensed Combined Statements of Operations

The pro forma adjustments included in the unaudited pro forma condensed combined statements of operations for the six months ended September 30, 2019 and year ended March 31, 2019 are as follows:

- (AA) Elimination of interest income on the Trust Account and related tax impact due to reclassification of the cash and marketable securities held in the Trust Account that became available to fund the Business Combination. HSAC's tax provision for the six months ended September 30, 2019 was solely due to the interest income generated during the period and, as such, the entire provision for income taxes of \$0.2 million was eliminated.
- (BB) Elimination of transaction costs previously recorded by HSAC of \$0.4 million related to the Business Combination.
- (CC) Elimination of interest expense and forgiveness of interest previously recorded in relation to outstanding Promissory Notes due to the RTW Entities, RSL and entities affiliated with BVF.

3. Earnings per Share

Earnings per share represents the net earnings per share calculated using the historical weighted-average ISL units and the issuance of additional shares in connection with the Business Combination, assuming the shares were outstanding since April 1, 2018. As the Business Combination and related proposed equity transactions are being reflected as if they had occurred at the beginning of the periods presented, the calculation of weighted-average shares outstanding for basic and diluted net income (loss) per share assumes that the shares issued relating to the Business Combination have been outstanding for the entire periods presented.

As part of the Business Combination, 1,800,000 shares held by the Sponsor became subject to vesting requirements and have been excluded from the shares outstanding in the calculation of basic and diluted pro forma earnings per share.

Pro Forma Shares Outstanding – Basic and Diluted	
HSAC merger consideration shares	42,080,376
Founder shares	2,875,000
Common shares held by current HSAC stockholders	11,500,000
Sponsor restricted shares	<u>(1,800,000)</u>
Pro forma non-redeemable shares outstanding – basic and diluted	<u>54,655,376</u>

	Six Months Ended September 30, 2019	Year Ended March 31, 2019
Pro Forma Basic and Diluted Net Loss Per Share		
Pro forma net loss attributable to common stockholders	\$(34,403,494)	\$(28,600,322)
Basic and diluted non-redeemable shares outstanding	54,655,376	54,655,376
Pro forma basic and diluted net loss per share	\$ (0.63)	\$ (0.52)

COMPARATIVE SHARE INFORMATION

The following table sets forth summary historical comparative share information for HSAC and ISL and unaudited pro forma condensed combined per share information of HSAC after giving effect to the Business Combination.

The pro forma book value information reflects the Business Combination as if it had occurred on September 30, 2019. The weighted average shares outstanding and net earnings per share information reflect the Business Combination as if it had occurred on April 1, 2018.

This information is only a summary and should be read together with the selected historical financial information summary included elsewhere in this prospectus, and the historical financial statements of HSAC and ISL and related notes that are included elsewhere in this prospectus. The unaudited pro forma combined per share information of HSAC and ISL is derived from, and should be read in conjunction with, the unaudited pro forma condensed combined financial statements and related notes included elsewhere in this prospectus.

The unaudited pro forma combined earnings per share information below does not purport to represent the earnings per share which would have occurred had the companies been combined during the periods presented, nor earnings per share for any future date or period. The unaudited pro forma combined book value per share information below does not purport to represent what the value of HSAC and ISL would have been had the companies been combined during the periods presented.

	<u>ISL</u> <u>(Historical)</u>	<u>HSAC</u> <u>(Historical)</u>	<u>Pro Forma</u> <u>Combined</u>
As of and for the Six Months Ended September 30, 2019			
Book value per share ⁽¹⁾	\$ (0.30)	\$ 0.43	\$ 2.20
Net loss per non-redeemable share – basic and diluted	\$ (0.44)	\$ (0.16)	\$ (0.63)
Weighted average non-redeemable shares outstanding – basic and diluted	78,906,250	2,875,000	54,655,376
Net income per redeemable share – basic and diluted		\$ 0.07	
Weighted average redeemable shares outstanding – basic and diluted		11,500,000	
As of and for the Year Ended March 31, 2019			
Book value per share	N/A	N/A	N/A
Net loss per share – basic and diluted ⁽²⁾	\$ (0.63)	\$ (0.00)	\$ (0.52)
Weighted average non-redeemable shares outstanding – basic and diluted ⁽²⁾	45,333,048	2,500,000	54,655,376

(1) Book value per share = Total stockholders' equity (deficit)/Total basic (or diluted) outstanding shares.

(2) Historical net loss per share and weighted average shares outstanding for HSAC are based on the period from December 6, 2018 (Inception) through March 31, 2019.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Immunovant Sciences Ltd.

Opinion on the Financial Statements

We have audited the accompanying combined and consolidated balance sheets of Immunovant Sciences Ltd. (the Company) as of March 31, 2019 and 2018, the related combined and consolidated statements of operations, comprehensive loss, equity and cash flows for the year ended March 31, 2019 and the period from December 19, 2017 to March 31, 2018, and the related notes (collectively referred to as the “combined and consolidated financial statements”). In our opinion, the combined and consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2019 and 2018, and the results of its operations and its cash flows for the year ended March 31, 2019 and the period from December 19, 2017 to March 31, 2018 in conformity with U.S. generally accepted accounting principles.

The Company’s ability to continue as a going concern

The accompanying combined and consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1[B] to the financial statements, the Company has incurred losses from operations since inception, has insufficient capital to fund its operations, and has stated that substantial doubt exists about the Company’s ability to continue as a going concern. Management’s evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 1[B]. The combined and consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

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

Iselin, New Jersey
May 29, 2019

IMMUNOVANT SCIENCES LTD.
Combined and Consolidated Balance Sheets

	MARCH 31,	
	2018	2019
Assets		
Current assets:		
Cash	\$ —	\$ 6,985,089
Prepaid expenses	113,170	2,632,044
Income tax receivable	—	48,876
Value-added tax receivable	—	2,912,809
Total current assets	113,170	12,578,818
Property and equipment, net	—	54,108
Deferred initial public offering costs	—	1,195,053
Total assets	\$ 113,170	\$ 13,827,979
Liabilities and Equity		
Current liabilities:		
Accounts payable	\$ 1,135,865	\$ 207,524
Accrued expenses	474,020	6,224,566
Due to Roivant Sciences Ltd.	—	58,556
Total liabilities	1,609,885	6,490,646
Commitments and contingencies (Note 9)		
Equity:		
Common shares, par value \$0.00001 per share, 1,000,000,000 shares authorized, 78,906,250 issued and outstanding at March 31, 2019	—	789
Common shares subscribed	—	(750)
Additional paid-in capital	—	31,829,654
Net parent investment	(1,657,695)	—
Accumulated other comprehensive income	160,980	345,513
Accumulated deficit	—	(24,837,873)
Total equity	(1,496,715)	7,337,333
Total liabilities and equity	\$ 113,170	\$ 13,827,979

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

IMMUNOVANT SCIENCES LTD.
Combined and Consolidated Statements of Operations

	PERIOD FROM DECEMBER 19, 2017 TO MARCH 31, 2018	YEAR ENDED MARCH 31, 2019
Operating expenses:		
Research and development (includes \$203,406 and \$1,192,770 of share-based compensation expense during the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019, respectively)(1)	\$ 33,815,863	\$ 25,733,274
General and administrative (includes \$249,716 and \$115,494 of share-based compensation expense during the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019, respectively)(2)	369,279	2,691,946
Total operating expenses	34,185,142	28,425,220
Other expense, net	—	155,480
Loss before provision for income taxes	(34,185,142)	(28,580,700)
Income tax expense	—	18,724
Net loss	\$ (34,185,142)	\$ (28,599,424)
Net loss per common share – basic and diluted	\$ (3.42)	\$ (0.63)
Weighted average common shares outstanding – basic and diluted	10,000,000	45,333,048

- (1) Includes \$843,773 and \$3,582,269 of costs allocated from Roivant Sciences Ltd. during the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019, respectively.
- (2) Includes \$369,279 and \$1,179,789 of costs allocated from Roivant Sciences Ltd. during the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019, respectively.

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

IMMUNOVANT SCIENCES LTD.
Combined and Consolidated Statements of Comprehensive Loss

	PERIOD FROM DECEMBER 19, 2017 TO MARCH 31, 2018	YEAR ENDED MARCH 31, 2019
Net loss	\$ (34,185,142)	\$(28,599,424)
Other comprehensive income:		
Foreign currency translation adjustment	160,980	184,533
Total other comprehensive income	160,980	184,533
Comprehensive loss	<u>\$ (34,024,162)</u>	<u>\$(28,414,891)</u>

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

IMMUNOVANT SCIENCES LTD.
Combined and Consolidated Statements of Equity

	COMMON SHARES		COMMON SHARES	ADDITIONAL PAID-IN-CAPITAL	NET PARENT INVESTMENT	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL EQUITY
	SHARES	AMOUNT	SUBSCRIBED					
Balance at December 19, 2017	—	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Net transfers from parent	—	—	—	—	32,527,447	—	—	32,527,447
Foreign currency translation adjustment	—	—	—	—	—	—	160,980	160,980
Net loss	—	—	—	—	(34,185,142)	—	—	(34,185,142)
Balance at March 31, 2018	—	\$ —	\$ —	\$ —	\$ (1,657,695)	\$ —	\$ 160,980	\$ (1,496,715)
Net transfers from parent	—	—	—	—	5,419,246	—	—	5,419,246
Foreign currency translation adjustment	—	—	—	—	—	—	34,729	34,729
Net loss	—	—	—	—	(4,368,384)	—	—	(4,368,384)
Balance at July 6, 2018 (date of formation)	10,000,000	\$ 100	\$ (100)	\$ —	\$ (606,833)	\$ —	\$ 195,709	\$ (411,124)
Common share subscription	65,000,000	650	(650)	—	—	—	—	—
Issuance of common shares, net	3,906,250	39	—	14,745,721	—	—	—	14,745,760
Transfer to Accumulated Deficit	—	—	—	—	606,833	(606,833)	—	—
Cash contribution	—	—	—	13,900,550	—	—	—	13,900,550
Capital contribution – share-based compensation	—	—	—	922,181	—	—	—	922,181
Capital contribution – expenses allocated from Roivant Sciences, Ltd.	—	—	—	2,230,398	—	—	—	2,230,398
Share-based compensation	—	—	—	30,804	—	—	—	30,804
Foreign currency translation adjustment	—	—	—	—	—	—	149,804	149,804
Net loss	—	—	—	—	—	(24,231,040)	—	(24,231,040)
Balance at March 31, 2019	<u>78,906,250</u>	<u>\$ 789</u>	<u>\$ (750)</u>	<u>\$ 31,829,654</u>	<u>\$ —</u>	<u>\$ (24,837,873)</u>	<u>\$ 345,513</u>	<u>\$ 7,337,333</u>

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

IMMUNOVANT SCIENCES LTD.
Combined and Consolidated Statements of Cash Flows

	PERIOD FROM DECEMBER 19, 2017 TO MARCH 31, 2018	YEAR ENDED MARCH 31, 2019
Cash flows from operating activities:		
Net loss	\$ (34,185,142)	\$(28,599,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	453,122	1,308,264
Depreciation expense	—	10,240
Unrealized currency translation adjustment	160,980	184,533
Changes in operating assets and liabilities:		
Prepaid expenses	(113,170)	(2,518,874)
Income tax receivable	—	(48,876)
Value-added tax receivable	—	(2,912,809)
Accounts payable	1,135,865	(928,341)
Accrued expenses	474,020	4,911,690
Due to Roivant Sciences Ltd.	—	46,020
Net cash used in operating activities	<u>(32,074,325)</u>	<u>(28,547,577)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(51,812)
Net cash used in investing activities	<u>—</u>	<u>(51,812)</u>
Cash flows from financing activities:		
Capital contributions	—	16,130,948
Net Parent investment	32,074,325	5,063,967
Net proceeds from issuance of common shares	—	14,910,760
Payment of deferred initial public offering costs	—	(521,197)
Net cash provided by financing activities	<u>32,074,325</u>	<u>35,584,478</u>
Net change in cash	—	6,985,089
Cash – beginning of period	—	—
Cash – end of period	<u>\$ —</u>	<u>6,985,089</u>
Non-cash investing and financing activities:		
Purchase of property and equipment in amounts due to Roivant Sciences Ltd.	<u>\$ —</u>	<u>\$ 12,536</u>
Reclassification of net parent investment to accumulated deficit	<u>\$ —</u>	<u>\$ 606,833</u>
Common share issuance costs in accrued expenses	<u>\$ —</u>	<u>\$ 165,000</u>
Deferred initial public offering costs in accrued expenses	<u>\$ —</u>	<u>\$ 673,856</u>
Supplementary disclosure of cash paid:		
Income taxes	<u>\$ —</u>	<u>\$ 67,500</u>

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

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 1 — Description of Business and Liquidity

[A] Description of Business:

Immunovant Sciences Ltd. and its subsidiaries (collectively, the “Company”) is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for patients suffering from debilitating 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 was founded on July 6, 2018 as a Bermuda Exempted Limited Company and a wholly owned subsidiary of Roivant Sciences Ltd. (“RSL”). In July 2018, the Company incorporated as its wholly owned subsidiaries, Immunovant Sciences Holdings Ltd. (“ISHL”), a private limited company incorporated under the laws of England and Wales and Immunovant, Inc., a Delaware corporation based in the United States of America. In August 2018, the Company incorporated its wholly owned subsidiary, Immunovant Sciences GmbH (“ISG”), a limited liability company formed under the laws of Switzerland. ISG holds all of the Company’s intellectual property rights.

On December 19, 2017, Roivant Sciences GmbH (“RSG”), a wholly owned subsidiary of RSL, entered into a license agreement (the “HanAll Agreement”) with HanAll BioPharma Co., Ltd., a Korean limited liability company (“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. On December 7, 2018, RSG entered into an Assignment and Assumption Agreement (the “Assignment Agreement”) with ISG to assign this technology, as well as RSG’s know how and patents necessary for the development, manufacture or commercialization of any compound or product based on the technology licensed from HanAll. These patents and know-how, initially sublicensed by the Company from RSG in August 2018, formed the basis of the Company’s development of its primary investigational product, IMVT-1401. Please refer to Note 3 for further details.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, acquiring product candidates, and preparing for and advancing them into clinical development. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

[B] Going Concern and Management’s Plans:

The Company has not been capitalized with sufficient funding to conduct its operations. Certain costs of conducting the Company’s operations were paid by RSL or RSL’s wholly owned subsidiaries, Roivant Sciences, Inc. (“RSI”) and RSG. The Company has not generated any revenues 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. Since the Company has limited cash on hand to complete its clinical development and no credit facilities, the Company is dependent upon RSL and its affiliates to provide services and funding to support the operations of the Company until, at least, such time as an external financing is completed.

The accompanying combined and consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The combined and consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company anticipates incurring additional losses until such time, if ever, it can obtain marketing approval to sell, and then generate significant sales from a product. Substantial additional financing will be needed by the Company to fund its operations and to develop and commercialize a product. As a result, there is substantial doubt about the Company’s ability to continue as a going concern.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 1 — Description of Business and Liquidity (cont.)

The Company will seek to obtain additional capital through the sale of debt or equity financings, or other arrangements; however, there can be no assurance that the Company will be able to raise additional capital when needed or under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company's ability to pay dividends or make other distributions to shareholders. If the Company is unable to obtain such additional financing, operations would need to be scaled back or discontinued. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations.

The Company's future operations are highly dependent on a combination of factors, including (1) the timely and successful completion of additional financing discussed above; (2) the success of its research and development programs; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies, (4) the Company's ability to manage growth of the organization; (5) the Company's ability to protect its technology and products; and, ultimately (6) regulatory approval and market acceptance of a product.

Note 2 — Summary of Significant Accounting Policies

[A] Basis of Presentation:

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

The Company's 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 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 (See Note 3), 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 and accordingly, the assets, liabilities and expenses relating to the Company's operations have been separated from RSL in the financial statements for periods prior to and after the Company's formation through March 31, 2019. The financial statements as of and for the period ended March 31, 2018, and for the year ended March 31, 2019 include reasonable allocations for assets and liabilities and expenses attributable to the Company's operations. Beginning on July 6, 2018 (date of formation), the combined and consolidated financial statements include the accounts of Immunovant Sciences Ltd. and its wholly owned subsidiaries, ISHL, Immunovant, Inc., and ISG. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The carve-out financial information includes both direct and indirect expenses. The historical direct expenses consist primarily of the upfront license fees paid to HanAll, salaries of research and development employees directly involved in the Company's activities, share-based compensation for such employees, preclinical and clinical trial related expenses, research expenses and fees paid to scientific advisors. The indirect expenses consist of allocated employee costs, share-based compensation, legal, professional and consulting fees attributable to the Company and general and administrative overhead allocated as a proportion of the time spent by employees directly involved in the Company's activities compared to the total time spent by all the RSI employees.

Prepaid expenses, other current assets, fixed assets, accounts payable, and accrued liabilities reflect 100% of the assets and liabilities directly related to the Company's operations. Compensation and related expenses were allocated based on the relative percentage of time utilized on company matters by the respective RSI employee. The allocation of all other assets, liabilities and expenses was based on management estimates.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 2 — Summary of Significant Accounting Policies (cont.)

The Company believes that the assumptions underlying the allocations of direct and indirect expenses as well as assets and liabilities in the carve-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 for the period from December 19, 2017 to March 31, 2018 and for the period from April 1, 2018 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.

[B] Use of Estimates:

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

Financial instruments that potentially subject the Company to concentration of credit risk include cash. At March 31, 2019 substantially all of the cash balance is deposited in two banking institutions that the Company believes are of high credit quality and are in excess of federally insured levels. The Company maintains its cash with accredited financial institutions 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 March 31, 2019, cash consisted of cash in bank deposits held at financial institutions.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 2 — Summary of Significant Accounting Policies (cont.)

[F] Property and Equipment:

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

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

[G] Contingencies:

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

[H] 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.

[I] Income Taxes:

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the combined and consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between amounts in the combined and consolidated financial statements

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 2 — Summary of Significant Accounting Policies (cont.)

and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income tax (benefit) expense in the accompanying statement of operations in the period that includes the enactment date.

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

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

[J] Share-based Compensation:

Share-based awards to employees and directors are valued at fair value on the date of the grant and that fair value is recognized as share-based compensation expense over the requisite service period. The Company values its stock options that only have service vesting requirements or performance-based awards without market conditions using the Black-Scholes option pricing model. For performance-based awards with market conditions, the Company determines the fair value of awards as of the grant date using a Monte Carlo simulation model.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate and the fair value of the Company's common shares. Since the Company has no option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. The expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers. The Company accounts for pre-vesting award forfeitures when they occur.

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

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

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 2 — Summary of Significant Accounting Policies (cont.)

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

[L] Foreign Currency:

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

[M] Net Loss Per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common shareholders 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 shareholders by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. For the period from December 19, 2017 to March 31, 2018, there were no instruments outstanding and the net loss per share was calculated as if the shares issued at formation were outstanding for the period ended March 31, 2018. For the year ended March 31, 2019, options to purchase 387,000 common shares were not included in the calculation of diluted weighted-average number of common shares outstanding because they were anti-dilutive given the net loss of the Company. 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.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 2 — Summary of Significant Accounting Policies (cont.)

[N] Recently Issued 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. Early adoption is permitted.

The Company plans to adopt the requirements of the new lease standard effective April 1, 2019. The Company will elect 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 financial statements. The Company will elect 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 will 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 will elect 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. The Company does not expect the adoption of the standard to have a material impact on the combined and consolidated financial statements.

In June 2018, the FASB issued ASUNo. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU No. 2018-07. ASU No. 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company’s combined and consolidated financial position, results of operations and related disclosures.

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

[O] Recently Adopted Accounting Pronouncements:

In January 2016, the FASB issued ASUNo. 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* (“ASU No. 2016-01”) which requires entities with financial liabilities measured using the fair value option in ASC 825 to recognize the changes in fair value of liabilities caused by a change in instrument-specific credit risk (own credit risk) in other comprehensive income. The ASU is effective for public business entities in fiscal years beginning after December 15, 2017. Entities can early adopt certain provisions of the new standard, including the provision related to financial liabilities measured under the fair value option. The Company adopted ASU No. 2016-01 as of April 1, 2018. The adoption of ASU No. 2016-01 did not have a material impact on the Company’s combined and consolidated financial statements and related disclosures.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 2 — Summary of Significant Accounting Policies (cont.)

In November 2016, the FASB issued ASUNo. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force, or ASU No. 2016-18). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU No. 2016-18 is effective for annual reporting periods beginning after December 15, 2017 and is required to be adopted using a retrospective approach, if applicable, with early adoption permitted. The Company adopted ASU No. 2016-18 on April 1, 2018. The adoption of ASU No. 2016-18 did not have a material impact on the Company's combined and consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASUNo. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU No. 2017-01"), which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU No. 2017-01 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. The Company has adopted this ASU as of April 1, 2018, with no impact on its financial statements.

In February 2018, the FASB issued ASUNo. 2018-02, *Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU No. 2018-02"). ASU No. 2018-02 allows companies to reclassify stranded tax effects resulting from the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU No. 2018-02 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The adoption of ASU 2018-02 on April 1, 2018 did not have a material impact on the Company's combined and consolidated financial statements.

Note 3 — License Agreement

On December 19, 2017, RSG, a wholly owned subsidiary of RSL, entered into 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.

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

- Upfront, non-refundable payment of \$30.0 million;
- Up to \$20.0 million in shared (50%) research, development, and out-of-pocket costs incurred by HanAll;
- Up to an aggregate of \$452.5 million upon the achievement of certain development, regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens on net product sales subject to reduction on a product-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 1st 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 period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 3 — License Agreement (cont.)

The initial in-license by RSG in December 2017 did not meet the definition of a business as the Company only received inputs in the form of an in-process research and development asset (“IPR&D”) that was licensed from HanAll. RSG did not hire, or receive, any workforce or employees working on IMVT-1401, or any research, clinical or manufacturing equipment that would qualify as processes. Further, RSG did not assume any contracts, licenses or agreements between HanAll and any third party with respect to IMVT-1401. RSG had to independently develop all clinical processes and procedures for its clinical trials through the use of internal and external resources once appropriate and acceptable resources have been identified and obtained. Therefore, the initial transaction with HanAll was not considered a business combination. Further, since the IPR&D asset had not reached technological feasibility and had no alternative future use, the \$30.0 million upfront payment made by RSG was expensed as research and development expenses. The upfront payment incurred by RSL has been included in the combined and consolidated statements of operations for the period from December 19, 2017 to March 31, 2018.

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 Agreement to assign 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 \$37,750,000. The aggregate purchase price was determined based on the historical costs incurred by RSL prior to the assignment of IMVT-1401 which are reflected in the accompanying combined and consolidated financial statements of the Company as described in the basis of presentation Note 2[A]. As a result of the assignment of IMVT-1401 by RSG to ISG, the Company recorded a Swiss value-added tax receivable of \$2,912,809 as of March 31, 2019 which is reflected as a capital contribution from RSL as of March 31, 2019.

The Company evaluated the initial sublicense and subsequent assignment of IMVT-1401 from RSG and assumption of all of the net liabilities related to IMVT-1401 from RSG pursuant to the guidance in ASC No. 805-50, *Business Combinations-Related Issues*, related to the transfer of assets between entities under common control. The initial sublicense and subsequent assignment of IMVT-1401 was not considered to be a transfer of a business as substantially all the fair value of the transferred assets was concentrated in the IPR&D asset. Transfers of assets between entities under common control that do not qualify as transfers of a business, are accounted for prospectively and the Company would record the recognized assets and liabilities at the carrying amounts based on the historical cost of its parent, RSL. Since the initial in-license of, IMVT-1401 on December 19, 2017, was expensed by RSL as described above, the IPR&D asset initially sub-licensed and subsequently assigned from RSG did not have a carrying value (no cost basis). Accordingly, no asset was recognized in the Company’s combined and consolidated financial statements related to the sublicense of IMVT-1401.

In May 2019 the Company achieved its first development and regulatory milestone which will result in a \$10.0 million milestone payment. (See Note 10)

Note 4 — Accrued Expenses

Accrued expenses consist of the following:

	MARCH 31,	
	2018	2019
Research and development expenses	\$ 474,020	\$ 4,814,926
Legal and other professional fees	—	1,105,446
Other expenses	—	304,194
Total accrued expenses	<u>\$ 474,020</u>	<u>\$ 6,224,566</u>

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 5 — Related Party Transactions

In addition to the agreements discussed in Note 3, in August 2018, the Company entered into services agreements (the “Services Agreements”) with RSI and RSG, under which RSI and RSG agreed to provide services related to development, administrative and financial activities to the Company during its formative period. Under each Services Agreement, the Company will pay or reimburse RSI or RSG, as applicable, for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI or RSG employees, RSI or RSG, as applicable, will charge back the employee compensation expense plus a pre-determined markup. 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 us or RSI or RSG, as applicable, upon 90 days’ written notice. The combined and consolidated financial statements also include third-party expenses that have been paid by RSI, RSG and RSL since the inception of the Company. Total expense, inclusive of base salary, fringe benefits and share-based compensation, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company’s matters. From the inception of the Company through March 31, 2019 the Company was charged \$2,270,961 by RSI, RSG and RSL which \$2,230,398 and \$40,563 were treated as deemed capital contributions and amounts due to Roivant Sciences Ltd. in the accompanying combined and consolidated financial statements, respectively.

Note 6 — Equity

[A] Overview:

The Company’s Memorandum of Association, filed on July 6, 2018 in Bermuda, authorized the creation of one class of shares. As of March 31, 2019 the Company had 1,000,000,000 shares authorized with a par value of \$0.00001 per share. On September 20, 2018 the Company increased its issued and outstanding shares to 75,000,000 post stock split as discussed in [C] below.

[B] Transactions:

Upon the Company’s formation, RSL subscribed for 100 shares of the Company’s share capital and an additional 650 shares in September 2018 prior to the stock split.

During the year ended March 31, 2019, RSL made aggregate cash contributions of \$13,900,550 to the Company.

In December 2018 and January 2019, the Company issued 2,604,166 and 1,302,084 common shares respectively, at \$3.84 per share to unrelated investors for total net proceeds of \$14,745,760.

[C] Stock Split:

On September 20, 2018 upon approval of the Board of Directors and the Company’s sole member, RSL, the Company effected a stock split of its authorized, issued and outstanding shares at a ratio of 100,000-to-1. The stock split increased the total number of authorized shares from 10,000 to 1,000,000,000, increased the number of shares outstanding from 750 to 75,000,000, and decreased the par value from \$1.00 to \$0.00001. All information in the accompanying combined and consolidated financial statements and notes thereto regarding common share amounts and prices per common share has been adjusted to reflect the application of the stock split on a retroactive basis.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 7 — Income Taxes

	YEAR ENDED MARCH 31, 2018	YEAR ENDED MARCH 31, 2019
Loss before income taxes:		
United States	\$ —	\$ (1,034,420)
Switzerland	(34,185,142)	(27,246,911)
Bermuda	—	(405,313)
United Kingdom	—	(19,958)
Other	—	125,902
Total loss before income taxes:	<u>\$ (34,185,142)</u>	<u>\$ (28,580,700)</u>
Current taxes:		
United States – Federal	\$ —	\$ 6,813
United States – State	—	11,911
Switzerland	—	—
Bermuda	—	—
United Kingdom	—	—
Other	—	—
Total current tax expense:	—	18,724
Deferred taxes:		
United States – Federal	—	—
Switzerland	—	—
Bermuda	—	—
United Kingdom	—	—
Other	—	—
Total deferred tax expense:	—	—
Total income tax provision:	<u>\$ —</u>	<u>\$ 18,724</u>

The Company is not subject to taxation under the laws of Bermuda as it is a Bermuda Exempted Limited Company. A reconciliation of income tax provision computed at the Bermuda statutory rate (0%) to income tax provision reflected in the consolidated financial statements is as follows:

	YEAR ENDED MARCH 31, 2018	YEAR ENDED MARCH 31, 2019
Income tax provision	\$—	\$—
Foreign rate differential	(3,710,522)	(3,847,028)*
Valuation Allowance	3,710,522	5,144,004
Rate Changes	—	(673,295)**
Credits	—	(604,957)
Total income tax provision:	<u>\$—</u>	<u>\$18,724</u>

* Primarily related to operations, including permanent differences in Switzerland, the United Kingdom, and the United States at rates different than the Bermuda rate.

** Related to rate changes in Switzerland and the United Kingdom

The Company's effective tax rate for the year ended March 31, 2018 was 0.00%, and for the year ended March 31, 2019 was (0.07)%, driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

IMMUNOVANT SCIENCES LTD.**Notes to Combined and Consolidated Financial Statements****Note 7 — Income Taxes (cont.)**

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2019 are as follows:

	YEAR ENDED MARCH 31, 2018	YEAR ENDED MARCH 31, 2019
Deferred Tax Assets:		
Intangible Assets	\$ 3,406,155	\$ 5,000,391
Net Operating Losses	393,563	3,022,799
Share Based Compensation	—	289,900
Credits	—	559,518
Bonuses not yet paid	—	65,482
Subtotal	3,799,718	8,938,090
Valuation Allowance:	(3,799,718)	(8,910,048)
Deferred Tax Liabilities:		
Other	—	(16,674)
Depreciation	—	(11,368)
Total Net Deferred Taxes:	<u>\$ —</u>	<u>\$ —</u>

As of March 31, 2019, the Company has net operating loss carryforwards in the following jurisdictions: Switzerland of approximately \$22.9 million, which will expire as of March 31, 2026, and the United Kingdom of approximately \$0.2 million, which has an indefinite carryforward. The Company has research and development credit carryforwards in the United States in the amount of \$0.6 million which will begin to expire in the fiscal year ending March 31, 2039.

The Company assesses the realizability of the net deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and record a valuation allowance as necessary. Due to the Company's cumulative loss position which provides significant negative evidence difficult to overcome, the Company has recorded a valuation allowance of \$3.8 million, for the year ended March 31, 2018, and \$8.9 million for the year ended March 31, 2019, representing the portion of the net deferred tax assets that is not more likely than not to be realized. The amount of the net deferred tax assets considered realizable, could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. The Company will continue to assess the realizability of net deferred tax assets at each consolidated balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

There are outside basis differences related to our investment in subsidiaries for which no deferred taxes have been recorded as these would not be subject to tax on repatriation as Bermuda has no tax regime for Bermuda exempted limited companies, and the United Kingdom tax regime relating to company distributions generally provides for exemption from tax for most overseas profits, subject to certain exceptions.

The Company is subject to tax and will file initial income tax returns in the United Kingdom, Switzerland, and United States federal, state, and local jurisdictions. The Company will be subject to tax examinations once those returns are filed in all applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the consolidated results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. There are no uncertain tax benefits recorded as of March 31, 2018 or as of March 31, 2019.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 8 — Share-Based Compensation

Stock Options:

In September 2018, the Company adopted its 2018 Equity Incentive Plan (the “2018 Plan”), under which 7,500,000 common shares are reserved for grant. 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, and other stock 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. 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 ten-year contractual term. Options that are forfeited or expire are available for future grants.

At March 31, 2019, a total of 7,113,000 common shares were available for future issuance under the 2018 Plan.

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

	YEAR ENDED MARCH 31, 2019
Risk-free interest rate	2.38% – 2.97%
Expected term, in years	6.04 – 6.07
Expected volatility	74.79% – 75.11%
Expected dividend yield	—%

[A] Stock Options Granted to Employees:

During the year ended March 31, 2019, the Company granted stock option awards for 387,000 common shares under the 2018 Plan to employees of the Company. These options had a weighted-average exercise price of \$2.01 per share at the grant date and a weighted-average fair value of \$1.35 per share at the grant date. The weighted average remaining contractual life was 9.64 years as of March 31, 2019. The total intrinsic value of options outstanding was \$707,130 for the year ended March 31, 2019. The intrinsic value is the difference between the estimated fair value of the Company’s common shares, as determined by the Board of Directors, and the exercise price of the stock option.

For the year ended March 31, 2019, share-based compensation expense under the 2018 Plan was as follows:

	YEAR ENDED MARCH 31, 2019
Research and development expenses	\$ 28,510
General and administrative expenses	2,294
Total share-based compensation	<u>\$ 30,804</u>

At March 31, 2019, total unrecognized compensation expense related to non-vested stock option awards was \$491,574 and is expected to be recognized over the remaining weighted-average service period of 3.52 years. There were no vested or exercisable options outstanding. The Company accounts for forfeitures as they occur.

[B] Share-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 Immunovant, Inc., the Company recorded share-based compensation expense of \$453,122 and \$1,277,460 for the period from December 19, 2017 to March 31, 2018 and for the year ended March 31, 2019, respectively.

IMMUNOVANT SCIENCES LTD.

Notes to Combined and Consolidated Financial Statements

Note 8 — Share-Based Compensation (cont.)

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.

Shared-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 9 — Commitments and Contingencies

As of March 31, 2018, the Company did not have any ongoing material financial commitments other than the Sublicense Agreement entered into with RSG. As of March 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.

Note 10 — Subsequent Events

The Company has evaluated subsequent events through May 29, 2019 the date these combined and consolidated financial statements were available to be issued.

In May 2019, the Company achieved its first development and regulatory milestone under the HanAll Agreement which will result in a \$10.0 million milestone payment that the Company expects to pay during the second quarter of the year ending March 31, 2020.

IMMUNOVANT SCIENCES LTD.
CONDENSED COMBINED AND CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	<u>March 31,</u> <u>2019</u>	<u>September 30,</u> <u>2019</u>
Assets		
Current assets:		
Cash	\$ 6,985,089	\$ 18,991,649
Prepaid expenses	2,632,044	512,850
Income tax receivable	48,876	4,827
Value-added tax receivable	2,912,809	2,920,940
Total current assets	<u>12,578,818</u>	<u>22,430,266</u>
Property and equipment, net	54,108	45,327
Deferred offering costs	1,195,053	1,677,929
Total assets	<u>\$ 13,827,979</u>	<u>\$ 24,153,522</u>
Liabilities and Equity/(Deficit)		
Current liabilities:		
Accounts payable	\$ 207,524	\$ 1,176,236
Accrued expenses	6,224,566	8,195,749
Due to Roivant Sciences Ltd.	58,556	3,057,298
Convertible promissory note payable to Roivant Sciences Ltd.	—	2,500,000
Convertible promissory notes payable	—	32,500,000
Income tax payable	—	10,786
Total liabilities	<u>6,490,646</u>	<u>47,440,069</u>
Commitments and contingencies (Note 8)		
Equity/(deficit):		
Common shares, par value \$0.00001 per share, 1,000,000,000 shares authorized, 78,906,250 issued and outstanding at March 31, 2019 and September 30, 2019	789	789
Common shares subscribed	(750)	—
Additional paid-in capital	31,829,654	36,090,133
Accumulated other comprehensive income	345,513	1,378
Accumulated deficit	<u>(24,837,873)</u>	<u>(59,378,847)</u>
Total equity/(deficit)	<u>7,337,333</u>	<u>(23,286,547)</u>
Total liabilities and equity/(deficit)	<u>\$ 13,827,979</u>	<u>\$ 24,153,522</u>

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

IMMUNOVANT SCIENCES LTD.
CONDENSED COMBINED AND CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Six Months Ended September 30,	
	2018	2019
Operating expenses:		
Research and development (includes \$799,377 and \$2,372,150 of share-based compensation expense for the six months ended September 30, 2018 and 2019, respectively)(1)	\$ 10,080,112	\$ 28,806,867
General and administrative (includes \$38,697 and \$1,337,302 of share-based compensation expense for the six months ended September 30, 2018 and 2019, respectively)(2)	528,175	5,747,593
Total operating expenses	10,608,287	34,554,460
Interest expense	—	249,315
Other expense/(income), net	106,092	(318,806)
Loss before provision for income taxes	(10,714,379)	(34,484,969)
Income tax expense	3,985	56,005
Net loss	\$ (10,718,364)	\$ (34,540,974)
Net loss per common share – basic and diluted	\$ (0.77)	\$ (0.44)
Weighted average common shares outstanding – basic and diluted	13,907,104	78,906,250

(1) Includes \$2,734,441 and \$152,435 of costs allocated from Roivant Sciences Ltd. for the six months ended September 30, 2018 and 2019, respectively.

(2) Includes \$292,723 and \$513,995 of costs allocated from Roivant Sciences Ltd. for the six months ended September 30, 2018 and 2019, respectively.

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

IMMUNOVANT SCIENCES LTD.
CONDENSED COMBINED AND CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Six Months Ended	
	September 30,	
	2018	2019
Net loss	\$ (10,718,364)	\$ (34,540,974)
Other comprehensive income/(loss):		
Foreign currency translation adjustment	140,527	(344,135)
Total other comprehensive income/(loss)	140,527	(344,135)
Comprehensive loss	<u>\$ (10,577,837)</u>	<u>\$ (34,885,109)</u>

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

IMMUNOVANT SCIENCES LTD.
CONDENSED COMBINED AND CONSOLIDATED STATEMENTS OF EQUITY/(DEFICIT)
(UNAUDITED)

	Common Shares		Common Shares Subscribed	Additional Paid-In- Capital	Net Parent Investment	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Equity/ (Deficit)
	Shares	Amount						
Balance at March 31, 2018	—	\$ —	\$ —	\$ —	\$(1,657,695)	\$ —	\$ 160,980	\$ (1,496,715)
Net transfers from parent	—	—	—	—	5,419,246	—	—	5,419,246
Foreign currency translation adjustment	—	—	—	—	—	—	34,729	34,729
Net loss	—	—	—	—	(4,368,384)	—	—	(4,368,384)
Balance at July 6, 2018 (date of formation)	<u>10,000,000</u>	<u>\$ 100</u>	<u>\$ (100)</u>	<u>\$ —</u>	<u>\$ (606,833)</u>	<u>\$ —</u>	<u>\$ 195,709</u>	<u>\$ (411,124)</u>
Common share subscription	65,000,000	650	(650)	—	—	—	—	—
Transfer to Accumulated Deficit	—	—	—	—	606,833	(606,833)	—	—
Cash contribution	—	—	—	7,020,869	—	—	—	7,020,869
Capital contribution – share- based compensation	—	—	—	481,471	—	—	—	481,471
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	1,471,600	—	—	—	1,471,600
Share-based compensation	—	—	—	1,324	—	—	—	1,324
Foreign currency translation adjustment	—	—	—	—	—	—	105,798	105,798
Net loss	—	—	—	—	—	(6,349,980)	—	(6,349,980)
Balance at September 30, 2018	<u>75,000,000</u>	<u>\$ 750</u>	<u>\$ (750)</u>	<u>\$ 8,975,264</u>	<u>\$ —</u>	<u>\$ (6,956,813)</u>	<u>\$ 301,507</u>	<u>\$ 2,319,958</u>
	Common Shares Shares	Common Shares Amount	Common Shares Subscribed	Additional Paid-In- Capital	Net Parent Investment	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Equity/ (Deficit)
Balance at March 31, 2019	78,906,250	\$ 789	\$ (750)	\$31,829,654	\$ —	\$(24,837,873)	\$ 345,513	\$ 7,337,333
Settlement of common share subscription	—	—	750	—	—	—	—	750
Capital contribution – share- based compensation	—	—	—	53,344	—	—	—	53,344
Capital contribution – expenses allocated from Roivant Sciences Ltd.	—	—	—	551,027	—	—	—	551,027
Share-based compensation	—	—	—	3,656,108	—	—	—	3,656,108
Foreign currency translation adjustment	—	—	—	—	—	—	(344,135)	(344,135)
Net loss	—	—	—	—	—	(34,540,974)	—	(34,540,974)
Balance at September 30, 2019	<u>78,906,250</u>	<u>\$ 789</u>	<u>\$ —</u>	<u>\$36,090,133</u>	<u>\$ —</u>	<u>\$(59,378,847)</u>	<u>\$ 1,378</u>	<u>\$(23,286,547)</u>

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

IMMUNOVANT SCIENCES LTD.
CONDENSED COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Six Months Ended September 30,	
	2018	2019
Cash flows from operating activities:		
Net loss	\$ (10,718,364)	\$ (34,540,974)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	838,074	3,709,452
Depreciation expense	—	9,795
Unrealized currency translation adjustment	140,527	(344,135)
Loss on disposal of property and equipment	—	13,307
Write-off of deferred offering costs	—	1,397,743
Other	—	(38,356)
Changes in operating assets and liabilities:		
Prepaid expenses	(874,830)	2,119,194
Income tax receivable	—	44,049
Value-added tax receivable	—	(8,131)
Accounts payable	(698,173)	962,710
Accrued expenses	2,803,246	663,870
Due to Roivant Sciences Ltd.	—	111,170
Income tax payable	—	10,786
Net cash used in operating activities	<u>(8,509,520)</u>	<u>(25,889,520)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(8,319)
Net cash used in investing activities	<u>—</u>	<u>(8,319)</u>
Cash flows provided by financing activities:		
Capital contributions	8,492,469	551,027
Net parent investment	5,063,967	—
Payment of deferred offering costs	—	(554,128)
Proceeds from notes payable to Roivant Sciences Ltd.	—	7,906,750
Repayment of convertible promissory note payable to Roivant Sciences Ltd.	—	(2,500,000)
Proceeds from convertible promissory notes payable	—	35,000,000
Repayment of convertible promissory notes payable	—	(2,500,000)
Settlement of common shares subscribed	—	750
Net cash provided by financing activities	<u>13,556,436</u>	<u>37,904,399</u>
Net change in cash	5,046,916	12,006,560
Cash – beginning of period	—	6,985,089
Cash – end of period	<u>\$ 5,046,916</u>	<u>\$ 18,991,649</u>
Non-cash investing and financing activities:		
Purchase of property and equipment in accounts payable	<u>\$ 31,710</u>	<u>\$ 6,002</u>
Reclassification of net parent investment to accumulated deficit	<u>\$ 606,833</u>	<u>\$ —</u>
Deferred offering costs in accrued expenses	<u>\$ —</u>	<u>\$ 1,177,929</u>

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

IMMUNOVANT SCIENCES LTD.

NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 1 — Description of Business and Liquidity

[A] Description of Business:

Immunovant Sciences Ltd. and its subsidiaries (collectively, the “Company”) 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 was founded on July 6, 2018 as a Bermuda Exempted Limited Company and a wholly owned subsidiary of Roivant Sciences Ltd. (“RSL”). In July 2018, the Company incorporated as its wholly owned subsidiaries, Immunovant Sciences Holdings Ltd. (“ISHL”), a private limited company incorporated under the laws of England and Wales and Immunovant, Inc., a Delaware corporation based in the United States of America. In August 2018, the Company incorporated its wholly owned subsidiary, Immunovant Sciences GmbH (“ISG”), a limited liability company formed under the laws of Switzerland. ISG holds all of the Company’s intellectual property rights.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, acquiring product candidates, and preparing for and advancing them into clinical development. The Company has determined that it has one operating and reporting segment.

[B] Going Concern and Management’s Plans:

The Company has not been capitalized with sufficient funding to conduct its operations. Certain costs of conducting the Company’s operations were paid by RSL or RSL’s wholly owned subsidiaries, Roivant Sciences, Inc. (“RSI”) and Roivant Sciences GmbH (“RSG”). The Company has not generated any revenues 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. Since the Company has limited cash on hand to complete its clinical development and no credit facilities, the Company is dependent upon RSL and its affiliates to provide services and funding to support the operations of the Company until, at least, such time as an external financing is completed.

The accompanying condensed combined and consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The condensed combined and consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company anticipates incurring additional losses until such time, if ever, it can obtain marketing approval to sell, and then generate significant sales from a product. Substantial additional financing will be needed by the Company to fund its operations and to develop and commercialize a product. As a result, there is substantial doubt about the Company’s ability to continue as a going concern.

The Company will seek to obtain additional capital through the sale of debt or equity financings, or other arrangements; however, there can be no assurance that the Company will be able to raise additional capital when needed or under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company’s ability to pay dividends or make other distributions to shareholders. If the Company is unable to obtain such additional financing, operations would need to be scaled back or discontinued. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations.

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 1 — Description of Business and Liquidity (cont.)

The Company's future operations are highly dependent on a combination of factors, including (1) the timely and successful completion of additional financing discussed above; (2) the success of its research and development programs; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies; (4) the Company's ability to manage growth of the organization; (5) the Company's ability to protect its technology and products; and, ultimately (6) regulatory approval and market acceptance of a product.

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 September 30, 2019 and the interim condensed combined and consolidated statements of operations, comprehensive loss, cash flows and equity/(deficit) for the six months ended September 30, 2018 and 2019 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. 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 financial position at September 30, 2019 and the combined and consolidated results of operations and cash flows for the six months ended September 30, 2018 and 2019. The results for the six months ended September 30, 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.

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 (See Note 3), 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 Immunovant Sciences Ltd. and its wholly owned subsidiaries, ISHL, Immunovant, Inc., and ISG. 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 the carve-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).

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 2 — Summary of Significant Accounting Policies (cont.)

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.

[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, share-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] Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentration of credit risk include cash. At September 30, 2019, substantially all of the cash balance is deposited in two banking institutions that the Company believes are of high credit quality and are in excess of federally insured levels. The Company maintains its cash with accredited financial institutions 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 September 30, 2019, cash consisted of cash in bank deposits held at financial institutions.

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 2 — Summary of Significant Accounting Policies (cont.)

[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.

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 2 — Summary of Significant Accounting Policies (cont.)

The Company's financial instruments consist of cash, accounts payable, accrued expenses, amounts due to Roivant Sciences Ltd., convertible promissory note payable to Roivant Sciences Ltd. and convertible promissory notes payable. 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 expense/(income), 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 shareholder 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 shareholder by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. 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. For the six months ended September 30, 2018 and 2019, options to purchase 243,000 and 6,401,154 common shares, respectively, and the convertible promissory notes issued in the six months ended September 30, 2019 were not included in the calculation of diluted weighted-average number of common shares outstanding because they were anti-dilutive given the net loss of the Company.

[J] Deferred Offering Costs

Offering costs comprised of legal, accounting, underwriting fees and other costs incurred through June 30, 2019 were directly related to the Company's proposed initial public offering. In August 2019, the Company's Board of Directors decided to discontinue the Company's initial public offering registration process. Accordingly, the Company has written off deferred offering costs previously capitalized in the amount of \$1,397,743, in general and administrative expense in the accompanying condensed combined and consolidated statement of operations for the six months ended September 30, 2019.

On September 29, 2019, the Company entered into a share exchange agreement (the "Share Exchange Agreement") with Health Sciences Acquisitions Corporation ("HSAC") (See Note 3). Legal, accounting and other costs that are directly related to the proposed business combination pursuant to the Share Exchange Agreement are capitalized as deferred offering costs and will be charged to equity upon completion of the proposed business combination.

[K] Recently Issued Accounting Pronouncements:

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss

IMMUNOVANT SCIENCES LTD.

NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 2 — Summary of Significant Accounting Policies (cont.)

impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. The Company is currently evaluating the new standard and its impact on the combined and consolidated financial statements.

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

[L] Recently Adopted Accounting Pronouncements:

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASU No. 2016-02”), a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 requires lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. The Company has adopted this ASU as of April 1, 2019, 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.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU No. 2018-07”). ASU No. 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees,

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 2 — Summary of Significant Accounting Policies (cont.)

with certain exceptions. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company has adopted this ASU as of April 1, 2019, with no impact on the Company's condensed combined and consolidated financial statements and related disclosures.

Note 3 — 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.

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

- Upfront, non-refundable payment of \$30.0 million;
- Up to \$20.0 million in shared (50%) research, development, and out-of-pocket costs incurred by HanAll;
- Up to an aggregate of \$452.5 million upon the achievement of certain development, regulatory and sales milestones; and
- Tiered royalties ranging from the mid-single digits to mid-teens on net product sales subject to reduction on a product-by-product and country-by-country basis, until the later of (1) expiration of patent and regulatory exclusivity or (2) the 1st 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 six months ended September 30, 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 \$37,750,000. As a result of the assignment of IMVT-1401 by RSG to ISG, the Company recorded a Swiss value-added tax receivable of \$2,920,940 as of September 30, 2019 which is reflected as a capital contribution from RSL as of September 30, 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 on August 2, 2019. The milestone payment was recorded as research and development expense in the accompanying condensed combined and consolidated statements of operations for the six months ended September 30, 2019.

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 3 — Material Agreements (cont.)

Share Exchange Agreement

On September 29, 2019, the Company entered into the Share Exchange Agreement with HSAC and RSL which is subject to approval by HSAC's stockholders. Upon the closing of the transactions contemplated in the Share Exchange Agreement (the "Closing"), among other things, HSAC will acquire all of the issued and outstanding shares of the Company, and the Company will become a wholly owned subsidiary of HSAC. Upon the Closing, HSAC will change its name to "Immunovant, Inc." and RSL will hold a majority interest in the combined company.

As a result of the transaction, an aggregate of approximately 43,000,000 shares of HSAC's common stock will be issued (or reserved for issuance pursuant to currently exercisable options) and exercisable options that are issued and outstanding as of immediately prior to the Closing, subject to pre-closing adjustment for certain indebtedness of the Company (other than indebtedness convertible into the Company's capital stock).

On Closing, under the Share Exchange Agreement, any outstanding options to purchase the Company's common shares, whether vested or unvested, will be converted into an option to purchase shares of HSAC's common stock, subject to pre-closing adjustment for certain indebtedness of the Company (other than indebtedness convertible into the Company's common shares).

Note 4 — Accrued Expenses

Accrued expenses consist of the following:

	<u>March 31,</u> <u>2019</u>	<u>September 30,</u> <u>2019</u>
Research and development expenses	\$ 4,814,926	\$ 5,109,808
Legal and other professional fees	1,105,446	2,394,343
Other expenses	<u>304,194</u>	<u>691,598</u>
Total accrued expenses	<u>\$ 6,224,566</u>	<u>\$ 8,195,749</u>

Note 5 — Related Party Transactions

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

IMMUNOVANT SCIENCES LTD.

NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 5 — Related Party Transactions (cont.)

Company based upon the relative percentage of time utilized on the Company's matters. For the six months ended September 30, 2019, the Company was charged \$613,086 by RSI, RSG and RSL of which \$551,027 was treated as deemed capital contributions and \$62,059 as amounts due to Roivant Sciences Ltd. 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 \$5,000,000 (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 \$5,000,000 (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 9). On September 26, 2019, each of RSL and the RTW Entities consented to the prepayment of \$2,500,000 aggregate principal amount of the RSL Convertible Promissory Note bringing the principal balance of the RSL Convertible Note to \$2,500,000.

On July 17, 2019, the Company entered into an interest-free promissory note payable with RSL in the amount of \$2,906,750 (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 \$150,548 other payables due to Roivant Sciences Ltd. are included in the accompanying condensed combined and consolidated balance sheet as of September 30, 2019.

Note 6 — Income Taxes

The Company's effective tax rate for the six months ended September 30, 2018 was (0.04)%, and for the six months ended September 30, 2019 was (0.16)%, driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

Note 7 — Share-Based Compensation

Stock Options:

In September 2018, the Company adopted its 2018 Equity Incentive Plan (the "2018 Plan"), under which 7,500,000 common shares are reserved for grant. Subsequently, in July 2019, the 2018 Plan was amended and restated to increase the number of common shares reserved for grant to 9,750,000. 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, and other stock 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. 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 ten-year contractual term. Options that are forfeited or expire are available for future grants.

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 7 — Share-Based Compensation (cont.)

At September 30, 2019, a total of 3,348,846 common shares were available for future issuance under the 2018 Plan.

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:

	Six Months Ended September 30, 2019
Risk-free interest rate	1.78 – 2.25%
Expected term, in years	5.75 – 6.11
Expected volatility	74.69 – 75.73%
Expected dividend yield	—%

[A] Stock Options Granted:

A summary of the Company’s stock option activity under the 2018 Plan is as follows:

	Options Outstanding		
	Number of options	Weighted- Average Exercise Price	Remaining Contractual Term (Years)
Balance – March 31, 2019	387,000	\$ 2.01	9.64
Granted	6,970,284	\$ 3.84	
Forfeited/Cancelled	(956,130)	\$ 3.63	
Balance – September 30, 2019	6,401,154	\$ 3.76	9.71
Exercisable – September 30, 2019	275,935	\$ 3.38	9.56

There were no options exercised during the six months ended September 30, 2019. The options granted during the six months ended September 30, 2019 had a weighted-average fair value of \$2.55 per share at the grant date.

For the six months ended September 30, 2019, share-based compensation expense under the 2018 Plan was as follows:

	Six Months Ended September 30,	
	2018	2019
Research and development expenses	\$1,193	\$2,369,491
General and administrative expenses	131	1,286,617
Total share-based compensation	<u>\$1,324</u>	<u>\$3,656,108</u>

At September 30, 2019, total unrecognized compensation expense related to non-vested stock option awards was \$14,269,809 and is expected to be recognized over the remaining weighted-average service period of 3.53 years. There were 275,935 vested and exercisable options outstanding as of September 30, 2019. The Company accounts for forfeitures as they occur.

[B] Share-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 Immunovant, Inc., the Company recorded share-based compensation expense of \$836,750 and \$53,344 for the six months ended September 30, 2018 and 2019, respectively.

IMMUNOVANT SCIENCES LTD.

NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 7 — Share-Based Compensation (cont.)

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.

Shared-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 8 — Commitments and contingencies

As of September 30, 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 9 — Convertible promissory notes payable

On August 1, 2019, the Company issued two convertible promissory notes for an aggregate principal amount of \$25,000,000 (the "RTW Convertible Promissory Notes") payable to the RTW Entities, investors of the Company. The RTW Convertible Promissory Notes bear interest at 5% per annum and are due on March 31, 2020, the date upon which all unpaid interest and principal shall be due and payable. Prepayment of the RTW Convertible Promissory Notes prior to the maturity date is 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, the RTW Entities and RSL consented to the prepayment of \$2,500,000 aggregate principal amount of the RTW Convertible Promissory Notes.

On September 26, 2019, the Company issued four convertible promissory notes for an aggregate principal amount of \$10,000,000 (the "BVF Convertible Promissory Notes") payable to entities affiliated with Biotechnology Value Fund, L.P. ("BVF"). The BVF Convertible Promissory Notes bear interest at 5% per annum and are due on March 31, 2020, the date upon which all unpaid interest and principal shall be due and payable. Prepayment of the BVF Convertible Promissory Notes prior to the maturity date is 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.

The RSL Convertible Promissory Note (See Note 5), RTW Convertible Promissory Notes and BVF Convertible Promissory Notes (together, the "Convertible Promissory Notes") include various conversion and redemption rights upon merger, certain financing events, change in control or maturity. The Convertible Promissory Notes will automatically convert immediately prior to the consummation of the transaction contemplated in the Share Exchange Agreement (See Note 3) for an aggregate of 3,500,000 shares of common stock of HSAC upon the closing of the transaction.

IMMUNOVANT SCIENCES LTD.
NOTES TO CONDENSED COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 9 — Convertible promissory notes payable (cont.)

The embedded conversion features of the Convertible Promissory Notes are determined to be contingent beneficial conversion features. As such, no conversion feature will be separated from the related debt instrument at issuance. As a result, the Company did not record any amounts for the embedded conversion and redemption features at issuance and as of September 30, 2019. During the six months ended September 30, 2019, the conditions allowing holders of the Convertible Promissory Notes to convert or redeem were not met.

The Convertible Promissory Notes were entered into to provide the Company with additional resources to conduct its business. As of September 30, 2019, the aggregate outstanding principal balance of the RTW Convertible Promissory Notes and BVF Convertible Promissory Notes is \$32,500,000. Interest expense of \$190,411 incurred on the RTW Convertible Promissory Notes and BVF Convertible Promissory Notes is recognized within interest expense in the accompanying condensed combined and consolidated statements of operations for the six months ended September 30, 2019 and accrued expenses in the accompanying condensed combined and consolidated balance sheet as of September 30, 2019.

Note 10 — Subsequent events

The Company has evaluated subsequent events through November 25, 2019, the date these condensed combined and consolidated financial statements were available to be issued and determined that no subsequent events have occurred that would require recognition in the condensed combined and consolidated financial statements or disclosures in the notes.

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HEALTH SCIENCES ACQUISITIONS CORPORATION
FOR THE PERIOD FROM DECEMBER 6, 2018 (INCEPTION) THROUGH DECEMBER 31, 2018**

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Report of Independent Registered Public Accounting Firm

To the Stockholder and the Board of Directors of
Health Sciences Acquisitions Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Health Sciences Acquisitions Corporation (the “Company”) as of December 31, 2018, the related statements of operations, changes in stockholder’s equity and cash flows, for the period from December 6, 2018 (inception) through December 31, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the period from December 6, 2018 (inception) through December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as the Company’s auditor since 2018.
New York, New York
May 2, 2019

HEALTH SCIENCES ACQUISITIONS CORPORATION
BALANCE SHEET
DECEMBER 31, 2018

ASSETS	
Current asset – cash	\$325,000
Deferred offering costs	<u>80,000</u>
Total Assets	<u>\$405,000</u>
LIABILITIES AND STOCKHOLDER'S EQUITY	
Current liabilities:	
Accrued expenses	\$ 448
Accrued offering costs	80,000
Promissory note-related party	<u>300,000</u>
Total Current Liabilities	<u>380,448</u>
Commitments	
Stockholder's Equity	
Common stock, \$0.0001 par value; 5,000,000 shares authorized; 2,875,000 shares issued and outstanding ⁽¹⁾	288
Additional paid-in capital	24,712
Accumulated deficit	<u>(448)</u>
Total Stockholder's Equity	<u>24,552</u>
Total Liabilities and Stockholder's Equity	<u>\$405,000</u>

(1) Includes up to 375,000 shares subject to forfeiture if the over-allotment option is not exercised in full or in part by the underwriters (see Note 4).

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
STATEMENT OF OPERATIONS
FOR THE PERIOD FROM DECEMBER 6, 2018 (INCEPTION) THROUGH DECEMBER 31, 2018

Formation costs	\$ 448
Net Loss	\$ (448)
Weighted average shares outstanding, basic and diluted ⁽¹⁾	<u>2,500,000</u>
Basic and diluted net loss per share	\$ (0.00)

- (1) Excludes an aggregate of up to 375,000 shares subject to forfeiture if the over-allotment option is not exercised in full or in part by the underwriters (see Note 4).

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
STATEMENT OF CHANGES IN STOCKHOLDER'S EQUITY
FOR THE PERIOD FROM DECEMBER 6, 2018 (INCEPTION) THROUGH DECEMBER 31, 2018

	Common Stock (1)		Additional Paid-In Capital	Accumulated Deficit	Total Stockholder's Equity
	Shares	Amount			
Balance – December 6, 2018 (inception)	—	\$ —	\$ —	\$ —	\$ —
Issuance of common stock to Sponsor ⁽¹⁾	2,875,000	288	24,712	—	25,000
Net loss	—	—	—	(448)	(448)
Balance – December 31, 2018	<u>2,875,000</u>	<u>\$ 288</u>	<u>\$ 24,712</u>	<u>\$ (448)</u>	<u>\$ 24,552</u>

(1) Includes 375,000 shares subject to forfeiture if the over-allotment option is not exercised in full or in part by the underwriters (see Note 4).

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
STATEMENT OF CASH FLOWS
FOR THE PERIOD FROM DECEMBER 6, 2018 (INCEPTION) THROUGH DECEMBER 31, 2018

Cash Flows from Operating Activities	
Net loss	\$ (448)
Changes in operating assets and liabilities:	
Accrued expenses	<u>448</u>
Net cash used in operating activities	<u>—</u>
Cash Flows from Financing Activities	
Proceeds from issuance of common stock to Sponsor	25,000
Proceeds from promissory note – related party	<u>300,000</u>
Net cash provided by financing activities	<u>325,000</u>
Net Change in Cash	<u>325,000</u>
Cash – beginning of the period	<u>—</u>
Cash – end of the period	<u><u>\$325,000</u></u>
Non-cash investing and financing activities:	
Deferred offering costs included in accrued offering costs	<u><u>\$ 80,000</u></u>

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS

Note 1 —Description of Organization and Business Operations

Health Sciences Acquisitions Corporation (the “Company”) was incorporated in Delaware on December 6, 2018. The Company was formed 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”).

Although the Company is not limited to a particular or geographic region for purposes of consummating a Business Combination, the Company intends to focus on businesses in the healthcare and healthcare-related industries in North America or Europe. The Company is an emerging growth company and, as such, the Company is subject to all of the risks associated with emerging growth companies.

As of December 31, 2018, the Company had not commenced any operations. All activity for the period from December 6, 2018 (inception) through December 31, 2018 relates to the Company’s formation and the proposed initial public offering (“Proposed Public Offering”), which is described below. The Company will not generate any operating revenues until after the completion of its initial Business Combination, at the earliest. The Company anticipates it will generate non-operating income in the form of interest income from the proceeds derived from the Proposed Public Offering. The Company has selected December 31 as its fiscal year end.

The Company’s ability to commence operations is contingent upon obtaining adequate financial resources through a Proposed Public Offering of 10,000,000 units (the “Units” and, with respect to the shares common stock included in the Units being offered, the “Public Shares”) at \$10.00 per Unit (or 11,500,000 Units if the underwriters’ over-allotment option is exercised in full), which is discussed in Note 3, and the sale of 10,000,000 warrants (the “Private Warrants”) at a price of \$0.50 per Private Warrant in a private placement to Health Sciences Holdings, LLC, a Delaware limited liability company (the “Sponsor”), that will close simultaneously with the Proposed Public Offering.

The Company’s management has broad discretion with respect to the specific application of the net proceeds of the Proposed Public Offering and the sale of the Private Warrants, although substantially all of the net proceeds are intended to be applied generally toward consummating a Business Combination. The Company’s initial Business Combination must be with one or more target businesses that together have a fair market value of at least 80% of the assets held in the Trust Account (as defined below) (excluding the deferred underwriting fees and taxes payable on the income earned on the Trust Account) at the time of the agreement to enter into a Business Combination. The Company will only complete a Business Combination if the post-transaction Company owns or acquires 50% or more of the outstanding voting securities of the target or otherwise acquires a controlling interest in the target sufficient for it not to be required to register as an investment company under the Investment Company Act 1940, as amended (the “Investment Company Act”). There is no assurance that the Company will be able to complete a Business Combination successfully. Upon the closing of the Proposed Public Offering, management has agreed that an amount equal to at least \$10.00 per Unit sold in the Proposed Public Offering, including a portion of the proceeds from the sale of the Private Warrants, will be held in a trust account (“Trust Account”), located in the United States and invested in U.S. government securities, within the meaning set forth in Section 2(a)(16) of the Investment Company Act, with a maturity of 180 days or less or in any open-ended investment company that holds itself out as a money market fund selected by the Company meeting the conditions of Rule 2a-7 of the Investment Company Act, as determined by the Company, until the earlier of: (i) the completion of a Business Combination and (ii) the distribution of the Trust Account, as described below.

The Company will provide its holders of the outstanding Public Shares (the “public stockholders”) with the opportunity to convert all or a portion of their Public Shares upon the completion of a Business Combination either (i) in connection with a stockholder meeting called to approve the Business Combination or (ii) by means of a tender offer. The decision as to whether the Company will seek stockholder approval of a Business Combination or conduct a tender offer will be made by the Company, solely in its discretion. The public stockholders will be entitled to convert their Public Shares for a pro rata portion of the amount then in the Trust Account (initially \$10.00 per Public Share, plus any pro rata interest earned on the funds held in the Trust Account and not previously released to the Company to pay its income and franchise tax obligations). There will be no redemption rights upon the completion of a Business Combination with respect to the Company’s warrants. The Public Shares subject to redemption will be recorded at a redemption value and classified as temporary equity upon the completion of the Proposed Public Offering in accordance with the Accounting Standards Codification (“ASC”) Topic 480 “Distinguishing Liabilities from Equity.”

**HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS**

The Company will proceed with a Business Combination if the Company has net tangible assets of at least \$5,000,001 upon such consummation of a Business Combination and, if the Company seeks stockholder approval, a majority of the shares voted are voted in favor of the Business Combination. If a stockholder vote is not required by law and the Company does not decide to hold a stockholder vote for business or other legal reasons, the Company will, pursuant to its Amended and Restated Certificate of Incorporation, conduct the redemptions pursuant to the tender offer rules of the U.S. Securities and Exchange Commission (“SEC”) and file tender offer documents with the SEC prior to completing a Business Combination. If, however, stockholder approval of the transactions is required by law, or the Company decides to obtain stockholder approval for business or legal reasons, the Company will offer to redeem shares in conjunction with a proxy solicitation pursuant to the proxy rules and not pursuant to the tender offer rules. If the Company seeks stockholder approval in connection with a Business Combination, the Company’s Sponsor, officers and directors (the “initial stockholders”) have agreed (i) to vote their Founder Shares (as defined in Note 4) and any Public Shares acquired in or after the Proposed Public Offering in favor of a Business Combination, (ii) not to convert any shares owned by them in connection therewith and (iii) not to sell any of their shares to the Company in a tender offer. Additionally, each public stockholder may elect to convert their Public Shares irrespective of whether they vote for or against the proposed transaction.

Notwithstanding the foregoing, if the Company seeks stockholder approval of a Business Combination and it does not conduct conversion pursuant to the tender offer rules, the Amended and Restated Certificate of Incorporation provides that a public stockholder, together with any affiliate of such stockholder or any other person with whom such stockholder is acting in concert or as a “group” (as defined under Section 13 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), will be restricted from converting its shares with respect to more than an aggregate of 20% or more of the Public Shares, without the prior consent of the Company.

The initial stockholders have agreed (a) to waive their redemption rights with respect to their Founder Shares and Public Shares held by them in connection with the completion of a Business Combination and (b) not to propose, or vote in favor of, an amendment to the Amended and Restated Certificate of Incorporation that would affect the substance or timing of the Company’s obligation to redeem 100% of its Public Shares if the Company does not complete a Business Combination, unless the Company provides the public stockholders with the opportunity to redeem their Public Shares in conjunction with any such amendment.

The Company will have until 24 months from the closing of the Proposed Public Offering to complete a Business Combination (the “Combination Period”).

If the Company is unable to complete a Business Combination within the Combination Period, the Company will (i) cease all operations except for the purpose of winding up, (ii) as promptly as reasonably possible but not more than ten business days thereafter, redeem 100% of the outstanding Public Shares for a pro rata portion of the funds held in the Trust Account, which redemption will completely extinguish public stockholders’ rights as stockholders (including the right to receive further liquidating distributions, if any), subject to applicable law, and (iii) as promptly as reasonably possible following such redemption, subject to the approval of the Company’s remaining stockholders and the Company’s board of directors, dissolve and liquidate, subject in each case to the Company’s obligations under Delaware law to provide for claims of creditors and the requirements of other applicable law. There will be no redemption rights or liquidating distributions with respect to the Company’s warrants, which will expire worthless if the Company fails to complete a Business Combination within the Combination Period.

The initial stockholders have agreed to waive their liquidation rights with respect to the Founder Shares and Private Shares if the Company fails to complete a Business Combination within the Combination Period. However, if the Sponsor, officers and directors acquire Public Shares in or after the Proposed Public Offering, such Public Shares will be entitled to liquidating distributions from the Trust Account if the Company fails to complete a Business Combination within the Combination Period. The underwriters have agreed to waive their rights to their deferred underwriting commissions (see Note 5) held in the Trust Account in the event the Company does not complete a Business Combination within the Combination Period and, in such event, such amounts will be included with the funds held in the Trust Account that will be available to fund the redemption of the Public Shares. In the event of such distribution, it is possible that the per share value of the assets remaining available for distribution will be less than the Proposed Public Offering price per Unit (\$10.00).

**HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS**

In order to protect the amounts held in the Trust Account, the initial stockholders have agreed to be liable to the Company if and to the extent any claims by a vendor for services rendered or products sold to the Company, or a prospective target business with which the Company has discussed entering into a transaction agreement, reduce the amounts in the Trust Account to below \$10.00 per Public Share, except as to any claims by a third party who executed a valid and enforceable agreement with us waiving any right, title, interest or claim of any kind they may have in or to any monies held in the trust account and except as to any claims under our indemnity of the underwriters of this offering against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"). Moreover, in the event that an executed waiver is deemed to be unenforceable against a third party, the initial stockholders will not be responsible to the extent of any liability for such third party claims. The Company will seek to reduce the possibility that the initial stockholders will have to indemnify the Trust Account due to claims of creditors by endeavoring to have all vendors, service providers (except the Company's independent registered accounting firm), prospective target businesses or other entities with which the Company does business, execute agreements with the Company waiving any right, title, interest or claim of any kind in or to monies held in the Trust Account.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC.

The Company does not have sufficient liquidity to meet its anticipated obligations over the next year from the date of issuance of these financial statements. In connection with the Company's assessment of going concern considerations in accordance with Accounting Standards Update ("ASU") 2014-15, "Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern," management has determined that the Company has access to funds from the Sponsor that are sufficient to fund the working capital needs of the Company until the earlier of the consummation of the Proposed Public Offering or one year from the date of issuance of these financial statements.

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, 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.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

**HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS**

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Accordingly, the actual results could differ significantly from those estimates.

Deferred Offering Costs

Deferred offering costs consist of legal, accounting, underwriting fees and other costs incurred through the balance sheet date that are directly related to the Proposed Public Offering and that will be charged to stockholders' equity upon the completion of the Proposed Public Offering. Should the Proposed Public Offering prove to be unsuccessful, these deferred costs, as well as additional expenses to be incurred, will be charged to operations.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2018. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception.

The provision for income taxes was deemed to be immaterial for the period from December 6, 2018 (inception) through December 31, 2018.

Net Loss Per Share

Net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period, excluding shares of common stock subject to forfeiture. Weighted average shares were reduced for the effect of an aggregate of 375,000 shares of common stock that are subject to forfeiture if the over-allotment option is not exercised by the underwriters (see Note 5). At December 31, 2018, the Company did not have any dilutive securities and other contracts that could, potentially, be exercised or converted into shares of common stock and then share in the earnings of the Company. As a result, diluted loss per share is the same as basic loss per share for the period presented.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage of \$250,000. At December 31, 2018, the Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS

Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC 820, "Fair Value Measurements and Disclosures," approximates the carrying amounts represented in the balance sheet, primarily due to their short-term nature.

Recent Accounting Pronouncements

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, "Disclosure Update and Simplification," amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholder's equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of income is required to be filed. The Company anticipates its first presentation of the expanded disclosure requirements on the changes in stockholders' equity will be included in its first quarterly report on Form 10-Q.

Management does not believe that any other recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

Note 3 —Public Offering

Pursuant to the Proposed Public Offering, the Company intends to offer for sale 10,000,000 Units (or 11,500,000 Units if the underwriters' over-allotment option is exercised in full) at a purchase price of \$10.00 per Unit. Each Unit consists of one share of common stock and one redeemable warrant ("Public Warrant"). Each Public Warrant entitles the holder to purchase one-half of one share of common stock at a price of \$11.50 per share, subject to adjustment (see Note 6).

Note 4 —Related Party Transactions

Founder Shares

In December 2018, the Sponsor purchased 2,875,000 shares (the "Founder Shares") of the Company's common stock for an aggregate price of \$25,000. The Founder Shares include an aggregate of up to 375,000 shares subject to forfeiture to the extent that the underwriters' over-allotment option is not exercised in full or in part, so that the initial stockholders will own, on an as-converted basis, 20% of the Company's issued and outstanding shares after the Proposed Public Offering (assuming the initial stockholders do not purchase any Public Shares in the Proposed Public Offering).

The initial stockholders have agreed not to transfer, assign or sell any of the Founder Shares (except to certain permitted transferees) until, with respect to 50% of the Founder Shares, the earlier of (i) six months after the date of the consummation of a Business Combination, or (ii) the date on which the closing price of the Company's common stock equals or exceeds \$12.50 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days within any 30-trading day period commencing after a Business Combination and, with respect to the remaining 50% of the Founder Shares, six months after the date of the consummation of a Business Combination, or earlier in each case, if, subsequent to a Business Combination, the Company consummates a subsequent liquidation, merger, stock exchange or other similar transaction which results in all of the Company's stockholders having the right to exchange their common stock for cash, securities or other property.

Private Placement

The Sponsor has agreed to purchase an aggregate of 10,000,000 Private Warrants at a price of \$0.50 per Private Warrant, for an aggregate purchase price of \$5,000,000, in a private placement that will occur simultaneously with the closing of the Proposed Public Offering. Each Private Warrant is exercisable to purchase one-half of one share of common stock at a price of \$11.50 per share. A portion of the proceeds from the Private Warrants will be added to the proceeds from the Proposed Public Offering to be held in the Trust Account. If the Company does not complete a Business Combination within the Combination Period, the proceeds of the sale of the Private Warrants will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law), and the Private Warrants will expire worthless.

HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS

Promissory Note — Related Party

On December 19, 2018, the Sponsor agreed to loan the Company an aggregate of up to \$300,000 to cover expenses related to the Proposed Public Offering (the “Promissory Note”). The Promissory Note is non-interest bearing and payable on the completion of the Proposed Public Offering. At December 31, 2018, the Company had \$300,000 in borrowings outstanding under the Promissory Note.

Related Party Loans

In addition, in order to finance transaction costs in connection with a Business Combination, the initial stockholders or their affiliates may, but are not obligated to, loan the Company funds as may be required (“Working Capital Loans”). If the Company completes a Business Combination, the Company would repay the Working Capital Loans out of the proceeds of the Trust Account released to the Company. Otherwise, the Working Capital Loans would be repaid only out of funds held outside the Trust Account. In the event that a Business Combination does not close, the Company may use a portion of proceeds held outside the Trust Account to repay the Working Capital Loans, but no proceeds held in the Trust Account would be used to repay the Working Capital Loans. Except for the foregoing, the terms of such Working Capital Loans, if any, have not been determined and no written agreements exist with respect to such loans. The Working Capital Loans would either be repaid upon consummation of a Business Combination, without interest, or, at the lender’s discretion, up to \$200,000 of such Working Capital Loans may be convertible into warrants of the post-Business Combination entity at a price of \$0.50 per warrant. The warrants would be identical to the Private Warrants. At December 31, 2018, no Working Capital Loans are outstanding.

Share Purchase Obligation

The Sponsor has entered into an agreement to purchase an aggregate of \$20,000,000 of the Company’s shares of common stock in a private placement that would occur concurrently with the consummation of our initial business combination. The capital from such private placement may be used as part of the consideration to the sellers in our initial business combination, and any excess capital from such private placement would be used for working capital in the post-transaction company.

Administrative Support Agreement

The Company has agreed, commencing on the effective date of the Proposed Public Offering through the earlier of the Company’s consummation of a Business Combination and its liquidation, to pay the Sponsor a total of \$10,000 per month for office space, utilities and secretarial support.

Note 5—Commitments

Registration Rights

The holders of the Founder Shares, Private Warrants (including securities contained therein) and any shares that may be issued upon conversion of Working Capital Loans will be entitled to registration rights pursuant to an agreement to be signed prior to or on the effective date of Proposed Public Offering. The holders of a majority of these securities are entitled to make up to two demands that the Company register such securities. The holders of the majority of the Founder Shares can elect to exercise these registration rights at any time commencing three months prior to the date on which these shares of common stock are to be released from escrow. The holders of a majority of the Private Warrants or units issued in payment the Working Capital Loans may elect to exercise these registration rights at any time commencing on the date that the Company consummates a Business Combination. In addition, the holders have certain “piggy-back” registration rights with respect to registration statements filed subsequent to the consummation of a Business Combination. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

**HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS**

Underwriting Agreement

The Company will grant the underwriters a 45-day option from the date of Proposed Public Offering to purchase up to 1,500,000 additional Units to cover over-allotments, if any, at the Proposed Public Offering price less the underwriting discounts and commissions.

The underwriters will be entitled to a cash underwriting discount of \$0.20 per Unit, or \$2,000,000 in the aggregate (or \$2,300,000 in the aggregate if the underwriters' option to purchase additional Units is exercised in full), payable upon the closing of the Proposed Public Offering. In addition, the underwriters will be entitled to a deferred fee of \$0.35 per Unit, or \$3,500,000 in the aggregate (or \$4,025,000 in the aggregate if the underwriters' option to purchase additional Units is exercised in full). The deferred fee will become payable to the underwriters from the amounts held in the Trust Account solely in the event that the Company completes a Business Combination, subject to the terms of the underwriting agreement.

Note 6 —Stockholders' Equity

Common Stock — The Company is authorized to issue to 5,000,000 shares of common stock with a par value of \$0.0001 per share. The Company plans on filing an amendment to its Amended and Restated Certificate of Incorporation prior to the closing date of the Proposed Public Offering such that the Company will be authorized to issue a sufficient number of shares of common stock in connection with the Proposed Public Offering. Holders of common stock are entitled to one vote for each share. At December 31, 2018, there were 2,875,000 shares of common stock issued and outstanding, of which an aggregate of up to 375,000 shares are subject to forfeiture to the extent that the underwriters' over-allotment option is not exercised in full or in part, so that the initial stockholders will collectively own 20% of the Company's issued and outstanding common stock after the Proposed Public Offering (assuming the initial stockholders do not purchase any Public Shares in the Proposed Public Offering).

Warrants — The Public Warrants will become exercisable on the later of (a) 30 days after the completion of a Business Combination or (b) 12 months from the closing of the Proposed Public Offering. The Public Warrants will expire five years after the completion of a Business Combination or earlier upon redemption or liquidation.

The Company will not be obligated to deliver any shares of common stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of common stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to the Company satisfying its obligations with respect to registration. No warrant will be exercisable and the Company will not be obligated to issue shares of common stock upon exercise of a warrant unless the common stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the warrants.

The Company has agreed that, as soon as practicable, but in no event later than thirty (30) business days, after the closing of a Business Combination, the Company will use its best efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of common stock issuable upon exercise of the warrants. The Company will use its best efforts to cause the same to become effective and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the warrants in accordance with the provisions of the warrant agreement. In addition, the Company has agreed to use its best efforts to register the shares of common stock that are issuable upon exercise of the warrants under state blue sky laws, to the extent an exemption is not available. Notwithstanding the foregoing, if a registration statement covering the shares of common stock issuable upon exercise of the warrants has not been declared effective by the 90th business day following the closing of a Business Combination and during any period when the Company shall have failed to maintain an effective registration statement, warrant holders may, until such time as there is an effective registration statement, exercise the warrants on a cashless basis pursuant to the exemption provided by Section 3(a)(9) of the Securities Act.

Once the warrants become exercisable, the Company may redeem the Public Warrants:

- in whole and not in part;
- at a price of \$0.01 per warrant;

HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO FINANCIAL STATEMENTS

- 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 the notice of redemption to the warrant holders.

The Private Warrants will be identical to the Public Warrants underlying the Units being sold in the Proposed Public Offering, except that the Private Warrants and the common stock issuable upon the exercise of the Private Warrants will not be transferable, assignable or salable until after the completion of a Business Combination, subject to certain limited exceptions. Additionally, the Private Warrants will be exercisable on a cashless basis and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement. The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. If the Company is unable to complete a Business Combination within the Combination Period and the Company liquidates the funds held in the Trust Account, holders of warrants will not receive any of such funds with respect to their warrants, nor will they receive any distribution from the Company's assets held outside of the Trust Account with the respect to such warrants. Accordingly, the warrants may expire worthless.

Note 7 —Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were available to be issued. Based upon this review, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

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HEALTH SCIENCES ACQUISITIONS CORPORATION
FOR NINE MONTHS ENDED SEPTEMBER 30, 2019**

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HEALTH SCIENCES ACQUISITIONS CORPORATION
CONDENSED BALANCE SHEETS

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	(Unaudited)	
ASSETS		
Current assets		
Cash	\$ 1,610,350	\$ 325,000
Prepaid expenses	152,103	—
Total Current Assets	<u>1,762,453</u>	<u>325,000</u>
Deferred offering costs	—	80,000
Cash and marketable securities held in Trust Account	116,024,698	—
Total Assets	<u>\$117,787,151</u>	<u>\$ 405,000</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accrued expenses	\$ 306,115	\$ 448
Accrued offering costs	—	80,000
Income taxes payable	31,510	—
Promissory note – related party	—	300,000
Total Current Liabilities	<u>337,625</u>	<u>380,448</u>
Deferred underwriting fee payable	4,025,000	—
Total Liabilities	<u>4,362,625</u>	<u>380,448</u>
Commitments and contingencies (Note 5)		
Common stock subject to possible redemption, 10,842,452 shares at redemption value	<u>108,424,520</u>	<u>—</u>
Stockholders' Equity		
Common stock, \$0.0001 par value; 30,000,000 shares authorized; 3,532,548 and 2,875,000 shares issued and outstanding (excluding 10,842,452 and no shares subject to possible redemption) as of September 30, 2019 and December 31, 2018, respectively ⁽¹⁾	353	288
Additional paid-in capital	4,692,712	24,712
Retained earnings/(Accumulated deficit)	<u>306,941</u>	<u>(448)</u>
Total Stockholders' Equity	<u>5,000,006</u>	<u>24,552</u>
Total Liabilities and Stockholders' Equity	<u>\$117,787,151</u>	<u>\$ 405,000</u>

- (1) Included up to 375,000 shares subject to forfeiture if the over-allotment option was not exercised in full or in part by the underwriters. As a result of the underwriters election to fully exercise their over-allotment option, 375,000 Founder Shares are no longer subject to forfeiture. (see Note 4).

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating costs	\$ 395,157	\$ 462,899
Franchise taxes	24,600	49,650
Loss from operations	(419,757)	(512,549)
Other income:		
Interest income	683,140	1,024,698
Income before provision for income taxes	263,383	512,149
Provision for income taxes	(138,293)	(204,760)
Net income	\$ 125,090	\$ 307,389
Weighted average shares outstanding of redeemable common stock	11,500,000	11,500,000
Basic and diluted net income per share, redeemable common stock	\$ 0.05	\$ 0.07
Weighted average shares outstanding of non-redeemable common stock ⁽¹⁾	2,875,000	2,875,000
Basic and diluted net loss per share, non-redeemable common stock	\$ (0.14)	\$ (0.16)

- (1) Included up to 375,000 shares subject to forfeiture if the over-allotment option was not exercised in full or in part by the underwriters. As a result of the underwriters election to fully exercise their over-allotment option, 375,000 Founder Shares are no longer subject to forfeiture. (see Note 4).

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2019
(Unaudited)

	Common Stock (1)		Additional Paid in Capital	Retained Earnings/ (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount			
Balance – January 1, 2019	2,875,000	\$ 288	\$ 24,712	\$ (448)	\$ 24,552
Net loss	—	—	—	(450)	(450)
Balance – March 31, 2019 (unaudited)	2,875,000	\$ 288	\$ 24,712	\$ (898)	\$ 24,102
Sale of 11,500,000 Units, net of underwriting discounts and offering costs	11,500,000	1,150	108,091,435	—	108,092,585
Sale of 10,000,000 Private Warrants	—	—	5,000,000	—	5,000,000
Common stock subject to possible redemption	(10,829,943)	(1,083)	(108,298,347)	—	(108,299,430)
Net income	—	—	—	182,749	182,749
Balance – June 30, 2019 (unaudited)	3,545,057	355	4,817,800	181,851	5,000,006
Change in value of common stock subject to possible redemption	(12,509)	(2)	(125,088)	—	(125,090)
Net income	—	—	—	125,090	125,090
Balance – September 30, 2019 (unaudited)	<u>3,532,548</u>	<u>\$ 353</u>	<u>\$ 4,692,712</u>	<u>\$ 306,941</u>	<u>\$ 5,000,006</u>

- (1) Included up to 375,000 shares subject to forfeiture if the over-allotment option was not exercised in full or in part by the underwriters. As a result of the underwriters election to fully exercise their over-allotment option, 375,000 Founder Shares are no longer subject to forfeiture. (see Note 4).

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
CONDENSED STATEMENT OF CASH FLOWS
NINE MONTHS ENDED SEPTEMBER 30, 2019
(Unaudited)

Cash Flows from Operating Activities:	
Net income	\$ 307,389
Adjustments to reconcile net income to net cash used in operating activities:	
Interest earned on cash and marketable securities held in Trust Account	(1,024,698)
Changes in operating assets and liabilities:	
Prepaid expenses	(152,103)
Accrued expenses	305,667
Income taxes payable	31,510
Net cash used in operating activities	<u>(532,235)</u>
Cash Flows from Investing Activities:	
Investment of cash into Trust Account	(115,000,000)
Net cash used in investing activities	<u>(115,000,000)</u>
Cash Flows from Financing Activities:	
Proceeds from sale of Units, net of underwriting discounts paid	112,700,000
Proceeds from sale of Private Warrants	5,000,000
Advances from related party	50,000
Repayment of advances from related party	(50,000)
Repayment of promissory note – related party	(300,000)
Payment of offering costs	(582,415)
Net cash provided by financing activities	<u>116,817,585</u>
Net Change in Cash	<u>1,285,350</u>
Cash – Beginning of period	325,000
Cash – End of period	<u>\$ 1,610,350</u>
Supplementary cash flow information:	
Cash paid for income taxes	\$ 173,250
Non-Cash investing and financing activities:	
Initial classification of common stock subject to possible redemption	\$ 108,116,280
Change in value of common stock subject to possible redemption	\$ 308,240
Deferred underwriting fee payable	\$ 4,025,000

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

HEALTH SCIENCES ACQUISITIONS CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019
(Unaudited)

NOTE 1. DESCRIPTION OF ORGANIZATION AND BUSINESS OPERATIONS

Health Sciences Acquisitions Corporation (the “Company”) was incorporated in Delaware on December 6, 2018. The Company was formed 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”).

Although the Company is not limited to a particular or geographic region for purposes of consummating a Business Combination, the Company intends to focus on businesses in the healthcare and healthcare-related industries in North America or Europe. The Company is an emerging growth company and, as such, the Company is subject to all of the risks associated with emerging growth companies.

As of September 30, 2019, the Company had not commenced any operations, other than searching for a target business. All activity for the period from December 6, 2018 (inception) through September 30, 2019 relates to the Company’s formation, the initial public offering (“Initial Public Offering”), which is described below, and, after the Initial Public Offering, identifying a target company for a Business Combination. The Company will not generate any operating revenues until after the completion of its initial Business Combination, at the earliest. The Company generates non-operating income in the form of interest income from the proceeds derived from the Initial Public Offering.

The registration statement for the Company’s Initial Public Offering was declared effective on May 9, 2019. On May 14, 2019, the Company consummated the Initial Public Offering of 11,500,000 units (the “Units” and, with respect to the shares common stock included in the Units sold, the “Public Shares”), which includes the full exercise by the underwriters of the over-allotment option, at \$10.00 per Unit, generating gross proceeds of \$115,000,000, which is described in Note 3.

Simultaneously with the closing of the Initial Public Offering, the Company consummated the sale of 10,000,000 warrants (the “Private Warrants”) at a price of \$0.50 per Private Warrant in a private placement to Health Sciences Holdings, LLC, a Delaware limited liability company (the “Sponsor”), generating gross proceeds of \$5,000,000, which is described in Note 4.

Transaction costs amounted to \$6,907,415, consisting of \$2,300,000 of underwriting fees, \$4,025,000 of deferred underwriting fees and \$582,415 of other offering costs. At September 30, 2019, \$1,610,350 of cash was held outside of the Trust Account (as defined below) and is available for working capital purposes.

Following the closing of the Initial Public Offering on May 14, 2019, an amount of \$115,000,000 (\$10.00 per Unit) from the net proceeds of the sale of the Units in the Initial Public Offering and the sale of the Private Warrants was placed in a trust account (“Trust Account”) which will be invested in U.S. government securities, within the meaning set forth in Section 2(a)(16) of the Investment Company Act of 1940, as amended (the “Investment Company Act”), with a maturity of 185 days or less or in any open-ended investment company that holds itself out as a money market fund meeting the conditions of Rule 2a-7 of the Investment Company Act, as determined by the Company, until the earlier of: (i) the completion of a Business Combination or (ii) the distribution of the Trust Account, as described below.

The Company’s management has broad discretion with respect to the specific application of the net proceeds of the Initial Public Offering and the sale of the Private Warrants, although substantially all of the net proceeds are intended to be applied generally toward consummating a Business Combination. The Company’s initial Business Combination must be with one or more target businesses that together have a fair market value of at least 80% of the assets held in the Trust Account (excluding the deferred underwriting fees and taxes payable on the income earned on the Trust Account) at the time of the agreement to enter into a Business Combination. The Company will only complete a Business Combination if the post-transaction Company owns or acquires 50% or more of the outstanding voting securities of the target or otherwise acquires a controlling interest in the target sufficient for it not to be required to register as an investment company under the Investment Company Act 1940, as amended (the “Investment Company Act”). There is no assurance that the Company will be able to complete a Business Combination successfully.

The Company will provide its holders of the outstanding Public Shares (the “public stockholders”) with the opportunity to convert all or a portion of their Public Shares upon the completion of a Business Combination either (i) in connection with a stockholder meeting called to approve the Business Combination or (ii) by means of a tender offer. The decision as to whether the Company will seek stockholder approval of a Business Combination or conduct a tender offer will be made by the Company, solely in its discretion. The public stockholders will be entitled to convert their Public Shares for a pro rata portion of the amount then in the Trust Account (initially \$10.00 per Public Share, plus any pro rata interest earned on the funds held in the Trust Account and not previously released to the Company to pay its income and franchise tax obligations). There will be no redemption rights upon the completion of a Business Combination with respect to the Company’s warrants.

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The Company will proceed with a Business Combination if the Company has net tangible assets of at least \$5,000,001 upon such consummation of a Business Combination and, if the Company seeks stockholder approval, a majority of the shares voted are voted in favor of the Business Combination. If a stockholder vote is not required by law and the Company does not decide to hold a stockholder vote for business or other legal reasons, the Company will, pursuant to its Amended and Restated Certificate of Incorporation, conduct the redemptions pursuant to the tender offer rules of the U.S. Securities and Exchange Commission (“SEC”) and file tender offer documents with the SEC prior to completing a Business Combination. If, however, stockholder approval of the transactions is required by law, or the Company decides to obtain stockholder approval for business or legal reasons, the Company will offer to redeem shares in conjunction with a proxy solicitation pursuant to the proxy rules and not pursuant to the tender offer rules. If the Company seeks stockholder approval in connection with a Business Combination, the Company’s Sponsor, officers and directors (the “initial stockholders”) have agreed (i) to vote their Founder Shares (as defined in Note 4) and any Public Shares acquired in or after the Initial Public Offering in favor of a Business Combination, (ii) not to convert any shares owned by them in connection therewith and (iii) not to sell any of their shares to the Company in a tender offer. Additionally, each public stockholder may elect to convert their Public Shares irrespective of whether they vote for or against the proposed transaction.

Notwithstanding the foregoing, if the Company seeks stockholder approval of a Business Combination and it does not conduct conversions pursuant to the tender offer rules, the Amended and Restated Certificate of Incorporation provides that a public stockholder, together with any affiliate of such stockholder or any other person with whom such stockholder is acting in concert or as a “group” (as defined under Section 13 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), will be restricted from converting its shares with respect to more than an aggregate of 20% or more of the Public Shares, without the prior consent of the Company.

The initial stockholders have agreed (a) to waive their redemption rights with respect to their Founder Shares and Public Shares held by them in connection with the completion of a Business Combination and (b) not to propose, or vote in favor of, an amendment to the Amended and Restated Certificate of Incorporation that would affect the substance or timing of the Company’s obligation to redeem 100% of its Public Shares if the Company does not complete a Business Combination, unless the Company provides the public stockholders with the opportunity to redeem their Public Shares in conjunction with any such amendment.

The Company will have until May 14, 2021 to complete a Business Combination (the “Combination Period”). If the Company is unable to complete a Business Combination within the Combination Period, the Company will (i) cease all operations except for the purpose of winding up, (ii) as promptly as reasonably possible but not more than ten business days thereafter, redeem 100% of the outstanding Public Shares for a pro rata portion of the funds held in the Trust Account, which redemption will completely extinguish public stockholders’ rights as stockholders (including the right to receive further liquidating distributions, if any), subject to applicable law, and (iii) as promptly as reasonably possible following such redemption, subject to the approval of the Company’s remaining stockholders and the Company’s board of directors, dissolve and liquidate, subject in each case to the Company’s obligations under Delaware law to provide for claims of creditors and the requirements of other applicable law. There will be no redemption rights or liquidating distributions with respect to the Company’s warrants, which will expire worthless if the Company fails to complete a Business Combination within the Combination Period.

The initial stockholders have agreed to waive their liquidation rights with respect to the Founder Shares and Private Shares if the Company fails to complete a Business Combination within the Combination Period. However, if the Sponsor, officers and directors acquire Public Shares in or after the Initial Public Offering, such Public Shares will be entitled to liquidating distributions from the Trust Account if the Company fails to complete a Business Combination within the Combination Period. The underwriters have agreed to waive their rights to their deferred underwriting commissions (see Note 5) held in the Trust Account in the event the Company does not complete a Business Combination within the Combination Period and, in such event, such amounts will be included with the funds held in the Trust Account that will be available to fund the redemption of the Public Shares. In the event of such distribution, it is possible that the per share value of the assets remaining available for distribution will be less than the Initial Public Offering price per Unit (\$10.00).

In order to protect the amounts held in the Trust Account, the initial stockholders have agreed to be liable to the Company if and to the extent any claims by a vendor for services rendered or products sold to the Company, or a prospective target business with which the Company has discussed entering into a transaction agreement, reduce the amounts in the Trust Account to below \$10.00 per Public Share, except as to any claims by a third party who executed a valid and enforceable agreement with us waiving any right, title, interest or claim of any kind they may have in or to any monies held in the trust account and except as to any claims under our indemnity of the underwriters from our Initial Public Offering against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the “Securities Act”). Moreover, in the event that an executed waiver is deemed to be unenforceable against a third party, the initial stockholders will not be responsible to the extent of any liability for such third-party claims. The Company will seek to reduce the possibility that the initial stockholders will have to indemnify the Trust Account due to claims of creditors by endeavoring to have all vendors, service providers (except the Company’s independent registered accounting firm), prospective target businesses or other entities with which the Company does business, execute agreements with the Company waiving any right, title, interest or claim of any kind in or to monies held in the Trust Account.

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NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X of the SEC. Certain information or footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a complete presentation of financial position, results of operations, or cash flows. In the opinion of management, the accompanying unaudited condensed financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

The accompanying unaudited condensed financial statements should be read in conjunction with the Company’s prospectus for its Initial Public Offering as filed with the SEC on May 10, 2019, as well as the Company’s Current Report on Form 8-K, as filed with the SEC on May 15, 2019. The interim results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ended December 31, 2019 or for any future periods.

Emerging growth company

The Company is an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, 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.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Use of estimates

The preparation of the unaudited condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of revenues and expenses during the reporting periods.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statement, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Accordingly, the actual results could differ significantly from those estimates.

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Common stock subject to possible redemption

The Company accounts for its common stock subject to possible redemption in accordance with the guidance in Accounting Standards Codification (“ASC”) Topic 480 “Distinguishing Liabilities from Equity.” Common stock subject to mandatory redemption is classified as a liability instrument and is measured at fair value. Conditionally redeemable common stock (including common stock that features redemption rights that is either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company’s control) is classified as temporary equity. At all other times, common stock is classified as stockholders’ equity. The Company’s common stock features certain redemption rights that are considered to be outside of the Company’s control and subject to occurrence of uncertain future events. Accordingly, at September 30, 2019, common stock subject to possible redemption is presented as temporary equity, outside of the stockholders’ equity section of the Company’s condensed balance sheets.

Offering costs

Offering costs consist of legal, accounting, underwriting fees and other costs incurred through the Initial Public Offering date that were directly related to the Initial Public Offering. Offering costs amounting to \$6,907,415 were charged to stockholders’ equity upon the completion of the Initial Public Offering.

Income taxes

The Company follows the asset and liability method of accounting for income taxes under ASC 740, “Income Taxes.” Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. As of September 30, 2019 and December 31, 2018, the Company had a deferred tax asset of approximately \$97,000 and \$0, respectively, which had a full valuation allowance recorded against it of approximately \$97,000 and \$0, respectively.

The Company’s currently taxable income primarily consists of interest income on the Trust Account. The Company’s general and administrative costs are generally considered start-up costs and are not currently deductible. During the three and nine months ended September 30, 2019, the Company recorded income tax expense of approximately \$138,000 and \$205,000, respectively, primarily related to interest income earned on the Trust Account. The Company’s effective tax rate for the three and nine months ended September 30, 2019 was approximately 52.5% and 40.0%, respectively, which differs from the expected income tax rate due to the start-up costs (discussed above) which are not currently deductible.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of September 30, 2019 and December 31, 2018. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception.

Net income (loss) per share

Net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. The Company has not considered the effect of warrants sold in the Initial Public Offering and private placement to purchase an aggregate of 10,750,000 shares of common stock in the calculation of diluted income (loss) per share, since the exercise of the warrants are contingent upon the occurrence of future events and the inclusion of such warrants would be anti-dilutive under the treasury stock method.

The Company’s statements of operations include a presentation of income (loss) per share for common shares subject to redemption in a manner similar to the two-class method of income (loss) per share. Net income per common share, basic and diluted for redeemable common stock is calculated by dividing the interest income earned on the Trust Account (net of applicable franchise and income taxes of approximately \$163,000 and \$254,000 for the three and nine months ended September 30, 2019, respectively) by the weighted average number of shares of redeemable common stock outstanding. Net loss per common share, basic and diluted for non-redeemable common stock is calculated by dividing the net income (loss), less income attributable to redeemable common stock, by the weighted average number of non-redeemable common stock outstanding for the period. Non-redeemable common stock includes the Founder Shares as these shares do not have any redemption features and do not participate in the income earned on the Trust Account.

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Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of a cash account in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage of \$250,000. At September 30, 2019 and December 31, 2018, the Company had not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

Financial instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurements and Disclosures," approximates the carrying amounts represented in the accompanying condensed balance sheets, primarily due to their short-term nature.

Recently issued accounting standards

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's unaudited condensed financial statements.

NOTE 3. INITIAL PUBLIC OFFERING

Pursuant to the Initial Public Offering, the Company sold 11,500,000 Units at a purchase price of \$10.00 per Unit, which includes the full exercise by the underwriters of their option to purchase an additional 1,500,000 Units at \$10.00 per Unit. Each Unit consists of one share of common stock and one redeemable warrant ("Public Warrant"). Each Public Warrant entitles the holder to purchase one-half of one share of common stock at a price of \$11.50 per whole share, subject to adjustment (see Note 7).

NOTE 4. RELATED PARTY TRANSACTIONS

Founder Shares

In December 2018, the Sponsor purchased 2,875,000 shares (the "Founder Shares") of the Company's common stock for an aggregate price of \$25,000. The Founder Shares included an aggregate of up to 375,000 shares subject to forfeiture to the extent that the underwriters' over-allotment option was not exercised in full or in part, so that the initial stockholders would own, on an as-converted basis, 20% of the Company's issued and outstanding shares after the Initial Public Offering (assuming the initial stockholders did not purchase any Public Shares in the Initial Public Offering). As a result of the underwriters' election to fully exercise their over-allotment option, 375,000 Founder Shares are no longer subject to forfeiture.

The initial stockholders have agreed not to transfer, assign or sell any of the Founder Shares (except to certain permitted transferees) until, with respect to 50% of the Founder Shares, the earlier of (i) six months after the date of the consummation of a Business Combination, or (ii) the date on which the closing price of the Company's common stock equals or exceeds \$12.50 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days within any 30-trading day period commencing after a Business Combination and, with respect to the remaining 50% of the Founder Shares, six months after the date of the consummation of a Business Combination, or earlier in each case, if, subsequent to a Business Combination, the Company consummates a subsequent liquidation, merger, stock exchange or other similar transaction which results in all of the Company's stockholders having the right to exchange their common stock for cash, securities or other property.

Private Placement

Simultaneously with the closing of the Initial Public Offering, the Sponsor purchased an aggregate of 10,000,000 Private Warrants at a price of \$0.50 per Private Warrant, for an aggregate purchase price of \$5,000,000. Each Private Warrant is exercisable to purchase one-half of one share of common stock at a price of \$11.50 per whole share. A portion of the proceeds from the Private Warrants were added to the proceeds from the Initial Public Offering held in the Trust Account. If the Company does not complete a Business Combination within the Combination Period, the proceeds from the sale of the Private Warrants will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law), and the Private Warrants will expire worthless.

Advances from Related Party

In May 2019, the Sponsor advanced the Company an aggregate of \$50,000 to cover expenses related to the Initial Public Offering. The advances were non-interest bearing and due on demand. The advances were repaid on May 15, 2019.

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Promissory Note – Related Party

On December 19, 2018, the Sponsor agreed to loan the Company an aggregate of up to \$300,000 to cover expenses related to the Initial Public Offering (the “Promissory Note”). The Promissory Note was non-interest bearing and payable on the completion of the Initial Public Offering. The outstanding amount of \$300,000 under the Promissory Note was repaid May 15, 2019.

Related Party Loans

In addition, in order to finance transaction costs in connection with a Business Combination, the initial stockholders or their affiliates may, but are not obligated to, loan the Company funds as may be required (“Working Capital Loans”). If the Company completes a Business Combination, the Company would repay the Working Capital Loans out of the proceeds of the Trust Account released to the Company. Otherwise, the Working Capital Loans would be repaid only out of funds held outside the Trust Account. In the event that a Business Combination does not close, the Company may use a portion of proceeds held outside the Trust Account to repay the Working Capital Loans, but no proceeds held in the Trust Account would be used to repay the Working Capital Loans. Except for the foregoing, the terms of such Working Capital Loans, if any, have not been determined and no written agreements exist with respect to such loans. The Working Capital Loans would either be repaid upon consummation of a Business Combination, without interest, or, at the lender’s discretion, up to \$200,000 of such Working Capital Loans may be convertible into warrants of the post-Business Combination entity at a price of \$0.50 per warrant. The warrants would be identical to the Private Warrants. There were no borrowings under the Working Capital Loans as of September 30, 2019.

Share Purchase Obligation

The Sponsor has entered into an agreement to purchase an aggregate of \$20,000,000 of the Company’s shares of common stock in a private placement that would occur concurrently with the consummation of a Business Combination. The capital from such private placement may be used as part of the consideration to the sellers in a Business Combination, and any excess capital from such private placement would be used for working capital in the post-transaction company.

Administrative Support Agreement

The Company entered into an agreement whereby, commencing on the May 9, 2019 through the earlier of the Company’s consummation of a Business Combination or its liquidation, the Company will pay the Sponsor a total of \$10,000 per month for office space, utilities and secretarial support. For the three and nine months ended September 30, 2019, the Company incurred \$30,000 and \$50,000, respectively, in fees for these services.

NOTE 5. COMMITMENTS

Registration Rights

Pursuant to a registration rights agreement entered into on May 9, 2019, the holders of the Founder Shares, Private Warrants (including securities contained therein) and any shares that may be issued upon conversion of Working Capital Loans will be entitled to registration rights. The holders of a majority of these securities are entitled to make up to two demands that the Company register such securities. The holders of the majority of the Founder Shares can elect to exercise these registration rights at any time commencing three months prior to the date on which these shares of common stock are to be released from escrow. The holders of a majority of the Private Warrants or units issued in payment the Working Capital Loans may elect to exercise these registration rights at any time commencing on the date that the Company consummates a Business Combination. In addition, the holders have certain “piggy-back” registration rights with respect to registration statements filed subsequent to the consummation of a Business Combination. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

Underwriting Agreement

The underwriters are entitled to a deferred fee of \$0.35 per Unit, or \$4,025,000 in the aggregate. The deferred fee will become payable to the underwriters from the amounts held in the Trust Account solely in the event that the Company completes a Business Combination, subject to the terms of the underwriting agreement.

NOTE 6. SHARE EXCHANGE AGREEMENT

On September 29, 2019, the Company entered into a share exchange agreement (the “Share Exchange Agreement”) with Immunovant Sciences Ltd. (“Immunovant”), a biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases, and shareholders of Immunovant, including Roivant Sciences Ltd. (“Roivant”). Upon the closing of the transactions contemplated in the Share Exchange Agreement (the “Closing”), among other things, the Company will acquire all of the issued and outstanding shares of Immunovant, and Immunovant will become a wholly owned subsidiary of the Company (the “Immunovant Business Combination”). Upon the Closing, the Company will change its name to “Immunovant, Inc.”

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As a result of the Immunovant Business Combination, an aggregate of approximately 43,000,000 shares of the Company's common stock will be issued (or reserved for issuance pursuant to currently exercisable options) and 10,000 shares of the Company's Series A preferred stock be issued to Roivant) in respect of shares of Immunovant capital stock and exercisable options that are issued and outstanding as of immediately prior to the Closing, subject to pre-closing adjustment for certain indebtedness of Immunovant (other than indebtedness convertible into Immunovant capital stock).

On the closing date of the Immunovant Business Combination, each option to purchase Immunovant's common shares (each, a "Company Option") that is outstanding under Immunovant's equity incentive plan immediately prior to the Closing, and each option or restricted stock units, whether vested or unvested, will, automatically and without any required action on the part of any holder or beneficiary thereof, be assumed by the Company and converted into an option to purchase shares of the Company's common stock (each, a "Converted Option"), subject to pre-closing adjustment for certain indebtedness of Immunovant (other than indebtedness convertible into Immunovant's common shares). Each Converted Option shall continue to have and be subject to the same terms and conditions as were applicable to such Company Option immediately before the Closing (including expiration date, vesting conditions, and exercise provisions).

The Share Exchange Agreement also calls for additional agreements, including, among others, the Sponsor Restricted Stock Agreement, the Lock-Up Agreement, and the Registration Rights Agreement.

The Business Combination will be consummated subject to the deliverables and provisions as further described in the Share Exchange Agreement.

NOTE 7. STOCKHOLDERS' EQUITY

Common Stock — On May 9, 2019, the Company filed an Amended and Restated Certificate of Incorporation such that the Company is authorized to issue 30,000,000 shares of common stock with a par value of \$0.0001 per share. Holders of common stock are entitled to one vote for each share. At September 30, 2019 and December 31, 2018, there were 3,532,548 and 2,875,000 shares of common stock issued and outstanding, excluding 10,842,452 and no shares of common stock subject to possible redemption, respectively. As a result of the underwriters' election to fully exercise their over-allotment option, 375,000 Founder Shares are no longer subject to forfeiture.

Warrants — The Public Warrants will become exercisable on the later of (a) 30 days after the completion of the Company's initial Business Combination or (b) May 14, 2020. The Public Warrants will expire five years after the completion of a Business Combination or earlier upon redemption or liquidation.

The Company will not be obligated to deliver any shares of common stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of common stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to the Company satisfying its obligations with respect to registration. No warrant will be exercisable and the Company will not be obligated to issue shares of common stock upon exercise of a warrant unless the common stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the warrants.

The Company has agreed that, as soon as practicable, but in no event later than thirty (30) business days after the closing of a Business Combination, the Company will use its best efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of common stock issuable upon exercise of the warrants. The Company will use its best efforts to cause the same to become effective and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the warrants in accordance with the provisions of the warrant agreement. In addition, the Company has agreed to use its best efforts to register the shares of common stock that are issuable upon exercise of the warrants under state blue sky laws, to the extent an exemption is not available. Notwithstanding the foregoing, if a registration statement covering the shares of common stock issuable upon exercise of the warrants has not been declared effective by the 90th business day following the closing of a Business Combination and during any period when the Company shall have failed to maintain an effective registration statement, warrant holders may, until such time as there is an effective registration statement, exercise the warrants on a cashless basis pursuant to the exemption provided by Section 3(a)(9) of the Securities Act.

Once the warrants become exercisable, the Company may redeem the Public Warrants:

- 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 the notice of redemption to the warrant holders.

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The Private Warrants are identical to the Public Warrants underlying the Units sold in the Initial Public Offering, except that the Private Warrants and the common stock issuable upon the exercise of the Private Warrants will not be transferable, assignable or salable until after the completion of a Business Combination, subject to certain limited exceptions. Additionally, the Private Warrants will be exercisable on a cashless basis and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a “cashless basis,” as described in the warrant agreement. The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. If the Company is unable to complete a Business Combination within the Combination Period and the Company liquidates the funds held in the Trust Account, holders of warrants will not receive any of such funds with respect to their warrants, nor will they receive any distribution from the Company’s assets held outside of the Trust Account with the respect to such warrants. Accordingly, the warrants may expire worthless.

NOTE 8. FAIR VALUE MEASUREMENTS

The Company classifies its U. S. Treasury and equivalent securities asheld-to-maturity in accordance with ASC 320 “Investments—Debt and Equity Securities.” Held-to-maturity securities are those securities which the Company has the ability and intent to hold until maturity. Held-to-maturity treasury securities are recorded at amortized cost on the accompanying condensed balance sheets and adjusted for the amortization or accretion of premiums or discounts.

At September 30, 2019, assets held in the Trust Account were comprised of \$8,823 in cash and \$116,015,875 in U.S. Treasury Bills.

The gross holding losses and fair value of held-to-maturity securities at September 30, 2019 are as follows:

	Held-To-Maturity	Amortized Cost	Gross Holding Gain	Fair Value
September 30, 2019	U.S. Treasury Securities (Mature on 11/14/2019)	<u>\$116,015,875</u>	<u>\$80,482</u>	<u>\$116,096,357</u>

The fair value of the Company’s financial assets and liabilities reflects management’s estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

- Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs based on our assessment of the assumptions that market participants would use in pricing the asset or liability.

Transfers to/from Levels 1, 2, and 3 are recognized at the end of the reporting period. There were no transfers between levels of the hierarchy for the three and nine months ended September 30, 2019. Level 1 instruments include investments in U.S. Treasury securities with an original maturity of 180 days or less.

NOTE 9. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the condensed financial statements were issued. Based upon this review, the Company did not identify any subsequent events that would have required adjustment or disclosure in the condensed financial statements.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the shares of common stock being registered. All amounts shown are estimates except for the SEC registration fee.

	<u>AMOUNT</u>
SEC registration fee	\$ 154,189
FINRA filing fee	(1)
Legal fees and expenses	100,000
Accounting fees and expenses	50,000
Printing and engraving expenses	15,000
Transfer agent and registrar fees and expenses	15,000
Miscellaneous fees and expenses	<u>55,811</u>
Total	<u>\$ 400,000</u>

(1) This fee is calculated based on the securities offered and the number of issuances and accordingly cannot be estimated at this time.

Discounts, concessions, commissions and similar selling expenses attributable to the sale of shares of common stock covered by this prospectus will be borne by the selling stockholders. We will pay all expenses (other than discounts, concessions, commissions and similar selling expenses) relating to the registration of the shares with the Securities and Exchange Commission, as estimated in the table above.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

Our amended and restated certificate of incorporation provides for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our bylaws provide for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law.

In addition, we have entered into indemnification agreements with our directors, officers, and some employees containing provisions which are in some respects broader than the specific indemnification provisions contained in the Delaware General Corporation Law. The indemnification agreements will require us, among other things, to indemnify our directors against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

In December 2018, we issued an aggregate of 2,875,000 shares of common stock to the Sponsor for an aggregate purchase price of \$25,000.

In May 2018, we issued an aggregate of 10,000,000 warrants to the Sponsor at \$0.50 per warrant (for a total purchase price of \$5,000,000), with each warrant exercisable for one share of common stock at an exercise price of \$11.50 per share.

In December 2019, upon the closing of the Business Combination, we issued an aggregate of 42,080,376 shares of common stock to the stockholders of ISL and 10,000 shares of Series A preferred stock to RSL.

ISL granted to certain employees, directors and consultants of it and its subsidiaries, options to purchase an aggregate of 9,013,667 common shares of ISL at exercise prices of \$0.93 to \$4.12 per common share under ISL's 2018 Equity Incentive Plan. Upon the closing of the Business Combination, such options were automatically and without any required action on the part of any holder or beneficiary thereof, were assumed by us and converted into options to purchase an aggregate of 4,408,287 shares of our common stock at exercise prices of \$1.91 to \$8.43 per share.

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None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe each of these transactions was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) as transactions by an issuer not involving any public offering or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

See the Exhibit Index on the page immediately preceding the signature page for a list of exhibits filed as part of this registration statement on FormS-1, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

See Index to combined and consolidated financial statements on PageF-1. All schedules have been omitted because they are not required or are not applicable.

ITEM 17. UNDERTAKINGS.

(a) The undersigned registrant hereby undertakes as follows:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

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- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining any liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or our securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the undersigned pursuant to the foregoing provisions, or otherwise, the undersigned has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a

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claim for indemnification against such liabilities (other than the payment by the undersigned of expenses incurred or paid by a director, officer or controlling person of the undersigned in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the undersigned will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

Exhibit Number	Description	Schedule/ Form	Incorporated by Reference		
			File No.	Exhibit	Filing Date
2.1+	Share Exchange Agreement, dated September 29, 2019, by and among Immunovant Sciences Ltd., the stockholders of Immunovant Sciences Ltd., Roivant Sciences Ltd., and Health Sciences Acquisitions Corporation.	8-K	001-38906	2.1	October 2, 2019
3.1	Amended and Restated Certificate of Incorporation of Immunovant, Inc.	8-K	001-38906	3.1	December 20, 2019
3.2	Amended and Restated Bylaws of Immunovant, Inc.	8-K	001-38906	3.2	December 20, 2019
4.1	Specimen Warrant Certificate.	S-1/A	333-230893	4.3	April 29, 2019
4.2	Form of Warrant Agreement by and between Continental Stock Transfer & Trust Company and Health Sciences Acquisitions Corporation.	S-1/A	333-230893	4.4	April 29, 2019
5.1*	Opinion of Cooley LLP.				
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
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.				

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Exhibit Number	Description	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filing Date
23.2*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm.				
23.3*	Consent of Cooley LLP (included in Exhibit 5.1).				
24.1*	Power of Attorney (included on signature page).				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York on the 17th day of January 2020.

IMMUNOVANT, INC.

By: /s/ Peter Salzmann, M.D.

Peter Salzmann, M.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Peter Salzmann, Pamela Yanchik Connealy and W. Bradford Middlekauff, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Peter Salzmann, M.D.</u> Peter Salzmann, M.D.	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	January 17, 2020
<u>/s/ Pamela Yanchik Connealy</u> Pamela Yanchik Connealy	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	January 17, 2020
<u>/s/ Frank M. Torti, M.D.</u> Frank M. Torti, M.D.	Chairperson of the Board of Directors	January 17, 2020
<u>/s/ Andrew Fromkin</u> Andrew Fromkin	Director	January 17, 2020
<u>/s/ Douglas Hughes</u> Douglas Hughes	Director	January 17, 2020
<u>/s/ George Migausky</u> George Migausky	Director	January 17, 2020
<u>/s/ Atul Pande, M.D.</u> Atul Pande, M.D.	Director	January 17, 2020
<u>/s/ Myrtle S. Potter</u> Myrtle S. Potter	Director	January 17, 2020



John T. McKenna
 +1 650 843 5059
 jmckenna@cooley.com

January 17, 2020

Immunovant, Inc.
 320 West 37th Street
 New York, NY 10018

Re: Immunovant, Inc. – Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Immunovant, Inc., a Delaware corporation (the “*Company*”), with respect to certain matters in connection with the filing by the Company of a Registration Statement on Form S-1 (the “*Registration Statement*”) with the Securities and Exchange Commission (“*SEC*”), including a related prospectus filed with the Registration Statement (the “*Prospectus*”), covering the resale by the selling securityholders named in the Prospectus of shares of common stock, par value of \$0.0001 per share (the “*Common Stock*”) consisting of:

- up to 42,080,376 shares of common stock issued pursuant to that certain Share Exchange Agreement, dated as of September 29, 2019 (the “*Share Exchange Agreement*”), by and among the Company, Immunovant Sciences Ltd. (“*ISL*”), a Bermuda exempted limited company, the stockholders of ISL and Roivant Sciences Ltd. (“*RSL*”), a Bermuda exempted limited company, as representative of such stockholders (the “*Exchange Shares*”);
- up to 2,875,000 shares of common stock held by Health Sciences Holdings, LLC (“*Sponsor*”) (the “*Sponsor Shares*”);
- up to 1,387,498 shares of common stock purchased by RTW Master Fund Ltd., RTW Innovation Master Fund, Ltd., RTW Venture Fund Limited and RSL in open market transactions (and together with the Exchange Shares and the Sponsor Shares, the “*Outstanding Shares*”); and
- up to 20,000,000 additional shares of common stock that may be issued pursuant to Section 3.6 of the Share Exchange Agreement (the “*Earnout Shares*”).

In addition, the Prospectus covers the issuance by the Company of up to 5,750,000 shares of Common Stock (the “*Warrant Shares*”) issuable upon the exercise of currently outstanding warrants that were previously issued by the Company in a transaction registered with the SEC (the “*Warrants*”).

In connection with this opinion, we have examined and relied upon (a) the Registration Statement and the Prospectus, (b) the Company’s Certificate of Incorporation, as amended, and Bylaws, each as currently in effect and in effect at the time of (i) entry into the Share Exchange Agreement, or (ii) the issuance of the Outstanding Shares, or (iii) the issuance of the Warrants, and (c) originals, or copies certified to our satisfaction, of such records, documents, certificates, opinions, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness and authenticity of all signatures on original documents; the authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as

Cooley LLP 3175 Hanover Street Palo Alto, CA 94304-1130
 t: (650) 843-5000 f: (650) 849-7400 cooley.com



Immunovant, Inc.
January 17, 2020
Page Two

copies thereof; and the accuracy, completeness and authenticity of certificates of public officials. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not sought independently to verify such matters.

With respect to the Earnout Shares and the Warrant Shares, we express no opinion to the extent that, notwithstanding its current reservation of shares of Common Stock, future issuances of securities, including the Earnout Shares or Warrant Shares, of the Company and/or adjustments to outstanding securities, including the Warrants, of the Company may cause the number of Earnout Shares to be issuable pursuant to the Share Exchange Agreement and Warrant Shares to be issuable pursuant to the Warrants to be exercisable for more shares of Common Stock than the number that then remain authorized but unissued.

Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that:

1. The Outstanding Shares have been validly issued and are fully paid and non-assessable.
2. The Earnout Shares, when issued in accordance with the terms of the Share Exchange Agreement, will be validly issued, fully paid and non-assessable.
3. The Warrant Shares, when issued and paid for in accordance with the terms of the Warrants, will be validly issued, fully paid and non-assessable.

This opinion is expressed as of the date hereof, and we disclaim any responsibility to advise you of any changes in the facts stated or assumed herein or any changes in applicable law.

We hereby consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to the Registration Statement.

Sincerely,

COOLEY LLP

By: /s/ JOHN T. MCKENNA
John T. McKenna

Cooley LLP 3175 Hanover Street Palo Alto, CA 94304-1130
t: (650) 843-5000 f: (650) 849-7400 cooley.com

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated May 29, 2019, with respect to the combined and consolidated financial statements of Immunovant Sciences Ltd. included in the Registration Statement (Form S-1) and related Prospectus of Immunovant, Inc. for the registration of 72,092,874 shares of its common stock.

/s/ Ernst & Young LLP

Iselin, New Jersey
January 17, 2020

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in the Registration Statement of Immunovant, Inc. on FormS-1, of our report dated May 2, 2019, relating to the balance sheet of Health Sciences Acquisitions Corporation as of December 31, 2018, and the related statements of operations, changes in stockholder's equity and cash flows for the period from December 6, 2018 (inception) through December 31, 2018, and to the reference to our Firm under the caption "Experts" in the Registration Statement.

/s/ WithumSmith+Brown, PC

New York, New York
January 17, 2020