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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-39045

IGM Biosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**77-0349194**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
325 E. Middlefield Road	
Mountain View, CA	**94043**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 965-7873

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	IGMS	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

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

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

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant, based on the closing price of a share of the Registrant's common stock on June 30, 2020 as reported by the NASDAQ Global Select Market on such date was approximately $513,600,000. Shares of the Registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

As of March 24, 2021, the Registrant had 25,574,983 shares of common stock, $0.01 par value per share, and 6,431,205 shares of non-voting common stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the Registrant's definitive Proxy Statement to be filed in connection with the Registrant's 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such definitive Proxy Statement will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2020.

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Show Special Note Regarding Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this report are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would,” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about: the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our discovery programs; our ability to utilize our IgM antibody platform to generate and advance additional product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; the commercializing of our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our expectations regarding the impact of the coronavirus (COVID-19) pandemic on our business; our anticipated use of our existing resources; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash and investments to fund our future operating expenses and capital expenditure requirements; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified professionals; the implementation of our business model, strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our IgM platform, product candidates and discovery programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; and the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties, and assumptions described in the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, or otherwise.

PART I

Item 1. Business.

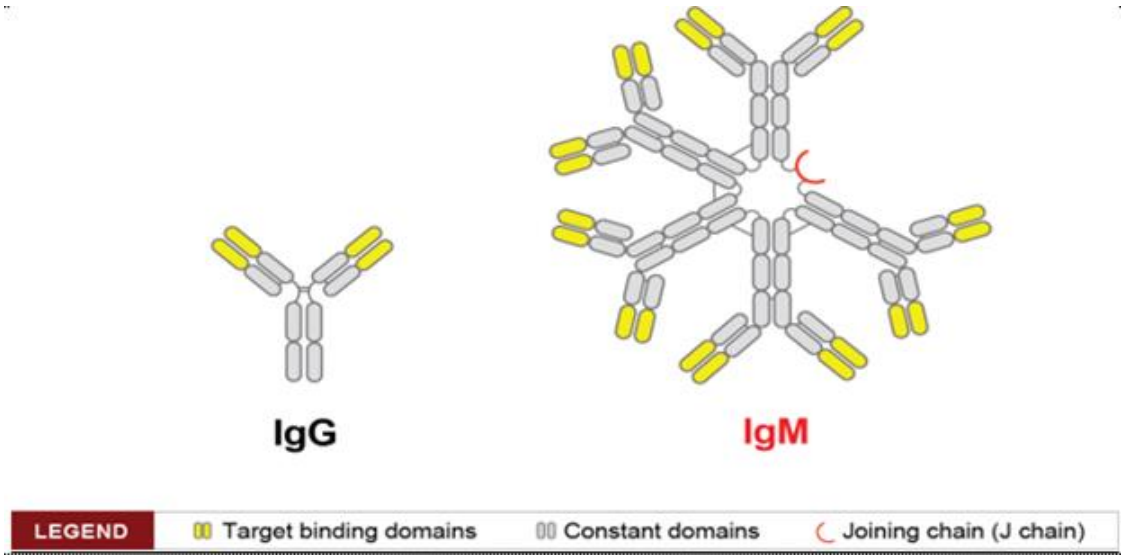
Overview

We are a biotechnology company pioneering the development of engineered IgM antibodies for the treatment of multiple diseases. IgM antibodies have inherent properties that we believe may enable them to bind more strongly to cells than comparable IgG antibodies. We have created a proprietary IgM antibody technology platform that we believe is particularly well suited for developing T cell engagers, receptor cross-linking agonists and targeted cytokines. Our lead product candidate, IGM-2323, a bispecific T cell engaging IgM antibody targeting CD20 and CD3 proteins, is in an ongoing Phase 1 clinical trial for the treatment of relapsed/refractory B cell Non-Hodgkin's lymphoma (NHL) patients. Our second product candidate, IGM-8444, is an IgM antibody targeting Death Receptor 5 (DR5) proteins which may prove to be useful for the treatment of patients with solid and hematologic malignancies. In September 2020, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-8444 for the treatment of solid cancers and NHL. Our pipeline also includes IGM-7354, a bispecific IgM antibody delivering interleukin-15 (IL-15) cytokines to PD-L1 expressing cells for the treatment of patients with solid and hematologic malignancies. We plan to file an investigational new drug (IND) application for IGM-7354 in 2021.

We believe that we have the most advanced research and development program focused on engineered therapeutic IgM antibodies. We have created a portfolio of patents and patent applications, know-how and trade secrets directed to our platform technology, product candidates and manufacturing capabilities, and we retain worldwide commercial rights to all of our product candidates and the intellectual property related thereto.

Immunoglobulin G (IgG) and Immunoglobulin M (IgM) are classes of antibodies that are naturally produced by the human immune system and are distinguishable by their structural properties.

Structural Comparison of IgG and IgM Antibodies



IgM antibodies have 10 binding domains compared to 2 for IgG antibodies. This inherent biological advantage enables:

- Stronger binding to cell surface targets, including those with low expression levels, which may result in better and more complete targeting of cancer cells;
- Stronger binding to difficult targets, such as tumor associated carbohydrates and glycosylated proteins, which has the potential to expand the range of addressable cancer targets;
- Greater ability to cross-link cell surface receptors, which may significantly enhance cellular signaling for killing cancer cells or stimulating T cells, which are a type of white blood cell that are an essential part of the immune system; and
- Substantially greater ability to utilize the complement dependent cytotoxicity (CDC) mechanism of killing targeted cells, which kills cancer cells without requiring the presence of immune cells; and
- Stronger binding to viral targets, which may result in more potent neutralization of viruses.

Despite these inherent biological advantages, while IgG antibodies have been broadly developed as therapeutic medicines, we believe the therapeutic potential of engineered IgM antibodies has remained largely unexplored.

Our Platform

We created our IgM platform to expand upon the inherent properties of IgM antibodies and to allow for the rapid development of engineered therapeutic antibodies. Significantly, our IgM platform allows us to create IgM antibodies with higher affinity and avidity than naturally occurring IgM antibodies. We believe our platform also allows us to utilize the strong and durable binding of IgM antibodies to kill cancer cells with T cells, induce programmed death of cancer cells or deliver immune stimulating cytokines to the region of the bound cell.

The versatility of our IgM platform positions us to evaluate multiple approaches to treat patients with solid and hematologic malignancies. Our ability to develop engineered IgM antibodies against various targets allows for the creation of a broad and differentiated product pipeline. Our initial oncology efforts are focused on three broad applications of IgM antibodies:

- **T cell engagers**: T cell to cancer cell engagement, including CD20 x CD3, CD123 x CD3, CD38 x CD3 and solid tumor target x CD3 programs, which we believe may have the potential to kill cancer cells through T cell directed cellular cytotoxicity (TDCC) and CDC while maintaining a favorable tolerability profile.
- **Receptor cross-linking agonists**: Tumor Necrosis Factor receptor Superfamily (TNFrSF) agonists, including DR5, which induces programmed death of cancer cells, as well as OX40, glucocorticoid-induced TNFr-related protein (GITR) and other TNFrSF members, which we believe may enhance the ability of the immune system to fight cancer.
- **Targeted cytokines**: Targeted cytokine delivery, including IL-15, which we believe may be helpful in inducing and maintaining immune responses to cancer.

Our Pipeline

Our lead product candidate, IGM-2323, is a CD20 x CD3 bispecific IgM antibody for the treatment of patients with CD20-positive cancer. CD20 is a protein commonly expressed on the surface of NHL cells and chronic lymphocytic leukemia (CLL) cells, while CD3 is a protein expressed on the surface of T cells. IGM-2323 contains 10 binding domains for CD20 and one binding domain for CD3. In October 2019, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-2323 for the treatment of relapsed/refractory B cell NHL patients, which is B cell NHL that has either not responded to initial treatment or responded to treatment but then returns. In December 2020 we announced our first clinical data with IGM-2323. Treatment with combination chemo-immunotherapy, such as with rituximab-based regimens, or high dose chemotherapy and bone marrow transplant, is generally effective and may cure approximately 50-70% of patients with aggressive B cell NHL. Indolent B cell NHL, which represents approximately 40% of B cell NHL cases, remains mostly incurable at advanced stages with current therapies.

Our second product candidate, IGM-8444, is an IgM antibody targeting DR5 for the treatment of patients with solid and hematologic malignancies. DR5 receptors are expressed on a broad range of solid tumors as well as leukemias and lymphomas, but their intracellular apoptotic signaling requires efficient cross-linking of at least three DR5 receptors. IGM-8444 demonstrated significantly enhanced apoptotic signaling compared to an IgG antibody with the same binding domains, resulting in >1,000 fold increased potency in killing cancer cells from multiple cancer cell types in our studies outside of living organisms (*in vitro*). In our studies in living organisms (*in vivo*), specifically cynomolgus monkeys, no untoward toxicity was observed with IGM-8444. In September 2020, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-8444 for the treatment of solid cancers and NHL.

Our third oncology product candidate, IGM-7354, is a bispecific IgM antibody that delivers IL-15 to PD-L1 expressing cells for the treatment of patients with solid and hematologic malignancies. In nature, IL-15 stimulates T cells and natural killer (NK) cells to proliferate and maintain their long-term survival. Our IgM platform allows us to attach IL-15 to the J chain of an IgM antibody targeting PD-L1. We expect to file an IND for IGM-7354 in 2021.

The following table highlights our lead oncology programs:

Mode	Target	Indications	Phase of Development					Worldwide Commercial Rights	Anticipated Milestones
			Discovery	Preclinical	Phase 1	Phase 2	Phase 3		
T cell Engager	IGM-2323 (CD20 x CD3)	NHL, CLL						IGM	Recommended Phase 2 dose: 2021
Receptor Cross-linking Agonist	IGM-8444 (DR5)	Solid and Hematologic Malignancies						IGM	Initial Phase 1 data in solid tumors: 2021
Targeted Cytokines	IGM-7354 (IL-15 x PD-L1)	Solid and Hematologic Malignancies						IGM	IND filing: 2021 (anticipated)

The following table highlights oncology discovery programs that we are currently prioritizing:

Mode	Target	Indications	Worldwide Commercial Rights
T cell Engagers	CD123 x CD3	Acute Myeloid Leukemia	IGM
	CD38 x CD3	Multiple Myeloma	
	Multiple Targets x CD3	Multiple Solid Tumors	
Receptor Cross-linking Agonists	OX40	Solid and Hematologic Malignancies	IGM
	GITR		

We estimate that these discovery programs are at least a year away from clinical studies, assuming they meet our requirements for advancement. We do not anticipate advancing all of these programs into clinical testing, and some of these programs may be supplanted by other IgM discovery programs. In addition to these oncology programs, we are also developing IgM antibodies for the possible prevention and treatment of COVID-19.

Our Team

Our management team and board of directors have decades of biotechnology experience and perspective in areas such as cancer biology, immunotherapy, immunology, antibody discovery, protein engineering and clinical development. They bring a strong history of leadership, innovation and research and development experience at leading companies, including Roche/Genentech, Amgen, Gilead Sciences, Novartis, Merck & Co., Celgene, Millennium Pharmaceuticals, Shire, Kite Pharma, Bavarian Nordic, and Northern Biologics. Members of our team were involved in the discovery, development or commercialization of multiple therapeutics, including Tecentriq, Yescarta, Zydelig, Avastin, Lucentis, Vectibix, Activase, TNKase and Kogenate.

Our Differentiated Approach and Proprietary Platform

We are developing IgM antibodies that have properties which we believe may enable them to bind more strongly to cancer cells than comparable IgG antibodies in many therapeutic applications. IgM antibodies have 10 binding domains compared to 2 for IgG antibodies, which results in far greater binding power to a cell surface target.

Over the past 40 years, the biotechnology industry's development of antibodies has yielded effective therapeutic drugs for the treatment of patients with a variety of diseases including cancer and autoimmune diseases. According to market research, antibody related therapies generated over $140 billion in reported worldwide sales in 2019. All of these antibodies are members of the IgG class. We are pioneering the development of new therapies based on the IgM class of antibodies. We believe our IgM antibodies could have therapeutic applications across a wide range of diseases, including oncology and infectious and autoimmune diseases.

There are two measures of target binding strength that are generally used in connection with antibodies:

- Affinity—the binding strength of each individual binding domain of the antibody bound to the target; and
- Avidity—the combined binding strength of all of the binding domains of the antibody bound to the target.

The greater number of binding domains of an IgM antibody results in far greater avidity to a cell surface or virus as compared with an IgG antibody with the same affinity per binding domain. The greater number of binding domains also allows IgM antibodies to bind more cell surface or viral targets in close proximity with a single antibody. The inherent biological advantages of IgM antibodies enable:

- Stronger binding to cell surface targets, including those with low expression levels, which may result in better and more complete targeting of cancer cells;
- Stronger binding to viral targets, which may result in more potent neutralization of viruses;
- Stronger binding to difficult targets, such as tumor associated carbohydrates and glycosylated proteins, which has the potential to expand the range of addressable cancer targets;
- Greater ability to cross-link cell surface receptors, which may significantly enhance cellular signaling for killing cancer cells or stimulating T cells; and
- Substantially greater ability to utilize the complement dependent cytotoxicity (CDC) mechanism of killing targeted cells, which kills cancer cells without requiring the presence of immune cells.

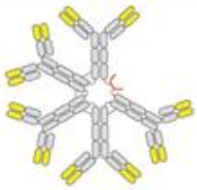
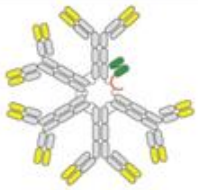
Development of IgM antibodies has been historically limited by difficulties encountered in the recombinant expression and manufacture of these antibodies. Through our focused efforts which began in 2010, we have developed a broad range of skills, knowledge and trade secrets that have allowed us to successfully express and manufacture a wide range of IgM antibodies.

We created our IgM platform to expand upon the inherent qualities of IgM antibodies and to allow for the rapid development of engineered therapeutic antibodies. Through our efforts, we have developed a wide variety of proprietary methods and techniques designed to achieve the following goals:

- **Expression and manufacture**: Overcome the traditional difficulties the pharmaceutical industry has experienced in recombinantly expressing and manufacturing IgM antibodies;
- **Engineered IgM antibodies**: Create IgM antibodies recombinantly, by transferring IgG binding domains to IgMs, to include the benefits of high affinity and high specificity IgG variable regions;
- **Bispecific platform**: Create bispecific antibodies with the benefits of the high avidity of 10 binding domains to one target combined with one binding domain to a second target;
- **Improved half-life**: Extend the serum half-life of recombinantly generated IgM antibodies; and
- **Complement modulation**: Modulate the CDC mechanism of IgM antibodies.

We believe that our IgM platform creates significant competitive advantages and can serve as the foundation for the development of a broad range of IgM based therapeutic drugs. The following table compares the key properties of IgG antibodies to those of naturally occurring IgM antibodies, as well as to our engineered IgM bispecific antibodies:

Properties of IgG vs IgM Antibodies

Structure	 IgG	 Naturally Occurring IgM	 Engineered IgM
Binding domains	2	10	10
Binding valency	Bivalent	Multivalent	Multivalent
Affinity	High	Low to Medium	High
Avidity	Low	Medium	High
Binding to low expression targets	Low	Medium	High
Binding to carbohydrate antigens	Low	Medium	High
Mechanism of cell killing	ADCC + CDC	CDC	TDCC + CDC
Antibody construct	Heavy chains Light chains	Heavy chains Light chains J chain	Heavy chains Light chains Modified J chain
Molecular weight	150kDa	960kDa	≥960kDa

LEGEND: Target binding domains; CD3 binding domain; Constant domains; J chain

Our Antibodies

T cell Engagers

We have been able to utilize the natural features of IgM antibodies to create unique and patent protected bispecific T cell engagers, which we believe may have the potential to kill cancer cells through TDCC and CDC while maintaining a favorable tolerability profile. Bispecific T cell engagers are designed to simultaneously target a desired tumor associated antigen on a cancer cell and CD3 (a protein that is expressed on the surface of T cells) and redirect the T cells to kill the cancer cells. In contrast to other bispecific antibody formats that bind to one or two target molecules on the surface of the cancer cell and to one CD3 molecule on the surface of the T cell, our IgM bispecific format provides 10 binding domains to the cancer cell and one binding domain to CD3. We believe that our IgM bispecific antibodies may successfully bind to cancer cells for longer periods and with more avidity compared to IgG bispecific antibodies, which may prove to be particularly advantageous for those cancer cells that express relatively lower amounts of the targeted protein on their surface.

Receptor Cross-linking Agonists

We are also using our IgM platform to develop IgM antibodies that bind to members of the TNFrSF. Members of the TNFrSF must be bound in clusters of at least three in order to send a strong biological signal to the cell. This family includes targets that will cause the death of cancer cells, such as DR5, and targets that will cause the proliferation of T cells, such as OX40 and GITR.

There have been multiple attempts to create IgG based therapeutic antibodies directed at DR5, OX40 and GITR. However, since IgG antibodies naturally bind only two DR5, OX40 or GITR cell surface proteins, their bivalent nature inherently limits their signaling efficacy. In contrast, we are utilizing the 10 binding domains of IgM antibodies to more efficiently cross-link these molecules on the cell surface. In multiple *in vitro* cell studies, we have observed that IgM antibodies have much greater potency than IgG antibodies with the same binding domains.

Targeted Cytokines

We are using our IgM platform to create bifunctional IgM antibodies with high avidity to selected cell surface targets to deliver potent, immune stimulating cytokines. These IgM antibodies will initially target the delivery of IL-15 to induce immune cell stimulation and proliferation. Targeted delivery of cytokines is designed to reduce systemic toxicities of cytokine therapy while enhancing immune system activity in the tumor microenvironment. Stimulation of the IL-15 pathway may be important in strengthening and maintaining both the endogenous and the synthetic T cell immune responses.

We believe that our IgM platform has certain inherent advantages for this application. Importantly, we believe that the high avidity and long-lasting binding of our IgM antibodies may help to effectively position the cytokine for delivery to a target cell for an extended period. We also believe that the high avidity of the IgM antibodies may allow binding of the cytokine delivery antibody to cells that have relatively low density of the surface target. Targeted IL-15 may also provide complementary effects when combined in a treatment regimen with our T cell engaging antibodies, such as CD20 x CD3 or our solid tumor T cell engagers.

Infectious Diseases

We are also applying our IgM platform to infectious disease as we believe IgM antibodies may provide improved virus neutralization. As we previously disclosed, we are working on a program to address the world-wide need to prevent and treat COVID-19 through targeting the SARS-CoV-2 virus. We believe that the extra avidity provided by an IgM antibody may produce more potent neutralization of the SARS-CoV-2 virus and subsequent mutated forms of the virus.

Our Product Candidates

We are leveraging our IgM platform to discover and develop product candidates for the treatment of cancer patients. Our lead product candidate, IGM-2323, is a CD20 x CD3 bispecific IgM antibody designed to treat patients with B cell NHL and other B cell malignancies. Our second product candidate, IGM-8444, is an IgM antibody targeting Death Receptor 5 (DR5) proteins for the treatment of patients with solid and hematologic malignancies. Our pipeline also includes IGM-7354, a bispecific IgM antibody delivering interleukin-15 (IL-15) cytokines to PD-L1 expressing cells for the treatment of patients with solid and hematologic malignancies.

Mode	Target	Indications	Phase of Development					Worldwide Commercial Rights	Anticipated Milestones
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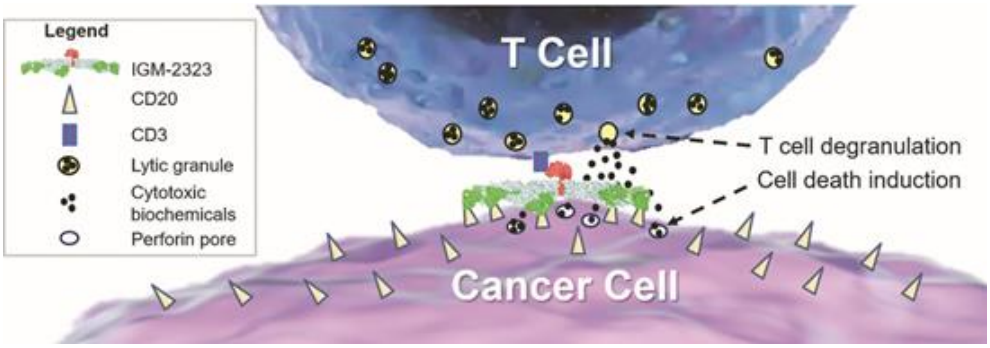
IGM-2323: CD20 x CD3 Bispecific IgM Antibody

Our lead product candidate, IGM-2323, is a CD20 x CD3 bispecific IgM antibody designed to treat patients with B cell NHL and other B cell malignancies. Our initial therapeutic goal with IGM-2323 is to safely and effectively treat relapsed/refractory B cell NHL patients. CD20 is a protein that is frequently expressed on the surface of malignant B cells, while CD3 is a protein that is expressed on the surface of T cells and is an essential activating molecule of the T cell. IGM-2323 has 10 binding domains to CD20 and a single binding domain to CD3 (specifically CD3ε). In addition, IGM-2323 contains a human serum albumin molecule attached to the Joining chain (J chain) to enhance its pharmacokinetic properties. The J chain naturally occurs in IgM antibodies and joins the IgM subunits into pentameric antibodies.

IGM-2323 is designed to simultaneously and stably bind a CD20 expressing cancer cell as well as CD3 on a cytotoxic T cell, bringing both cells into close proximity. This interaction mimics the normal T cell activation pathway leading the T cell to recognize and kill the cancer cell by releasing cytotoxic biochemicals (perforins and granzymes) that penetrate and perforate the cancer cell. The TDCC mediated killing mechanism of IGM-2323 on CD20 expressing cancer cells is shown in the diagram below.

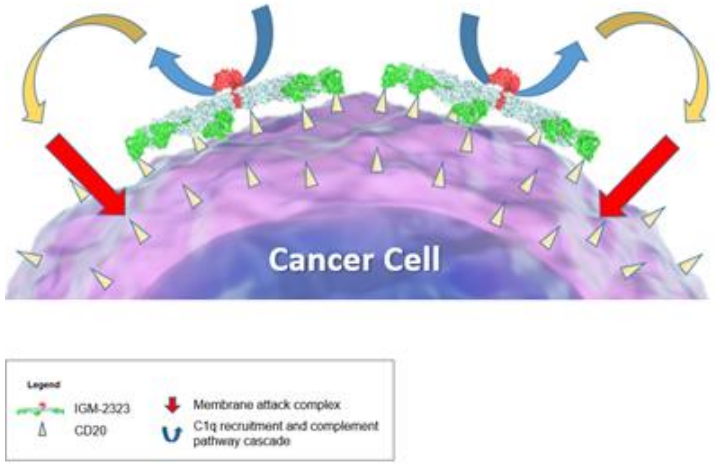
IGM-2323 Binding to a CD20 Positive Cancer Cell and Inducing TDCC



Schematic diagram of IGM-2323 binding a CD20 expressing B cancer cell and a CD3 expressing T cell for T cell directed cellular cytotoxicity (TDCC). Shown is the IGM-2323 induced T cell release (degranulation) of cytotoxic biochemicals from T cell lytic granules in close proximity to the cancer cell to induce perforin pore formation in the cell membrane, allowing cell entry of the cytotoxic biochemicals and induction of cancer cell death.

IGM-2323 also employs an additional mechanism to kill CD20 expressing cancer cells, known as complement dependent cytotoxicity (CDC). CDC is a mechanism by which antibodies can mediate specific targeted cell killing by activating the complement system. Components of the complement system are naturally present in humans, and IgM antibodies are the most efficient antibodies at engaging the complement system for CDC, with an approximately 100 fold increase in CDC relative to comparable IgG CD20 antibodies. The CDC mediated killing mechanism of CD20 expressing cancer cells by IGM-2323 is shown in the diagram below.

IGM-2323 Binding to a CD20 Positive Cancer Cell and Inducing CDC



Schematic diagram of IGM-2323 binding a CD20 expressing B cancer cell and recruiting components of the complement system from the serum to induce complement dependent cytotoxicity (CDC) through formation of a membrane attack complex.

We believe the dual mechanisms of action of IGM-2323, both TDCC and CDC, may further enhance its efficiency in eliminating CD20 expressing cancer cells and may decrease the likelihood of cancer escape or resistance.

We are planning to develop IGM-2323 as a treatment for patients diagnosed with CD20-expressing malignancies. In October 2019, we announced the dosing of the first patient in a Phase 1 clinical trial of IGM-2323 for the treatment of relapsed/refractory B cell NHL. In this multi-center open label trial, we are studying IGM-2323 initially as a single agent, where it is administered intravenously at a fixed-dose or via titration dosing, as part of a dose escalation in single patient cohorts followed by 3+3-based protocol, up to a planned maximum dose of 1000 mg, in patients with relapsed/refractory B cell NHL. IGM-2323 is being administered three times per cycle (each cycle is 21 days). The dose limiting toxicity window will be evaluated in the first cycle. The objective of this Phase 1 study is to provide an initial assessment of the safety, pharmacokinetics and preliminary efficacy of IGM-2323 in relapsed/refractory B cell NHL patients. If the therapy appears to be safe and tolerable and if significant evidence of efficacy is observed, we will expand the clinical testing of IGM-2323 in additional relapsed/refractory patients expected to express CD20 on their cancer cells, including diffuse large B cell lymphoma and/or relapsed/refractory follicular lymphoma, and potentially further to relapsed/refractory chronic lymphocytic leukemia and/or

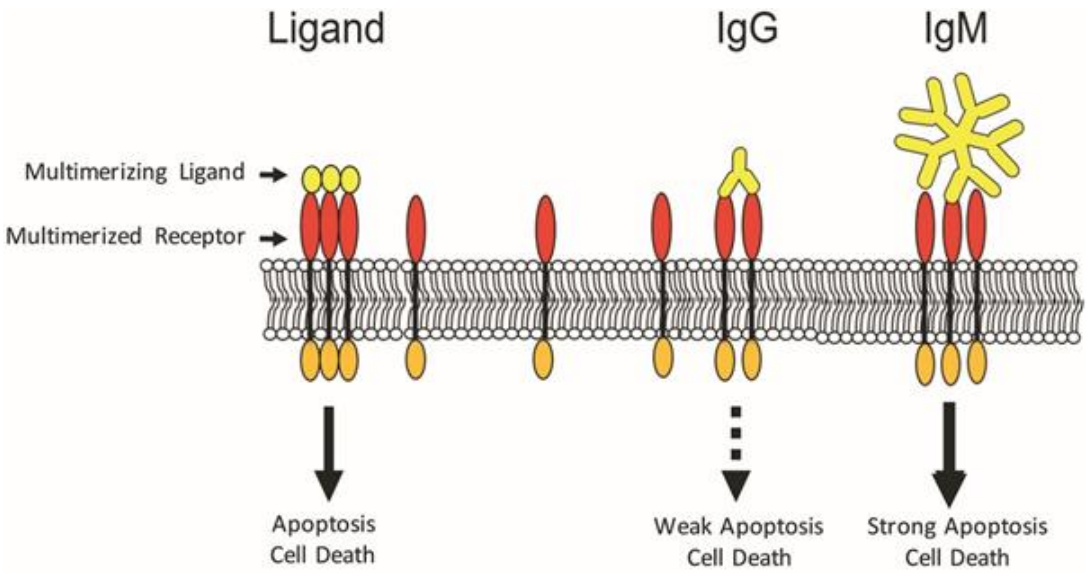
relapsed/refractory multiple myeloma. Additional combination studies adding IGM-2323 to standard of care regimens in earlier lines of treatment may be developed based upon initial results from this Phase 1 study.

We announced our first clinical data with IGM-2323 in December 2020, and we hope to announce a recommended Phase 2 dose for IGM-2323 in 2021.

IGM-8444: Death Receptor 5 Agonist IgM Antibody

Our second product candidate, IGM-8444, is an IgM antibody targeting DR5 for the treatment of patients with solid and hematologic malignancies. DR5 is a member of the TNFrSF and is often expressed on the surface of cancer cells. Similar to other members of the TNFrSF, strong signaling to effect a biological response requires that three or more DR5 receptor proteins be cross-linked together on the surface of a cancer cell through the binding of either the natural DR5 ligand (TRAIL) or an antibody or other therapeutic drug that can efficiently cross-link the DR5 receptors. Binding and cross-linking of DR5 receptors sends a signal to the cancer cell to induce programmed death of cancer cells, also known as apoptosis.

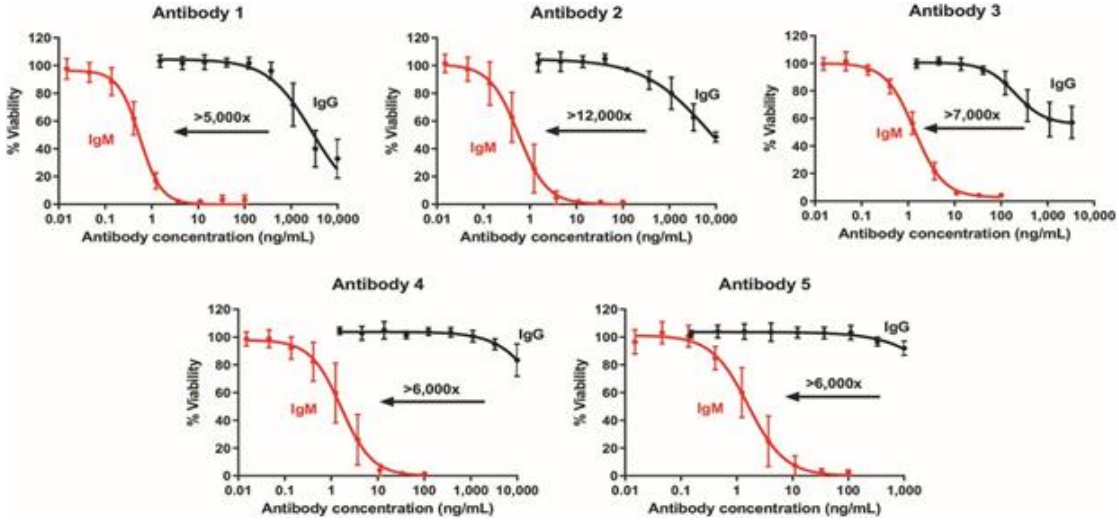
DR5 Signaling to Induce Programmed Death of Cancer Cells



DR5 is expressed in a broad range of solid tumors (e.g., colon, gastric, pancreatic, lung, breast and prostate tumors) as well as leukemias and lymphomas. Although DR5 is expressed on some normal cells in the body, cancer cells have been shown to be more sensitive to DR5 signaling compared to cells of healthy tissues. Various IgG DR5 antibodies have been tested in early stage clinical trials by other companies, but these IgG antibodies failed to demonstrate adequate efficacy. As IgG DR5 antibodies only bind to two DR5 receptors, these IgG antibodies may not have created sufficient cross-linking of DR5 to send an efficient apoptotic signal to the cancer cells, which may account for the relatively small number of monotherapy responses observed in the clinical trials of these IgG antibodies. In contrast, DR5 IgM antibodies have the capacity for multivalent binding of DR5, which results in cross-linked DR5 receptors on the cell surface.

In our laboratory studies, shown in the figure below, multiple DR5 IgM antibodies showed significantly enhanced *in vitro* efficacy compared to an IgG antibody with the same binding domains, often resulting in at least >1,000 fold increased potency in killing cancer cells from multiple cancer cell types with encouraging *in vitro* toxicity data. As shown in the figures below, we observed that multiple different engineered DR5 IgM antibodies were able to kill cancer cells at concentrations of 5,000-12,000 fold less than DR5 IgG antibodies with the same binding domains at equal concentrations.

Cell Line Killing Comparison of DR5 IgG and IgM Antibodies with Five Different Binding Domains



Human colon cancer cell line Colo205 was incubated in vitro with either DR5 IgG antibodies or IgM antibodies with the same binding domains at increasing concentrations. The ability of the antibodies to kill the cancer cells was tested after 24 hours of incubation. Shown are means ± 1 standard deviations of the percent viable (surviving cancer cells) cells at each antibody concentration tested. Studies were repeated between 2-6 times with similar results.

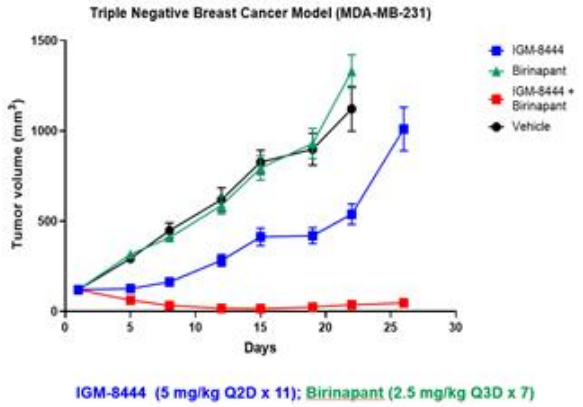
We are planning to develop IGM-8444 as a treatment for patients with solid and hematologic malignancies. In September 2020, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-8444. In this multicenter, open-label, dose-escalation and expansion Phase 1 clinical trial, we are studying IGM-8444 intravenously administered as a monotherapy and in combination with chemotherapy in patients with relapsed and/or refractory solid cancers and NHL. IGM-8444 is initially being administered on Days 1 and 15 of 28-day cycles until disease progression, unacceptable toxicity, patient withdrawal of consent, or study termination. Alternative dosing schedules may be evaluated. Dose limiting toxicity will be evaluated during the first cycle. The key objectives of this trial are to provide an initial assessment of the pharmacokinetics, safety, biomarkers and preliminary efficacy of IGM-8444 both as a single agent and in combination with standard of care chemotherapy. Additional combination studies in different indications with regimens expected to act synergistically with IGM-8444 may be developed based upon initial results from this Phase 1 clinical trial. We expect to report initial data from this Phase 1 trial in 2021.

IGM-8444 in Combination with Birinapant

Inhibitors of Apoptosis Proteins (IAPs) are a family of anti-apoptotic proteins that are normally expressed in cells as part of the cellular homeostatic balance to proapoptotic proteins. IAPs are overexpressed in a variety of human cancers contributing to unchecked cellular growth, tumor progression and resistance to treatments. Birinapant is a bivalent, small molecule Second Mitochondrial-derived Activator of Caspases (SMAC) mimetic that binds to and degrades IAPs.

We believe SMAC-mimetics, such as birinapant, have the potential to inhibit the overexpressed IAPs and re-establish the apoptosis signal. Moreover, we believe that SMAC-mimetics can be synergistic with a DR5 agonist such as IGM-8444. Accordingly, we tested IGM-8444 preclinically in combination with a number of SMAC-mimetics. Of all the combinations tested, the combination of IGM-8444 and birinapant showed the greatest cancer cell killing. In an *in vivo* study, the combination of IGM-8444 and birinapant nearly eliminated all tumor volume compared to vehicle and compared to IGM-8444 or birinapant alone.

Killing Activity of IGM-8444 in Combination with Birinapant *in vivo*



Human triple negative breast cancer cell line MDA-MB-231 was injected subcutaneously in mice and when tumor volumes reached ~120 mm3, mice were injected with 5 mg/kg of IGM-8444 every two days for a total of eleven injections, birinapant at 2.5 mg/kg every three days for a total of seven injections, a combination of both therapeutics or vehicle. The graph shows the mean tumor volumes ± standard error of the means of a total of 10 mice per group.

Based on these preclinical results, we intend to pursue IGM-8444 and birinapant as a combination therapy in a clinical study.

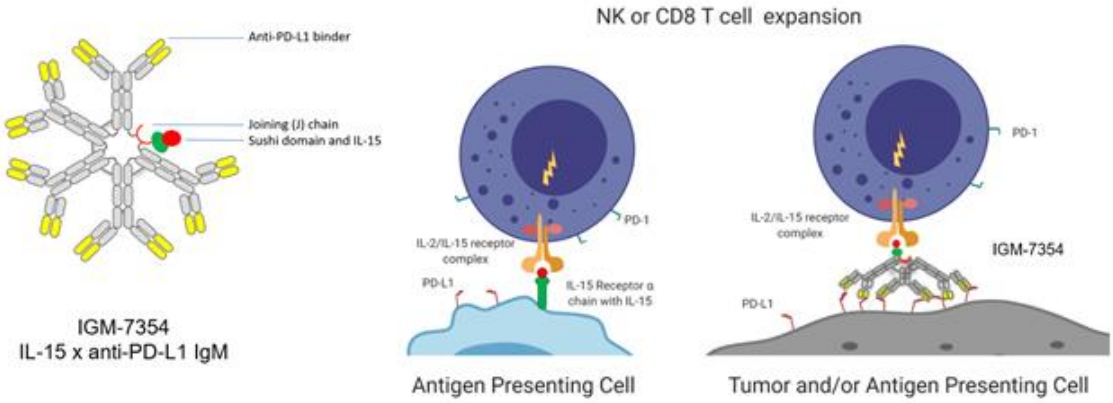
Birinapant was originally discovered and developed by TetraLogic Pharmaceuticals Corporation (TetraLogic) for the treatment of certain cancers and infectious diseases and was tested in various phase 1 and phase 2 clinical trials as a monotherapy and in combination with chemotherapeutic drugs and other agents. All monotherapy and combination studies were terminated due to a lack of clinical efficacy with the exception of one combination study in chronic hepatitis B which was discontinued due to cranial nerve palsies and one study sponsored by the National Cancer Institute in head and neck squamous cell carcinoma which remains open, but in which no patients are currently enrolled. In 2016, Medivir AB (Medivir) acquired all rights to birinapant from TetraLogic. In January 2021, we entered into an exclusive license agreement with Medivir through which we received global, exclusive development and commercialization rights for birinapant.

IGM-7354: IL-15 x PD-L1 Bispecific IgM Antibody

Our third oncology product candidate, IGM-7354, is a bifunctional IgM antibody delivering interleukin-15 (IL-15) cytokines to PD-L1 expressing cells for the treatment of patients with solid and hematologic malignancies.

In nature, IL-15 stimulates T cells and NK cells to proliferate and maintain their long-term survival. Our IgM platform allows us to attach IL-15 to the J chain of a targeting IgM antibody. We believe that this targeted delivery system for IL-15 will lead to the proliferation of T cells and NK cells in the tumor microenvironment and immune tissues targeted by the IgM antibody.

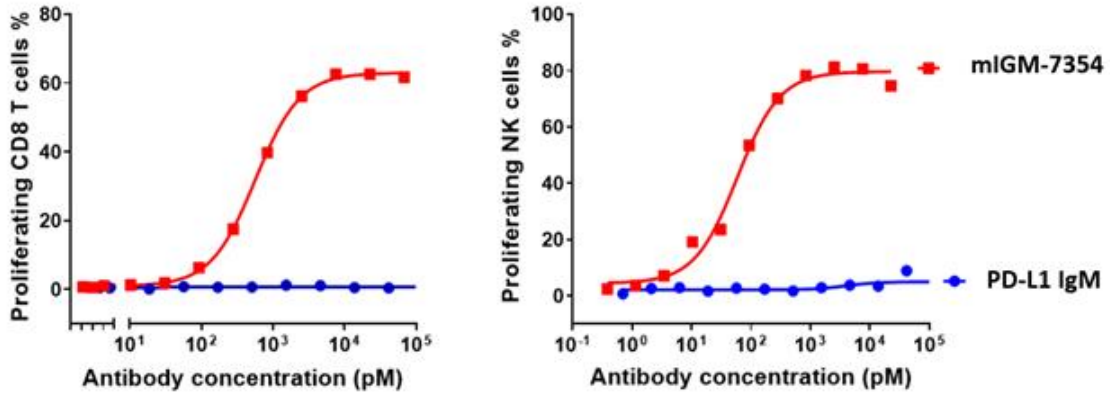
IL-15 Delivered by High Avidity anti-PD-L1 IgM Antibody



Left: Schematic diagram of IGM-7354, an anti-PD-L1 IgM antibody with IL-15 (red oval) attached to the J chain.
Right: Natural presentation of IL-15 versus presentation of IL-15 on IGM-7354 to CD8 or NK cells. The presentation of IL-15 on IGM-7354 can occur on both antigen presenting cells (APCs) and/or PD-L1-expressing tumor cells.

In an *in vitro* study, shown in the figure below, IL-15 x PD-L1 bifunctional IgM antibody mIGM-7354 enhanced proliferation in approximately 60% of CD8 T cells and 80% of NK cells, while a PD-L1 IgM antibody without IL-15 attached to the joining chain did not increase proliferation in CD8 T cells and NK cells. mIGM-7354 is the non-humanized version of IGM-7354 and was used as a surrogate molecule.

Comparative Activity of the PD-L1 IgM Antibody with and without IL-15 Fused to the J Chain



The PD-L1 IgM antibody with (mIGM-7354) and without IL-15 fused to the J chain was incubated at increasing concentrations with human peripheral blood mononuclear cells in vitro and the proliferation of CD8+ effector T cell and NK cells was evaluated after three to four days. Shown is a representative study from >10 repeat studies.

We have also performed *in vivo* tumor efficacy studies using two mouse tumor models:1) a mouse colon cancer cell line (CT26) engineered to express human PD-L1; and 2) a human breast cancer cell line (MDA-MB-231) that expresses PD-L1 in mice reconstituted with human immune cells. In both tumor models, mIGM-7354 inhibited tumor growth compared to vehicle control treatment groups and mice treated with an anti-PD-L1 IgG. In the CT26 tumor model, mice that were tumor free after treatment with mIGM-7354 rejected the growth of tumor when rechallenged. These findings demonstrate that mIGM-7354 enhances anti-tumor immunity in mice and can potentially support anti-tumor immune memory responses.

We expect to file an IND for IGM-7354 in 2021 in order to begin clinical testing in solid and hematologic malignancies. The proposed multi-center open label Phase 1 clinical trial would study IGM-7354 intravenously administered as part of a staggered monotherapy and in combination with chemotherapy 3+3 dose escalation in Phase 1 patients with solid tumor and hematologic malignancies. The objective of this Phase 1 clinical trial would be to provide an initial assessment of pharmacokinetics, safety, biomarker evaluation and preliminary efficacy of IGM-7354 as a single agent and in combination with a defined chemotherapy regimen, based on standard cancer response criteria.

Research and Discovery Programs

The following table highlights oncology discovery programs that we are currently prioritizing:

Mode	Target	Indications	Worldwide Commercial Rights
T cell Engagers	CD123 x CD3	Acute Myeloid Leukemia	IGM
	CD38 x CD3	Multiple Myeloma	
	Multiple Targets x CD3	Multiple Solid Tumors	
Receptor Cross-linking Agonists	OX40	Solid and Hematologic Malignancies	IGM
	GITR		

We estimate that most of these discovery programs are at least a year away from clinical studies, assuming they meet our requirements for advancement. We do not anticipate advancing all of these programs into clinical testing, and some of these programs may be supplanted by other IgM discovery programs. In addition to these oncology programs, we are also developing IgM antibodies for the possible prevention and treatment of COVID-19.

Third-Party Agreements

AbCellera Agreement

In September 2020, we entered into a multi-year, multi-target strategic research and license agreement with AbCellera Biologics Inc. (AbCellera) to facilitate the discovery and development of novel IgM antibodies. We may exercise an option to obtain ownership of all rights, title, and interests in the antibodies discovered and developed under the agreement for a selected target. Upon exercise of the option, we may be required to pay research and development fees, amounts related to achievement of downstream milestones, and royalties on net sales.

University of Texas Agreement

In October 2020, we entered into a multi-year patent and materials license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas Health Science Center at Houston for certain antibodies against the SARS-CoV-2 virus. Under the terms of the agreement, we are obligated to pay an upfront payment of $0.1 million, an annual license fee of up to $0.1 million, research and development fees aggregating up to $2.8 million upon the achievement of clinical and regulatory milestones and single digit royalties on future net sales of antibody products stemming from this agreement.

AvantGen Agreement

In December 2020, we entered into a multi-year patent and license agreement with AvantGen Inc. for certain antibodies against the SARS-CoV-2 virus. Under the terms of the agreement, we are obligated to pay an upfront payment of $0.2 million, an annual fee of up to $0.3 million upon the first and second anniversaries of the agreement, research and development fees aggregating up to $8.4 million upon the achievement of clinical and regulatory milestones and single digit royalties on future net sales of antibody products stemming from this agreement.

Medivir Agreement

In January 2021, we entered into an exclusive license agreement with Medivir AB through which we received global, exclusive development and commercialization rights for birinapant, a clinical-stage SMAC-mimetic that binds to and degrades IAPs, leading to apoptosis in tumor cells. The combination of IGM-8444 and birinapant has been shown to enhance anti-tumor activity preclinically. Under terms of the agreement, we made an upfront payment of $1.0 million upon signing the agreement, to be followed by an additional $1.5 million payment when birinapant is included by us in our clinical Phase 1 studies. Under the terms of the agreement, should birinapant be successfully developed and approved, we are obligated to make milestone payments up to a total of approximately $350.0 million, plus tiered royalties from the mid-single digits up to mid-teens on net sales.

Other Agreements

We have entered into certain other agreements pursuant to which we are evaluating antibody sequences from third parties. Under these agreements, we are able to research and initially develop some of our discovery programs and are required to make certain annual payments. Total expense recorded in connection with these agreements was $1.9 million for the year ended December 31, 2020. We also have the option to negotiate or enter into commercial license agreements with some of these third parties if we elect to continue development or commercialization of any product candidates resulting from these agreements. If we exercise our option to negotiate or enter into any commercial licenses with these third parties, we will be subject to additional payment obligations upon achievement of certain development, regulatory, commercialization and other milestones and low single digit royalty payments on product sales.

Manufacturing and Supply

We do not currently operate a current good manufacturing practice (cGMP) manufacturing facility. We expect to continue to rely for some time, on third parties for the manufacture of our product candidates for preclinical and clinical testing. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates.

We have spent significant resources developing our current manufacturing processes and know-how to produce sufficient yields and optimize functionality in conjunction with our contract manufacturing partners. Typically, we use Chinese hamster ovary (CHO) cells to produce IgM and bispecific IgM antibodies by transfecting those cells with plasmids containing genes encoding heavy chain (HC), light chain (LC) and J chain (JC) domains. To construct a bispecific IgM we use a plasmid containing a modified JC gene that encodes a single chain fragment variable (scFv) domain. The IgM pentamers, containing HC, LC and JC in an appropriate ratio (e.g., 10:10:1), are assembled within the CHO cells, and secreted into the cell supernatant, all of which are contained in a large single-use

bioreactor. The product IgM is harvested and purified to homogeneity using methods and processes developed by us. Our processes provide for cost-effective purification and formulation stability in the manufacturing of IgM antibodies.

We have completed construction of a cGMP manufacturing facility expected to be adequate for the manufacture of clinical trial drug materials. Once this facility becomes operational, we expect to manufacture clinical material for some of our current and future product candidates. We expect to continue to manufacture clinical materials for our first three product candidates, IGM-2323, IGM-8444 and IGM-7354, at outside partners for some extended period of time.

Subject to the clinical trial success of our product candidates, we plan to design and build a commercial manufacturing facility for the future commercial manufacturing of some or all of our commercial products.

To date, we have obtained bulk drug substance (BDS) for IGM-2323 and IGM-8444 from single-source third-party contract manufacturers. While any reduction or halt in supply of BDS from these contract manufacturers could limit our ability to develop our product candidates until replacement contract manufacturers are found and qualified, we believe that we have sufficient BDS to support our current clinical trial programs. Filling and finishing of the BDS for IGM-2323 and IGM-8444 has been completed at another third-party contract manufacturer.

We also expect to obtain BDS for IGM-7354 from a single-source third-party contract manufacturer, and we expect that filling and finishing of the BDS for IGM-7354 will be completed at another third-party contract manufacturer.

All of our product candidates are manufactured from a master cell bank of that antibody's production cell line. We have or intend to have one master cell bank for each product candidate that was or will be produced and tested in accordance with cGMP and applicable regulations. Each master cell bank is or will be stored in two independent locations, and we intend to produce working cell banks for each product candidate later in product development. It is possible that we could lose multiple cell banks from multiple locations and have our manufacturing severely impacted by the need to replace the cell banks. However, we believe we have adequate backup should any particular cell bank be lost in a catastrophic event.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Any product candidates that we successfully develop and commercialize will compete with new immunotherapies and other drug products that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop cancer treatments. There are many other companies that have commercialized and/or are developing immuno-oncology treatments for cancer, including large pharmaceutical and biotechnology companies, such as AbbVie, Amgen, AstraZeneca, Bristol-Myers Squibb, Merck, Novartis, Pfizer and Roche/Genentech.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (e.g., T cell engagers), adoptive cellular therapies (e.g., CAR-T), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin and targeted cancer vaccines.

With respect to our lead product candidate, IGM-2323, we are aware of other companies with competing clinical stage therapeutics that target CD20, which include, but are not limited to, Roche/Genentech, Regeneron, Xencor and Genmab.

With respect to our second product candidate, IGM-8444, we are aware of other companies with competing clinical stage therapeutics that target DR5, which include, but are not limited to, AbbVie, InhibRx, Genmab, Clover Biopharmaceuticals, Boehringer Ingelheim and Beijing Sunbio Biotech.

With respect to our third product candidate, IGM-7354, we are aware of other companies with competing clinical stage therapeutics that utilize targeted and untargeted IL-15, which include, but are not limited to, Roche/Genentech, Kadmon, Nektar, Xencor, ImmunityBio and Cytune Pharma.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for product candidates, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

The proprietary nature and protection of our platforms, product candidates and discovery programs, as well as our processes and know-how, are important to our business. We have sought patent protection in the United States and internationally for our platform technologies, research discoveries and product candidates. For our product candidates, we seek to pursue patent protection covering compositions of matter, methods of use including various treatment indications and methods of creation and manufacture. Throughout the innovation process, and continuing into the product development process, we also plan to seek to identify additional means of obtaining patent protection that would potentially enhance our commercial success, including obtaining patent protection for additional methods of use, such as additional medical indications, for our product candidates, treatment methods for specific patient populations using our product candidates and methods and tests to identify those patient populations, and the manufacture of our product candidates. We also seek to obtain patent protection for refinements and enhancements to our platform technologies. Our policy is to pursue, maintain and defend patent rights in strategic areas and to protect the technology, inventions, and improvements that are commercially important to the development of our business. We may also rely on trade secrets that may be important to the development of our business, and we may seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

To date, we have spent considerable effort securing intellectual property rights, including rights related to our platform technology and product candidates. Our patent portfolios covering our platform technology, product candidates, and related discovery programs, are summarized below.

Platform Technologies

As of December 31, 2020, our patent portfolio related to our platform technologies includes eleven patent families and includes issued U.S. and international patents directed to our modified J chain technology. The platform portfolio includes 17 granted patents, two allowed applications, 63 pending applications in active prosecution in 15 countries or regions, three pending Patent Cooperation Treaty (PCT) applications (one published), and one pending unpublished provisional application. These patent families are projected to expire between 2034 and 2041, absent

any patent term adjustments or extensions. We wholly own the rights to these patent families. Summaries of relevant published patent families are provided below.

The “Modified J Chain” family includes disclosure and claims related to IgM, IgA, and hybrid multimeric antibodies that include a J chain, where the J chain has been modified to include a binding moiety, e.g., an antibody or antibody fragment, or any other protein or non-protein moiety that can bind to a cognate binding partner (including antibody drug conjugates). The application family also includes disclosure and claims related to methods of making and using multimeric antibody molecules comprising a modified J chain, e.g., bispecific IgM antibodies. This patent family has a projected expiration date of April 2, 2035, absent any patent term adjustments or extensions. The Modified J Chain patent family includes granted patents in the United States (two patents), Australia, China, Europe (validated in Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, Great Britain, Hong Kong, Hungary, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Sweden, and Slovenia), Japan, Mexico, and Singapore, and is allowed in Israel. As of December 31, 2020, the patent family also includes pending patent applications in the United States (two applications), Australia, Brazil, Canada, China, Europe, India, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and South Africa. The granted U.S., European, and Chinese claims are directed to IgM antibodies (in the first United States patent) and IgM, IgA and hybrid antibodies (in Australia, Europe, Japan, Mexico, Singapore, and in the second United States patents) comprising a modified J chain with a binding moiety fused or chemically conjugated to selected regions of the J chain. Related claims are being prosecuted in the pending applications.

Two later-filed patent families are related to our “Modified J Chain” family. These two patent families both have a projected expiration date of September 30, 2036, absent any patent term adjustments or extensions. Patent applications in the first of these two families includes disclosure and claims related to multimeric antibodies (e.g., IgM, IgA, or hybrid multimeric antibodies) that include a modified J chain, where the modified J chain includes a binding moiety that modulates a T cell inhibitory pathway, e.g., CTLA4, PD-1, TIM3, LAG3, BTLA, VISTA or TIGIT. This family includes a granted Patent in Europe (validated in Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, and the United Kingdom). Patent applications in this family are pending in the United States, China, and Japan. Patent applications in the second of these two families includes disclosure and claims related to multimeric antibodies (e.g., IgM, IgA or hybrid multimeric antibodies) that include a modified J chain, where the modified J chain includes a moiety that affects adsorption, distribution, metabolism, and/or excretion (ADME) of the multimeric antibody. Exemplary moiety types include, but are not limited to, proteins that increase antibody serum half-life, proteins that affect receptor-mediated transcytosis, and proteins that increase retention of the multimeric antibody in an extravascular space. This patent family also supports product claims covering IGM-2323 (see below). A U.S. patent with claims covering IGM-2323 is granted in the United States. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe and Japan.

Our platform technology portfolio also includes a patent family with disclosure and claims related to J chain and IgM Fc mutations that inhibit binding of IgM to certain multimeric Ig receptors including the Fcαμ receptor, the Fcμ receptor, and the polymeric Ig receptor. The claims are related to IgM and IgM-derived antibodies that include these mutations, and have substantially increased serum half-lives relative to wild type IgM antibodies. The patent applications in this family have a projected expiration date of March 1, 2039, absent any patent term adjustments or extensions. The first of two United States patent applications is allowed, and the family includes pending applications in the United States, Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, and Singapore.

Our platform technology portfolio also includes a patent family that includes disclosure and claims related to IgM antibody Fc modifications that affect the ability of the IgM antibody to trigger complement-dependent cytotoxicity (CDC). Patent applications in this family disclose and claim single and combined human IgM Fc amino acid substitutions that reduce and/or completely inhibit IgM’s typical CDC activity. This application has a projected expiration date of April 6, 2038, absent any patent term adjustments or extensions. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, and Singapore.

Our platform technology portfolio includes an international patent application, filed under the Patent Cooperation Treaty (PCT) that discloses and claims multimeric molecules with non-antibody moieties on an IgM- or an IgA-based scaffold. For example, this application covers IgM or IgA based fusion proteins that include, e.g., ligands, soluble portions of receptors, or cytokines. An exemplary molecule includes an IgM-based scaffold where the IgM heavy chain constant regions are fused to a soluble portion of PD-L1. National stage patents filed from this PCT

application will have a projected expiration date of October 23, 2039, absent any patent term adjustments or extensions. The PCT application is in the international stage and will enter national stage prosecution on or before April 23, 2021 or May 23, 2021, depending on the jurisdiction.

We also own two patent families that include disclosure and claims related to multispecific IgM and IgA antibodies, respectively, where the multispecificity of the assembled IgM or IgA binding domains is created through knobs into holes or salt bridge modifications of the IgM or IgA heavy chain and/or light chain constant regions. The multispecific IgM patent family is titled "Constant Chain Modified Bispecific, Penta- and Hexavalent IgM Antibodies," and is projected to expire on September 4, 2034, absent any patent term adjustments or extensions. This family includes granted patents, in the United States, Australia, Europe (validated in Belgium, Denmark, Finland, France, Germany, Ireland, Luxembourg, the Netherlands, Norway, Sweden, Switzerland, and the United Kingdom), and Japan with claims related to bispecific IgM antibodies with specific heavy and light chain mutations to facilitate formation of bispecific binding regions. Related patent applications are pending in Australia, Brazil, Canada, China, India, and South Korea. The multispecific IgA patent family is titled "IgA Multi-specific Binding Molecules," and is projected to expire on February 10, 2035, absent any patent term adjustments or extensions. The family includes granted patents in the United States, Australia, and Europe (validated in Belgium, Denmark, Finland, France, Germany, Hong Kong, Ireland, Luxembourg, the Netherlands, Norway, Sweden, Switzerland, and the United Kingdom). Patent applications in this patent family are pending in Brazil, Canada, India, and South Korea.

Product Candidates and Discovery Pipeline

Our product candidates and discovery pipeline patent portfolio includes 18 patent families (one family in common with the platform portfolio) including claims directed to our product candidates. These include three patent families with claims directed to IGM-2323 (two published) and three patent families with claims directed to our DR5 IgM antibody product candidates, including IGM-8444 (two published). Our product and discovery pipeline portfolio also includes a granted U.S. patent with claims directed to IgM antibody superagonists specific for TNFrSF targets. As of December 31, 2020, our product and discovery pipeline portfolio includes ten granted patents, 85 applications in active prosecution in 13 countries or regions, one allowed application, three pending PCT applications (one published) and seven unpublished pending U.S. provisional applications. These patent families are projected to expire between 2036 and 2041, absent any patent term adjustments or extensions. We wholly own the rights to these patent families. Summaries of published patent families relevant to our product candidates and our discovery pipeline are provided below.

Two published patent families with claims directed to IGM-2323 have projected expiration dates of March 4, 2036, and September 30, 2036, respectively, absent any patent term adjustments or extensions. The first patent family includes claims directed to multimeric antibodies, e.g., IgM and IgA antibodies, that include the IGM-2323 CD20 antigen binding domains and methods of treating cancer patients with such antibodies. This patent family further discloses antibodies that include a modified J chain, where the modified J chain includes an antigen-binding domain specific for CD3-epsilon. This patent family includes claims that encompass to the IGM-2323 composition, as well as methods of making and using the same. Patents are granted in the United States, Australia, and Japan, that cover IGM-2323. Patent applications in this family are pending in the United States, Australia, Brazil, Canada, China, Europe, India, Israel, Japan, South Korea, New Zealand, and Singapore. The second family (the "ADME" family referred to above under platform applications), includes claims directed to multimeric, e.g., IgM and IgA antibodies, that include the IGM-2323 CD20 antigen binding domains and a modified J chain, where the modified J chain is fused to an antigen-binding domain specific for CD3-epsilon and also to human serum albumin (HSA). The application family also includes claims to methods of making and using the claimed antibodies. A U.S. patent with claims covering IGM-2323 is granted in the United States. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe, and Japan.

Our patent portfolio also includes eight patent families owned by us directed to our TNFrSF superagonist technology and product candidates. The first patent family includes disclosure and claims directed to multimeric superagonist antibodies that bind to any TNFrSF target. This family also includes disclosure and claims directed multimeric superagonist antibodies that bind to DR5 that relate to our DR5 IgM antibody product candidates. The application family, which we own, has a projected expiration date of January 20, 2036, absent any patent term adjustments or extensions, and includes two granted U.S. patents, as well as granted patents in Europe (validated in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, Hungary, Iceland, Ireland,

Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland & Liechtenstein, Turkey, and the United Kingdom), Australia, and Singapore. The claims in the first granted US patent as well as the Australian patent are generically directed to IgM-based TNFrSF superagonists and their use in treating cancer patients. The European patent contains similar claims, as well as claims that relate to our DR5 IgM product candidates, including IGM-8444. The claims in the second granted U.S. Patent and the granted patent in Singapore are directed to DR5 IgM product candidates, including IGM-8444. The patent family is also pending in Australia, Canada, China, Europe, India, Israel, Japan, South Korea, New Zealand, and Singapore, with claims relating broadly to TNFrSF superagonists and also to DR5 superagonists.

Four patent families are each directed to a specific TNFrSF target, OX40, GITR, CD137/4-1BB, and CD40, respectively, and have projected expiration dates of either July 19, 2037 or July 20, 2037, absent any patent term adjustments or extensions. The OX40 family has a projected expiration date of July 20, 2037, absent any patent term adjustments or extensions, and includes claims directed to a variety of different multimeric OX40 superagonist antibodies and their use for treating cancer patients. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe India, Israel, Japan, Mexico, and New Zealand. The GITR family has a projected expiration date of July 20, 2037, absent any patent term adjustments or extensions, and includes claims directed to a variety of different multimeric GITR superagonist antibodies and their use for treating cancer patients. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe India, Israel, Japan, Mexico, and New Zealand. The CD137/4-1BB family has a projected expiration date of July 19, 2037, absent any patent term adjustments or extensions, and includes claims directed to a variety of different multimeric CD137/4-1BB superagonist antibodies and their use for treating cancer patients. Patent applications in this family are pending in the United States, Australia, Canada, and Europe. The CD40 family has a projected expiration date of July 19, 2037, absent any patent term adjustments or extensions, and includes claims directed to a variety of different multimeric CD40 superagonist antibodies and their use for treating cancer patients. Patent applications in this family are pending in the United States, Australia, Canada, and Europe.

Our patent portfolio includes a patent family directed to combination cancer therapies that include a DR5 superagonist antibody, e.g., our DR5 IgM antibody product candidates, including IGM-8444, in combination with a chemotherapeutic agent, e.g., irinotecan, gemcitabine, or Venetoclax. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe, Japan, and South Korea. This family has a projected expiration date of February 25, 2039, absent any patent term adjustments or extensions.

Our patent portfolio also includes two patent families (one published) related to IGM-7354, our IL-15 x PD-L1 bispecific IgM antibody. The first patent family is directed to the identification and characterization of novel PD-L1 antibodies. This application family, titled “Anti-PD-L1 Antibodies,” has a projected expiration date of May 9, 2037, absent any patent term adjustments or extensions. Patent applications in this family are pending in the United States, Australia, Canada, China, Europe, India, Israel, Japan, South Korea, New Zealand, and Singapore.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against any third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the expiration of the patent, insofar as the patent covers the FDA-approved product. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products. While we plan to seek patent term extensions on any of our issued patents in any jurisdiction where these are available, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted and, if granted, the length of such extensions.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. We may therefore not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specified circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development, commercial strategies, drugs or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material 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 derivation proceedings in the USPTO to determine priority of invention.

For more information on these risks and other comprehensive risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

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 our product candidates.

U.S. Biologics Regulation

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 (GLP) regulation;
- 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 independent institutional review board (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 Biologics License Application (BLA) after completion of all pivotal 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 cGMPs 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 good clinical practices (GCPs); and
- FDA review and approval of a 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, 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 or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, 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 period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

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. 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 preclinical studies and clinical trials 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 and distribution of the investigational product in humans, to identify possible 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 and Review

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 studies and clinical trials, 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 the 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, 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 is often 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 GCPs. 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

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat patients with a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat patients with a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, 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 (as compared to ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating patients with 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.

Fast track designation, breakthrough therapy designation, priority review and regenerative medicine advanced therapy (RMAT) designation do not change the standards for approval but may expedite the development or approval process. 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 or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat patients with 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 drug designation must be requested before submitting a BLA. After the FDA grants orphan drug 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 shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic 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 or 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. Orphan drug exclusivity does not prevent the 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 drug may not receive orphan drug 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 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 the 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 cGMPs, 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 cGMPs 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 cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, 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, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions 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 (ACA) includes a subtitle called the 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 an approach to 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 are subject to significant uncertainty.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute, the federal False Claims Act, the Health Insurance Portability and Accountability Act (HIPAA) and similar foreign, federal and state fraud and abuse, transparency and privacy laws.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value, including stock options. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, 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 federal 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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, 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.

Civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent. For example, the federal False Claims Act prohibits any person or entity from knowingly

presenting, or causing to be presented, a false claim for payment to the federal government or 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. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare 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.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations, impose certain requirements on HIPAA covered entities, which include certain healthcare providers, healthcare clearing houses and health plans, and individuals and entities that provide services on their behalf that involves individually identifiable health information, known as business associates, relating to the privacy, security and transmission of individually identifiable health information.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Center for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to cover recipients, as defined by law, including physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective in 2022, these reporting obligations will be expanded to include payments and transfers of value made during the previous year to certain non-physician covered recipients, including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product. No regulatory authority has granted approval for a personalized cancer immunotherapy based on a vaccine approach, and there is no model for reimbursement of this type of product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, 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, a new licensure framework for follow on biologic products, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in November 2020, the United States Supreme Court held oral arguments on the ACA case from the U.S. Court of Appeals for the 5th Circuit, which upheld the District Court ruling that the individual mandate is unconstitutional, and is expected to issue a decision by mid-2021. It is uncertain how the Supreme Court will rule on this case. We cannot predict how this decision or future litigation will impact our business, or what other healthcare measures and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation may have on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional action is taken by Congress.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, for example, 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. 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. In 2020, HHS and CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and

manufacturers, importation of prescription drugs from Canada and other countries, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of these new rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the current administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the biopharmaceutical industry as a whole is unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, the Right to Try Act, which was enacted on May 30, 2018, provides a federal framework for certain patients with life-threatening diseases to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Employees and Human Capital

As of December 31, 2020, we had 107 full-time employees, 85 of whom were engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our employees. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to remain focused on corporate objectives and to achieve our corporate objectives.

Corporate Information

IGM Biosciences, Inc. was incorporated in Delaware in 1993 under the name Palingen, Inc. In December 2017, we established a Danish holding company (IGM Biosciences A/S (Holdco)); in April 2019, we dissolved Holdco.

Our principal executive offices are located at 325 E. Middlefield Road, Mountain View, California 94043, and our telephone number is (650) 965-7873. Our website address is www.igmbio.com.

IGM Biosciences, the IGM logo and our other registered or common law trademarks, trade names or service marks appearing in this Annual Report on Form 10-K are owned by us. This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, generally appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy and information statements and amendments to reports filed pursuant to Sections 13(a), and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act) are filed with the U.S. Securities and Exchange Commission (SEC). We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. Such documents and other information filed by us with the SEC are available free of charge on the Investor section of our website (investor.igmbio.com) when such reports are available on the SEC's website.

Investors and others should note that we may announce material information to the public through filings with the SEC, our website (www.igmbio.com), press releases, public conference calls, and public webcasts. We encourage our investors and others to review the information disclosed through such channels as such information could be deemed to be material information. Please note that this list may be updated from time to time.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. If any of these risks occur, our business, financial condition and operating results could be harmed, the trading price of our common stock could decline and you could lose part or all of your investment.

Risk Factor Summary

Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following:

- The COVID-19 pandemic, or other epidemic and pandemic diseases, could significantly disrupt our business.
- We are early in our development efforts and all of our product candidates are in preclinical development or early stage clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and commercialize one or more of our product candidates, our business will be materially adversely affected and we may never generate any product revenue.
- The use of engineered IgM antibodies is a novel and unproven therapeutic approach and our development of IGM-2323, IGM-8444, IGM-7354 and our discovery programs may never lead to a marketable product.
- Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval.
- If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, including as a result of competition for patients, we will be unable to complete these trials on a timely basis, if at all.
- Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public for any indication.
- We face significant competition from entities that have developed or may develop product candidates for the treatment of diseases that we are initially targeting, including companies developing novel treatments and technology platforms. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.
- The manufacturing of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.
- We may not be successful in our efforts to use and expand our IgM platform to build a pipeline of product candidates.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Risks Related to Our Business and the Development and Commercialization of Our Product Candidates

The COVID-19 pandemic could adversely impact our business, including our ongoing and planned clinical trials and preclinical research.

In December 2019, a novel strain of coronavirus (SARS-CoV-2) was reported to have surfaced in Wuhan, China, causing the disease COVID-19. Since then, the virus has spread widely, resulting in the World Health Organization characterizing COVID-19 as a pandemic. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration and severity of outbreaks, travel restrictions and social distancing in the United States and other countries, temporary closures of our facility, the facilities of our partners, clinical trial sites, service providers, suppliers or contract manufacturers or other business disruptions due to outbreaks of COVID-19, other related restrictions imposed by governments due to the COVID-19 pandemic and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise. As a result of the COVID-19 restrictions in California, the commencement of the build-out of our cGMP manufacturing facility in Mountain View was delayed by a few months, and if similar restrictions are reimposed or we experience further delays as a result of the COVID-19 pandemic, the timeline for the facility becoming fully operational could be negatively affected. As the COVID-19 pandemic continues, we could experience other disruptions that could severely impact our business, current and planned clinical trials and preclinical research, including:

- delays or difficulties in enrolling and retaining patients in our ongoing and planned clinical trials, and incurrence of additional costs as a result of any preclinical study and clinical trial delays and adjustments;
- challenges related to ongoing and increased operational expenses related to the COVID-19 pandemic;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays, outbreaks of COVID-19, shutdowns or continued business disruptions experienced by ourselves and our collaborators, third party manufacturers, suppliers and other providers, clinical trial sites, regulators and other third parties with whom we conduct business, which could materially and negatively impact our ability to conduct our business in the manner and on the timelines presently planned;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption or delays of key clinical trial activities, such as clinical trial site monitoring and collecting sufficient clinical data, due to the spread of COVID-19, patient safety considerations or limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations on resources that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people or restrictions on movement or access to our facilities as a result of government-imposed “shelter in place” or similar working restrictions;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research or to support manufacturing activities of our business and that of our suppliers or contractor;
- changes in clinical site policies and procedures for conducting clinical trials during the pandemic;

- changes in regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trial is conducted and incur unexpected costs, or require us to discontinue the clinical trial altogether; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations on employee resources or furlough of government or contractor personnel.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, the FDA has issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, and includes reporting requirements, and additional guidance on the Good Manufacturing Practice considerations for responding to COVID-19 infection and other topics. We may be required to make further adjustments to our clinical trials or business operations based on current or future guidance and regulatory requirements as a result of the COVID-19 pandemic.

In addition, our operations, and those of our contract research organizations (CROs), commercial manufacturing organizations (CMOs) and other contractors, consultants, and third parties could be subject to orders or restrictions imposed by the federal, state, local, or foreign government as a result of the COVID-19 pandemic. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers and suppliers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates and other supplies required for our manufacturing or testing operations could be disrupted if the operations of our suppliers or contractors are affected by the COVID-19 pandemic. Efforts to accelerate COVID-19 vaccine production and distribution, such as Operation Warp Speed, have affected the availability of certain materials used in the manufacture of our product candidates, resulting in manufacturing delays. If we, or our third-party suppliers and contract manufacturers, are unable to source necessary materials on a timely basis, we may experience further delays in our ability to manufacture our product candidates, which could affect the pace of our clinical trials until such materials once again become available.

While the extent of the impact of the current COVID-19 outbreak on our business and financial results is uncertain, we will continue to assess the impact that COVID-19 may have on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to avoid a material impact on our business, financial condition and operating results from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry.

We are early in our development efforts and all of our product candidates are in preclinical development or early stage clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and commercialize one or more of our product candidates, our business will be materially adversely affected and we may never generate any product revenue.

We are early in our development efforts and have not yet completed the development of any of our product candidates. As a result, we are not currently permitted to market or sell any of our product candidates in any country, and we may never be able to do so in the future. We have a limited number of product candidates and discovery programs, all of which are in preclinical development or early stage clinical development. We continue to dose patients in each of our Phase 1 clinical trials evaluating IGM-2323 and IGM-8444, our first two lead product candidates, but have not commenced any other clinical trial or completed any clinical trials, and we have not received marketing approval, for any of our product candidates. Our product candidates will require clinical development, evaluation of preclinical, clinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales, if ever. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals. Our ability to generate product revenue and achieve and sustain profitability depends on, among other things, obtaining regulatory approvals for our product candidates. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following:

- completing process development, manufacturing and formulation activities;
- initiating, enrolling patients in and completing clinical trials of product candidates on a timely basis;

- developing and maintaining adequate manufacturing capabilities either by ourselves or in connection with third-party manufacturers; and
- demonstrating with substantial evidence the efficacy, safety and tolerability of product candidates to the satisfaction of the FDA or any comparable foreign regulatory authority for marketing approval.

Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to develop product candidates at all, and our business will be materially adversely affected.

The use of engineered IgM antibodies is a novel and unproven therapeutic approach and our development of IGM-2323, IGM-8444, IGM-7354 and our discovery programs may never lead to a marketable product.

Our product candidates are based on engineered IgM antibody approaches that differ from current antibody therapies and are unproven. Our IgM antibodies ultimately may not be as safe or effective as IgG antibodies that have been approved or may in the future be approved by the FDA. Further, we are not aware of any therapeutic IgM antibodies that have been approved by the FDA. The scientific evidence to support the feasibility of developing our product candidates and discovery programs is both preliminary and limited. We may ultimately discover that our product candidates and discovery programs do not possess some of the properties that are necessary for therapeutic efficacy, and we may also discover that they do not possess those characteristics that we believe may be helpful for therapeutic effectiveness, including stronger binding that increases efficacy. Our IgM antibodies may also have significant undesirable characteristics, such as immunogenicity, which would limit their ability to be developed as effective and safe therapeutics. In addition, we may discover that our IgM antibodies are not as safe as IgG antibodies.

We may not succeed in demonstrating safety and efficacy of these product candidates or discovery programs in clinical trials, notwithstanding results in preclinical studies. As a result, we may never succeed in developing a marketable product. We may discover that the half-life, tissue distribution or other pharmacodynamic or pharmacokinetic characteristics of our IgM antibodies render them unsuitable for the therapeutic applications we have chosen or are not competitive with IgG antibodies. We may also experience manufacturing, formulation or stability problems with one or more of our IgM antibodies which may render them unsuitable for use as therapeutic drug products.

The FDA has limited experience with IgM antibody-based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, the FDA may require us to provide additional data to support our regulatory applications. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be subject to post-marketing testing requirements to maintain regulatory approval. In addition, upon obtaining any marketing approvals, we may have difficulty in establishing the necessary sales and marketing capabilities to gain market acceptance.

Moreover, advancing IGM-2323, IGM-8444, IGM-7354 and our discovery programs as novel products creates other significant challenges for us, including educating medical personnel regarding a novel class of engineered antibody therapeutics and their potential efficacy and safety benefits, as well as the challenges of incorporating our product candidates, if approved, into treatment regimens.

If any of our product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, and it may prove to be difficult or impossible to finance the further development of our pipeline. Any of these events would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive and difficult to design and implement. Clinical testing can take many years to complete, and its ultimate outcome is uncertain.

A failure of one or more clinical trials can occur at any stage of the process. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Interim or preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

In October 2019, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-2323, our lead product candidate, for the treatment of relapsed/refractory B cell NHL patients, and, in September 2020 we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-8444, our second product candidate, for the treatment of patients with solid cancers and NHL. We expect to file an IND for IGM-7354 for the treatment of patients with solid and hematological malignancies in 2021. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of these clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indication as our product candidates;

- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board (IRB) approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the inability to produce or obtain sufficient quantities of a product candidate to complete clinical trials;
- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial; and
- the impact of, and delays related to, health epidemics such as the COVID-19 pandemic;
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic partners that have responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including as a result of competition for patients, we will be unable to complete these trials on a timely basis, if at all.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the proximity of subjects to clinical sites, continued enrollment of prospective patients by clinical trial sites, efforts to facilitate timely enrollment, the eligibility criteria for the trial, the design of the clinical trial, patient referral practices of physicians, ability to obtain and maintain patient consents, ability to monitor patients adequately during and after treatment, risk that enrolled subjects will drop out before completion and clinicians' and patients' perceptions as to the potential advantages and disadvantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. In addition, enrollment of patients in our clinical trials and maintaining patients in our ongoing clinical trial could be delayed or limited as our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. Further, patients may not be able to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic.

In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. Moreover, because our product candidates represent a departure from existing cancer treatments, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, IgG antibody therapy or CAR-T treatment, rather than enroll patients in our clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. If we are unable to enroll a sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for such product candidates and our business will be harmed. Even if we are able to enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public for any indication.

All of our product candidates and discovery programs are in preclinical development or early stage clinical development, and not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from our product candidates could arise at any time during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. In October 2019, we announced the dosing of the first patient in our Phase 1 clinical trial of our lead product candidate, IGM-2323, and in September 2020, we announced the dosing of the first patient in our Phase 1 clinical trial of our second product candidate, IGM-8444. We only have initial safety data in humans from our Phase 1 clinical trial of IGM-2323 and we do not yet have any extensive safety data in humans from our Phase 1 clinical trial of IGM-8444. IGM-7354 and our discovery programs have not been tested on humans at all. While we are encouraged by the safety profile of IGM-2323 in our Phase 1 clinical trial to date, and we have observed a relatively low rate of cytokine release syndrome (CRS) in the 25 patients dosed to date, two patients have experienced more serious CRS, one patient with Grade 2 CRS and one with Grade 3 CRS. Both patients were almost unique among the patients participating in our clinical trial in that they had been previously treated with CAR-T drugs and had circulating B cells at the time of their participation in the trial. The only other patient who had been previously treated with CAR-T drugs and had circulating B cells at the time of treatment had Grade 1 CRS, and this DLBCL patient achieved a complete response. The two patients who had been previously treated with a CAR-T drug but did not have circulating B cells at the time of participation in the trial did not

experience any CRS. While this observation is preliminary, particularly given the small number of patients, we are taking steps to address possible CRS in those patients who have been previously treated with CAR-T drugs or have circulating B cells. It is possible that these steps or other steps that we take may not be successful, and we may see additional cases of serious CRS in future patients.

In our preclinical studies, we may observe undesirable characteristics of our product candidates. This may prevent us from advancing them into clinical trials, delay these trials or limit the extent of these trials. Despite our preclinical data, toxicity observations in clinical testing, if they occur, may limit our ability to develop IGM-2323, IGM-8444, IGM-7354 or any of our other product candidates or may constitute a dose limiting toxicity.

The results of ongoing or future clinical trials may also show that IGM-2323, IGM-8444, IGM-7354 and/or our discovery programs may cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable foreign regulatory authorities, or result in marketing approval from the FDA or comparable foreign regulatory authorities with restrictive label warnings or for limited patient populations, or result in potential product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication.

Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, limit the patient population who can use the product or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products.

We face significant competition from entities that have developed or may develop product candidates for the treatment of diseases that we are initially targeting, including companies developing novel treatments and technology platforms. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The development and commercialization of drugs and therapeutic biologics is highly competitive and subject to rapid and significant technological change. We are currently developing biotherapeutics that will compete with other drugs and therapies that currently exist or are being developed in the segments of the pharmaceutical, biotechnology and other related markets that develop oncology treatments. Product candidates we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory

approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do.

There are a large number of companies developing or marketing treatments for cancer, including most major pharmaceutical and biotechnology companies, as well as many smaller biotechnology companies. These treatments consist both of small molecule drug products as well as biologics that work by using antibody therapeutic platforms to address specific cancer targets. In addition, many companies, including large pharmaceutical and biotechnology companies such as AbbVie, Amgen, AstraZeneca, Bristol-Myers Squibb, Merck, Novartis, Pfizer and Roche/Genentech, are also developing treatments for cancer.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (*e.g.*, T cell engagers), adoptive cellular therapies (*e.g.*, CAR-T), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin and targeted cancer vaccines.

With respect to our lead product candidate, IGM-2323, we are aware of other companies with competing clinical stage therapeutics that target CD20 that include, but are not limited to, Roche/Genentech, Regeneron, Xencor and Genmab.

With respect to our second product candidate, IGM-8444, we are aware of other companies with competing clinical stage therapeutics that target DR5 that include, but are not limited to, AbbVie, InhibRx, Genmab, Clover Biopharmaceuticals, Boehringer Ingelheim and Bejing Sunbio Biotech.

With respect to IGM-7354, we are aware of other companies with competing clinical stage therapeutics that utilize targeted and untargeted IL-15 that include, but are not limited to, Roche/Genentech, Kadmon, Nektar, Xencor, ImmunityBio and Cytune Pharma.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than the products that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

The manufacturing of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.

We have spent significant resources to date on developing our current manufacturing processes and know-how to produce sufficient yields and optimize functionality in conjunction with our contract manufacturers. We have completed construction of our own cGMP manufacturing facility to produce some of our product candidates to conduct our clinical trials although it is not yet operational. We plan to construct additional manufacturing facilities to produce commercial supply for any approved products. To do so, we will need to scale our manufacturing

operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient yields needed to advance all of our product candidates and discovery programs in preclinical studies and clinical trials. Accordingly, we will be required to make significant further investments to expand our manufacturing facilities in the future, and our efforts to scale our internal manufacturing capabilities may not succeed.

Also, historically IgM antibodies have been particularly difficult to manufacture and CMOs have limited experience in the manufacturing of IgM antibodies. The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

All of our engineered antibodies are manufactured by culturing cells from a master cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP. It is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks, and we may fail to have adequate backup should any particular cell bank be lost in a catastrophic event. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts and the use of engineered IgM antibodies is a novel therapeutic approach. Failure to develop our own manufacturing capacity may hamper our ability to further process improvement, maintain quality control, limit our reliance on contract manufacturers and protect our trade secrets and other intellectual property.

We may not be successful in our efforts to use and expand our IgM platform to build a pipeline of product candidates.

A key element of our strategy is to leverage our IgM platform to expand our pipeline of antibody product candidates. Although our research and development efforts to date have resulted in a pipeline of product candidates, we may not be able to develop product candidates that are safe and effective. In addition, although we expect that our IgM platform will allow us to continue to develop a steady stream of product candidates, we may not prove to be successful at doing so. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, be competitive with alternatives, or otherwise achieve market acceptance. If we do not successfully develop and begin to commercialize product candidates, we will not be able to generate any product revenue, which would adversely affect business.

We may expend our limited resources to pursue product candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our programs, we must focus our programs on specific product candidates and indications and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or indications may not lead to the development of any viable commercial product and may divert resources away from better opportunities. For example, we are currently investing in a discovery program targeted at COVID-19, but may not ultimately pursue product candidates from this program, even if they appear to be safe and effective, if we believe that there is no longer a market need or opportunity for such a therapeutic. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the oncology or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable

commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the business, research and development and clinical expertise of Mr. Fred Schwarzer, our Chief Executive Officer, Dr. Bruce Keyt, our Chief Scientific Officer, Dr. Daniel Chen, our Chief Medical Officer, Mr. Misbah Tahir, our Chief Financial Officer, and Dr. Lisa Decker, our Chief Business Officer, as well as other members of our senior management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing, and sales and marketing personnel, and we face significant competition for experienced personnel. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Intense competition for attracting key skill-sets may limit our ability to retain and motivate these key personnel on acceptable terms.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. This high cost of living will increase the difficulty of attracting experienced personnel to our company, and we may be required to expend significant financial resources in our employee recruitment and retention efforts.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards 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 yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned or future clinical trials conducted with the altered materials. 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 our product candidates and jeopardize our ability to commence product sales and generate revenue.

The design or execution of our clinical trials may not support regulatory approval.

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in potential future Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. Failure to successfully obtain regulatory approval could have a material adverse impact on our business and financial performance.

Even if any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive price and otherwise will be accepted in the market. The antibodies we are developing use relatively new technologies. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our technologies, and the medical community and third-party payors may not accept and use, or provide favorable reimbursement for, any product candidates developed by us. The commercial success of our product candidates will depend upon their acceptance among physicians, patients, the medical community and third-party payors. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- limitations or warnings contained in the approved labeling for our product candidates;
- changes in the standard of care for the targeted indications for our product candidates;
- the clinical indications for which any product candidate is approved;
- lack of significant adverse side effects;
- the effectiveness of sales and marketing efforts;
- availability and extent of coverage and adequate reimbursement, as well as pricing, by managed care plans and other third-party payors, including government authorities;
- patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payors;
- timing of market introduction of our product candidate as well as competitive products;
- the potential and perceived advantages of our product candidate over alternative treatments;
- the degree of cost-effectiveness of our product candidate;

- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which any product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second or third-line therapy for particular indications;
- whether our product candidate can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidate or favorable publicity about competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the approval of other new therapies for the same indications;
- relative convenience and ease of administration of our product candidates; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and third-party payors, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for IGM-2323, IGM-8444, IGM-7354 or future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We may seek Orphan Drug Designation for certain indications for our product candidates in the future. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Generally, if a product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time. There are also limited circumstances where the FDA may reduce the seven-year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Historically, development of IgM antibodies has been limited by difficulties in recombinant expression and manufacture of these antibodies; therefore, the FDA may determine that we cannot assure the availability of sufficient quantities of our product candidates to the extent necessary to support marketing exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and approval standards. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would 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. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If reimbursement is not available or is not sufficient for our products, it is less likely that our products will be widely used.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Third-party payors, such as government healthcare programs, private health insurers and health maintenance organizations, decide which drugs they will cover and establish the level of reimbursement for such drugs. One third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. We cannot be certain that coverage and reimbursement will be available or adequate for any products that we develop. If coverage and adequate reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates, if approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future change to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors, including both government-funded and private payors, for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We focus our product candidate development on therapeutic IgM antibodies. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new developments, such as the development of vaccines or new therapeutics, may change the estimated incidence or prevalence of the diseases targeted by our programs. The number of patients may turn out to be lower than expected. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. The FDA often approves new cancer therapies only for use after one or more other treatments have failed. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy or surgery, is sometimes adequate to treat the patient. If first-line therapy proves unsuccessful, second-line therapies, such as additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these therapies, may be administered. Third- or fourth-line therapies may include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We may initially seek approval of our product candidates for patients who have failed one or more approved treatments. For instance, in October 2019, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-2323 for the treatment of relapsed/refractory B cell NHL patients, and in September 2020, we announced the dosing of the first patient in our Phase 1 clinical trial of IGM-8444 for the treatment of patients with solid cancers and NHL. Even if we obtain regulatory approval and significant market share for IGM-2323 or IGM-8444, because the potential target population may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. In addition, there is no guarantee that any of our product candidates, even if approved, would be approved as a particular line of treatment. In addition, even if any of our product candidates were approved for a particular line of treatment, we would likely have to conduct additional clinical trials prior to gaining approval as an earlier line of treatment.

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which will result in significant additional expense.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product.

For any approved product, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMPs and current good clinical practices (cGCP) for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- adverse publicity, fines, warning letters or holds on clinical trials;
- refusal by the FDA, EMA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off-label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the FDA's or comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or 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, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability.

If any product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and we will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for any future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny, including investigations by the FDA and other regulators of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls, a change in the indications for which they may be used or suspension or withdrawal of marketing approvals;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

We may need to have in place increased product liability coverage if and when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

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

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." Under this statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full Biologics License Application (BLA) for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, efficacy and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for a referenced product may be reduced to seven years.

Acquisitions or joint ventures could increase our capital requirements, disrupt our business, cause dilution to our stockholders, cause us to incur debt or assume contingent liabilities and otherwise harm our business.

We evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with any strategic partners or suppliers as a result of such a transaction;
- the assumption of additional indebtedness or contingent or otherwise unanticipated liabilities related to acquired companies;
- the issuance of our equity securities;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals;
- increases in our expenses and reductions in our cash available for operations and other uses;

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Future credit arrangements may restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. Moreover, we may not be able to identify suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly those in the European Union, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

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

As of December 31, 2020, we had 107 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. Additionally, as our product candidates and discovery programs enter and advance through preclinical studies and any clinical trials, we will need to expand our research, development, manufacturing, regulatory and sales and marketing capabilities or contract with other organizations to provide these capabilities for us. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their 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, which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates and discovery programs. If our management is unable to effectively manage our expected 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 our product candidates and

compete effectively with others in our industry will depend on our ability to effectively expand our organization and manage any future growth.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we or our CROs may collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by us. We manage and maintain our applications and data by utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. We face multiple risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls over these risks.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any third-party billing and collections provider we may utilize, may be vulnerable to cybersecurity attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), mandatory notification and reporting obligations, additional regulatory oversight, significant regulatory penalties and remediation expenses. There is no guarantee that we can protect our systems from breach. Unauthorized access, loss or dissemination of information or any mechanical failure of our or our third-party service providers' information technology systems could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, the European Union, and elsewhere are often uncertain, contradictory and in flux. For example, the California Consumer Privacy Act (the CCPA), which went into effect on January 1, 2020, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Aspects of the CCPA, and its interpretation and enforcement remain uncertain. The effects of this legislation potentially are far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA has been amended on multiple occasions, and it is unclear whether it will be further amended. California recently passed the California Privacy Rights Act (CPRA), which modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California consumers. It is possible that these consumer, health-related and data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations vary between states, may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Furthermore, the loss of clinical trial data from ongoing, completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates, if approved, and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change healthcare systems in ways that could affect our ability to sell any of our product candidates profitably, if such product candidates are approved for sale. 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 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.

In March 2010, the ACA was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry. Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price (AMP), for most branded and generic drugs, respectively;
- Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand 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;
- 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 certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- requirement that applicable manufacturers and group purchasing organizations report annually to the Centers for Medicare & Medicaid Services (CMS), information regarding certain payments and other transfers of value given to physicians and teaching hospitals, and any ownership or investment interest that physicians, or their immediate family members, have in their company;
- a requirement that manufacturers and authorized distributors of applicable drugs annually report information related to samples provided to practitioners;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending

Since its enactment, there remain judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. The Supreme Court is expected to issue a decision on this case by mid-2021. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 due to subsequent legislative amendments will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in 2020, the HHS and CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the current administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the biopharmaceutical industry as a whole is unclear.

In the European Union similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products and third-party payors' reimbursement policies might adversely affect our ability to sell any future products profitably.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

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 the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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 the SEC and other government agencies on which our operations may rely, including those 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 adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical 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 have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business may be subject to risks associated with conducting business internationally. Some of our clinical trial sites as well as some of our suppliers and collaborators, are located outside of the United States. We may also enter into additional non-U.S markets. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country’s or region’s political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes, including price controls;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- difficulties associated with staffing and managing foreign operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires, or outbreaks of health epidemics such as the COVID-19 pandemic.

Our business and current and future relationships with customers and third-party payors in the United States and elsewhere will be subject, directly or indirectly, to applicable federal and state anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research on product candidates and market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens on behalf of the government, through civil whistleblower, or qui tam actions, and the federal civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities, among other things, for knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that create, receive, maintain or transmit individually health information for or on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to “payments or other transfers of value” made to covered recipients, such as physicians (defined to include doctors, dentists, optometrists,

podiatrists and chiropractors) and teaching hospitals, and further that such applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members. The information reported annually is publicly available on a searchable website. Effective in 2022, these reporting obligations will be expanded to include payments and transfers of value made during the previous year to certain non-physician covered recipients, including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives;

- analogous state and foreign laws and regulations, including: 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 state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information relating to pricing and marketing information; and
- state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to

recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Business or economic disruptions could seriously harm our business and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, clinical trial sites, suppliers, regulators, and other third parties with whom we engage, could be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, epidemics, pandemics such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, CROs, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

All of our operations including our corporate headquarters are located in Mountain View, California. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. We do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

We have incurred significant losses since our inception. Our net loss for the years ended December 31, 2020, 2019, and 2018 was $81.4 million, $43.1 million and $22.7 million, respectively. As of December 31, 2020, our accumulated deficit was approximately $188.6 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate product revenue or achieve profitability. For example, our expenses could increase if we are required by the FDA to perform clinical trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in-house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have exclusively related to the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform. We are still in the early stages of developing our product candidates, and we have not completed development of any product

candidate. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Our ability to generate revenue and achieve profitability depends in large part on our ability, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenue from sales of products for the foreseeable future.

To generate product revenue and become and remain profitable, we must succeed in developing and commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including:

- successfully completing preclinical and clinical development of our product candidates in a timely manner;
- obtaining regulatory approval for such product candidates in a timely manner;
- satisfying any post-marketing approval commitments required by applicable regulatory authorities;
- developing an efficient, scalable and compliant manufacturing process for such product candidates, including expanding and maintaining manufacturing operations, commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- successfully launching commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining a continued acceptable safety profile following any marketing approval;
- achieving commercial acceptance of such product candidates as viable treatment options by patients, the medical community and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio, including our licensed intellectual property;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and
- attracting, hiring and retaining qualified personnel.

We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations.

All of our product candidates and discovery programs are in preclinical development or early stage clinical development. Developing drug products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates, which will increase our expenses. We will continue to require additional funding to complete the development and commercialization of our product candidates, to continue to advance our discovery programs, to expand our manufacturing facilities and to satisfy additional costs that we have incurred and expect to continue to incur in connection with operating as a public company. Such funding may not be available on acceptable terms or at all.

As of December 31, 2020, we had $366.3 million in cash and investments. We believe that our existing cash and investments will enable us to fund our operating expenses and capital expenditure requirements for at least one year past the issuance date of the financial statements included in this Form 10-K. Our estimate as to how long we expect our cash and investments to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. In addition, because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates, including expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and cost of capital expenditures to support our research, development and manufacturing efforts;
- the number and characteristics of other product candidates that we pursue;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide related to the COVID-19 pandemic;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through one or more public and private equity offerings, debt financings and strategic partnerships. We do not have any committed external source of funds. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our clinical or discovery programs or our business operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

We may from time to time raise additional capital through the sale of equity or convertible securities. If we issue additional shares of common stock at a discount from the current trading price of our common stock, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at

such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. In November 2020, our registration statement on Form S-3 (File No. 333-249863) was declared effective by the SEC, pursuant to which we may offer debt securities, preferred stock, common stock and certain other securities from time to time, up to a maximum aggregate amount of $400,000,000. On December 11, 2020, pursuant to the Form S-3 that was filed, we completed a public offering of 1,221,224 shares of our common stock, which included the exercise of the underwriters' option to purchase 333,333 shares in full, and pre-funded warrants to purchase an additional 1,334,332 shares of common stock for aggregate gross proceeds of $230.0 million. After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately $14.6 million, the aggregate net proceeds from our December 11, 2020 public offering were approximately $215.4 million.

If in the future we issue shares of common stock or securities convertible into common stock, our stockholders would experience dilution and, as a result, the market price of our common stock may decline. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock. Additionally, our stockholders may be further diluted by the exercise of the pre-funded warrants issued in December 2020 (see Note 7 to our financial statements included in this Form 10-K).

Further, if we raise additional capital through the sale of equity or convertible securities, the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available at all, may involve fixed payment obligations or agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through partnerships, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2020, we had $366.3 million of cash and investments. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or investments since December 31, 2020, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and general economic downturn.

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

As of December 31, 2020, we had net operating loss (NOL) carryforwards available to reduce future taxable income, if any, for federal and California income tax purposes of approximately $141.2 million and $129.4 million, respectively. At December 31, 2020, we also had federal and California research and development tax credit carryforwards of $8.3 million and $5.4 million, respectively, available to offset future income tax, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change," the corporation's ability to use its NOLs and other pre-change tax attributes such as research tax credits to offset its post-change taxable income or taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. We completed a Section 382 study and believe we have experienced two changes in ownership (see Note 1 to our financial statements included in this Form 10-K). Consequently, we may be limited in our ability to use our NOL carryforwards and other tax assets in a future year, if taxable income in that given year exceeds our cumulative 382 NOL utilization limit through that specific year. As a result, even if we attain profitability, it is possible 382 limitations on the ability to use our NOL carryforwards and other tax assets could adversely affect our future cash flows. In addition, our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. The Tax Cuts and Jobs Act of 2017 (Tax Act), as modified by the CARES Act, imposes certain limitations on the deduction of NOLs, including a limitation on use of NOLs generated in tax years that began on or after January 1, 2018 to offset 80% of taxable income in tax years beginning on or after January 1, 2021 and disallowance of carryback of NOLs arising in tax years beginning on or after January 1, 2021.

Changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our business, results of operations and financial condition.

Changes to U.S. tax laws that may be enacted in the future could impact the tax treatment of our foreign earnings. If we expand our international business activities, any changes in the U.S. taxation of such activities may increase our worldwide effective tax rate and adversely affect our business, results of operations and financial condition. On December 22, 2017, President Trump signed into law the Tax Act, which significantly revised the Code. The Tax Act, among other things, includes changes to U.S. federal tax rates and the taxation of foreign earnings and limitations on the deductibility of interest expense and modifies or repeals many business deductions and credits.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act (FFCR Act) and the CARES Act were enacted in March 2020. Both contain numerous tax provisions. In particular, the CARES Act modifies certain NOL-related provisions in the Tax Act, as described above, and relaxes the limitation on the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income for tax years beginning in 2019 or 2020.

Regulatory guidance under the Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. It is also possible that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the FFCR Act or the CARES Act.

Risks Related to Our Dependence on Third Parties

We currently rely on third-party manufacturers to produce our product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

We currently have limited in-house manufacturing experience and personnel. While we are in the process of operationalizing our own cGMP manufacturing facility for the manufacture of clinical trial drug materials, we expect to continue to rely for some time on third parties to manufacture our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and may do so for the commercial manufacture of some of our product candidates, if approved. To date, we have obtained bulk drug substance (BDS) for IGM-2323 and IGM-8444 from a single-source third-party contract manufacturer, and we expect to obtain BDS

for IGM-7354 from single-source third-party contract manufacturers as well. Any reduction or halt in supply of BDS from either of these contract manufacturers could severely constrain our ability to develop our product candidates until a replacement contract manufacturer is found and qualified. In addition, we currently rely on a third-party contract research organization for the conduct of our clinical assays and we have experienced, and may continue to experience, delays and interruptions, as well as quality and design errors, in this supply of information to us. If we are unable to arrange for and maintain such third-party manufacturing and analytical sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or clinical sample analysis data, or we may be delayed in doing so. If we are unable to arrange for and maintain such third-party manufacturing sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. If we were to experience an unexpected loss of supply of our product candidates, for any reason, whether as a result of manufacturing, supply or storage issues, the impacts of the COVID-19 pandemic or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Such failure or substantial delay or loss of supply could materially harm our business.

Reliance on third-party manufacturers entails risks to which we may not be subject if we manufactured product candidates ourselves, including:

- the possible failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- reliance on the third party for regulatory compliance and quality control and assurance and failure of the third party to comply with regulatory requirements;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications);
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possibility of termination or nonrenewal of the agreement by the third-party at a time that is costly or damaging to us.

In addition, the FDA, EMA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in sanctions being imposed on us, including fines, injunctions, civil penalties, restrictions on the product or on the manufacturing or laboratory facility, including license revocation, marketed product recall, suspension of manufacturing, product seizure, voluntary withdrawal of the product from the market, operating restrictions or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any

failure to deliver sufficient quantities of product candidates in a timely manner, would lead to a delay in, or failure to seek or obtain, regulatory approval of any of our product candidates. Furthermore, any change in manufacturer of our product candidates or approved products, if any, would require new regulatory approvals, which could delay completion of clinical trials or disrupt commercial supply of approved products.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Union and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable cGCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical

trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop, and license future product candidates may be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us.

Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

We rely on third parties for various operational and administrative aspects of our business, including for certain cloud-based software platforms, which impact our financial, operational and research activities. If any of these third parties fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third party consultants and contractors to provide certain operational and administrative services. These services include tax advice and clinical and research consultation. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on “cloud-based” platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, and computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

Future strategic partnerships may be important to us. We will face significant competition in seeking new strategic partners.

We have limited capabilities for drug development and manufacturing and do not yet have any capability for sales, marketing or distribution. For some of our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. The competition for strategic partners is intense. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the strategic partner’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions

generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product candidate.

Strategic partnerships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Even if we are successful in entering into collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements with other potential collaborators.

If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and adversely affected. Any collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the partner terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, and increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches the market.

If we are unable to maintain future strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.

Any future strategic partnerships we enter into may pose a number of risks, including the following:

- we may not be able to enter into critical strategic partnerships or enter them on favorable terms;
- strategic partners have significant discretion in determining the effort and resources that they will apply to such a partnership, and they may not perform their obligations as agreed or expected;
- strategic partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;
- product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates;
- a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates;

- disagreements with strategic partners, including disagreements over proprietary rights, ownership of intellectual property, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Risks Related to Our Intellectual Property

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

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. We are aware of third party patents and patent applications containing claims directed to most of our areas of product development, which patents and applications could potentially be construed to cover our product candidates and the use thereof to treat patients. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that third-party patents or patent applications of which we are aware may not ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position, even though we do not believe they are relevant to our business. Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. These patents may not expire before we receive marketing authorization for our product candidates, and they could delay the commercial launch of one or more future products. If our products were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms, or at all, our business, financial condition and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations, and we would be exposed to a threat of litigation.

In the biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace both within and outside the United States including patent infringement lawsuits, oppositions, *inter partes* review (IPR) and post-grant review (PGR) proceedings before the United States Patent and Trademark Office (USPTO), or the applicable foreign patent counterpart. The types of situations in which we may become a party to such litigation or proceedings include:

- we may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties, to obtain a judgment that our products or processes do not infringe those third parties' patents or to obtain a judgment that those parties' patents are invalid and/or unenforceable;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights or initiate other proceedings, including post-grant proceedings such as oppositions, IPRs or PGRs, we will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, 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 on our business, results of operations, financial condition and prospects. Any of these outcomes could have a material adverse effect on our business.

If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify, seek, obtain and maintain patent protection for our discoveries. As of December 31, 2020, our patent portfolio included 27 granted patents in seven countries or regions, 151 pending applications in active prosecution in 15 countries or regions, six pending Patent Cooperation Treaty (PCT) applications (four unpublished), and ten pending unpublished provisional applications. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies that have patent portfolios consisting of hundreds, and in some case even thousands, of granted patents. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. 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. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our owned or in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries or that effectively prevent third parties from commercializing competitive product candidates.

Moreover, the patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. We may be subject to a third-party preissuance submission of prior art to the USPTO or a foreign jurisdiction, and such prior art may affect the scope of any claims we ultimately get allowed or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented,

or deemed unenforceable, or such third parties may gain rights to such patents. We could also become involved in reexamination, inter parties review, post-grant review, opposition or derivation proceedings, challenging our patent rights or the patent rights of others. In addition, changes in law may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. If, our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued 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 by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities 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 fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful.

Third parties may seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement, which may lead to challenges to the validity or enforceability of our patents. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. 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 current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

- third parties may initiate opposition, IPR or PGR proceedings challenging the validity or scope of our patent rights, requiring us and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed or trade secrets not misappropriated by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. 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.

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 our common stock.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

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

Patents have a limited lifespan. In the 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. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. 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 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 those 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 upon regulatory approval of our product candidates. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension 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 can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If we are unable to protect the confidentiality of our trade secrets and proprietary information, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. For example, we treat our proprietary computational technologies, including unpatented know-how and other proprietary information, as trade secrets. Trade secrets and know-how can be difficult to protect. Trade secrets and know-how can also in some instances be independently derived or reverse-engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information, in part by entering into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, individuals with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

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 in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

We employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, trade secrets or other proprietary information 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 products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

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

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages,

we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent protection and patent prosecution for some of our product candidates may be dependent on, and the ability to assert patents and defend them against claims of invalidity may be maintained by, third parties.

There may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers.

If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third-party patents. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act (AIA), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to file third party submissions of prior art to the USPTO during patent prosecution and to challenge any issued patent in the USPTO (*e.g.*, via post-grant reviews or *inter partes* reviews). This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Recent United States Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. 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 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 and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors 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 intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights

of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Some of our discovery programs may include antibodies that are licensed from third parties pursuant to limited research licenses. If we decide to further develop or commercialize these discovery programs as future product candidates, we may need to exercise our option to enter into a commercial license with one or more of these third parties. If we are unable to successfully enter into those commercial licenses or if we breach the terms of our existing research licenses or future commercial licenses, we would not have the ability to continue the development and potential commercialization of such discovery programs.

We have in-licensed certain antibodies for our discovery programs from third parties. Under these license agreements, we are able to research and initially develop discovery programs and are required to make certain annual payments. We also have the option to negotiate or enter into commercial license agreements with these third parties if we elect to continue development or commercialization of any product candidates incorporating the in-licensed antibodies. If we exercise our option to negotiate or enter into any commercial licenses with these third parties, we will likely be subject to various additional obligations, which may include obligations with respect to funding, development and commercialization activities, and payment obligations upon achievement of certain milestones and royalties on product sales. If any of our existing antibody research licenses or future commercial licenses are terminated or breached, we may:

- lose our rights or options to research, develop or commercialize certain of our future product candidates;
- not be able to secure patent or trade secret protection for certain of our future product candidates;
- experience significant delays in the development or commercialization of certain of our future product candidates;
- not be able to obtain other licenses that may allow us to continue to progress the applicable programs on acceptable terms, if at all; or
- incur liability for damages.

Additionally, even if not terminated or breached, our intellectual property licenses may be subject to disagreements over contract interpretation which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations. If we experience any of the foregoing, it could have a materially adverse effect on our business.

Risks Related to Ownership of Our Securities

The market price of our common stock may be volatile, which could result in substantial losses for our securityholders.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- results and timing of our preclinical studies and clinical trials and studies and trials of our competitors' products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- actual or anticipated changes in our growth rate relative to our competitors;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;

- announcements by us, our strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock by us, our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters, crises or public health emergencies, such as the COVID-19 pandemic;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- announcements or expectations of additional financing efforts;
- general market conditions and market conditions for biotechnology stocks;
- overall fluctuations in U.S. equity markets; and
- other factors that may be unanticipated or out of our control

The stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

An active trading market for our common stock may not be sustained.

Prior to the closing of our initial public offering (IPO) in September 2019, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Select Market (Nasdaq), the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active market trading market for our common stock may not be sustained in the future. The lack of an active trading market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares, may impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

We are controlled by Haldor Topsøe Holding A/S and a concentrated group of stockholders, whose interests in our business may conflict with yours.

As of December 31, 2020, Haldor Topsøe Holding A/S (HTH), together with other holders of 5% or more of our outstanding capital stock and their respective affiliates, beneficially owned 23,528,133 shares, or 73.6%, of our outstanding capital stock (which includes 17,096,928 shares, or 66.9%, of our voting common stock). Accordingly, our principal stockholders will be able to control most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, including mergers and sales of all or substantially all of our assets. The interests of these principal stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily

those of other stockholders. For example, our concentration of ownership could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could cause the market price of our common stock to decline or prevent our stockholders from realizing a premium over the market price for their shares of our common stock.

In addition, pursuant to nominating agreements entered into between us and each of (i) HTH, (ii) Baker Brothers Life Sciences L.P. and 667, L.P. (together, Baker Brothers) and (iii) Redmile Biopharma Investments II, L.P., RAF, L.P. and Redmile Strategic Master Fund, LP (together, Redmile), for up to 12 years following the completion of our IPO, so long as HTH, Baker Brothers and Redmile, together with their respective affiliates, each beneficially own certain specified amounts of our capital stock, we will have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, (i) two individuals designated by HTH, (ii) one individual designated by Baker Brothers and (iii) one individual designated by Redmile, subject to certain customary conditions and exceptions. Each of HTH, Baker Brothers and Redmile, and their respective affiliates, may therefore have influence over management and control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation as currently in effect. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales could occur, could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amount of our common stock in the public market, the market price of our common stock could decline significantly.

In November 2020, our registration statement on Form S-3 (File No. 333-249863) was declared effective by the SEC, pursuant to which we may offer debt securities, preferred stock, common stock and certain other securities from time to time. On December 11, 2020, we completed a public offering of 1,221,224 shares of our common stock, which included the exercise of the underwriters' option to purchase 333,333 shares in full, and pre-funded warrants to purchase an additional 1,334,332 shares of common stock (see Note 7 to our financial statements included in this Annual Report on Form 10-K for additional information).

If in the future we issue shares of common stock or securities convertible into common stock, our stockholders would experience dilution and, as a result, the market price of our common stock may decline. We cannot predict the effect that future sales of our securities would have on the market price of our common stock. Additionally, our securityholders may be further diluted by the exercise of the pre-funded warrants issued in December 2020.

We and our directors and executive officers have agreed that for a period of 90 days after December 9, 2020, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or

indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock. Sales of stock by any of our directors, executive officers or principal stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our common stock (including common stock issuable upon conversion of our non-voting common stock) have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. In addition, we filed a registration statement on Form S-8 to register shares of our common stock reserved for future issuance under our equity compensation plans. As a result, shares registered under this registration statement will be available for sale in the public market subject to the satisfaction of applicable vesting arrangements and the exercise of such options and, in the case of our affiliates, the restrictions of Rule 144. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

We have broad discretion in how we use the net proceeds from our public offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

Our management team has broad discretion in the application of the net proceeds from our public offering in December 2020, and we may spend or invest these proceeds in a way with which our stockholders disagree. Accordingly, you will need to rely on our management team's judgment with respect to the use of these proceeds and these uses may not yield a favorable return to our stockholders and may negatively impact the price of our common stock. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value. The failure by management to apply these funds effectively could negatively affect our ability to operate and grow our business.

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

The trading market for our common stock depends 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 one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. In addition, 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.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. We have identified deficiencies in the past which we have taken steps to address. However, our efforts to remediate previous deficiencies may not be effective or prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

During the year ended December 31, 2020, we began using a new enterprise resource planning (ERP) system for financial reporting. As a result, we updated our internal controls to accommodate changes to our business processes and accounting procedures. In connection with our ongoing evaluation of our internal controls over financial reporting, we may make further upgrades to our finance and accounting systems. If we are unable to accomplish these objectives in a timely and effective manner, our ability to comply with the financial reporting requirements

and other rules that apply to reporting companies could be adversely impacted. Any failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock.

As a public company, we are required to disclose material changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Beginning with our Annual Report on Form 10-K for the year ending December 31, 2020, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404.

To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and maintain a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and continue to implement a continuous reporting and improvement process for internal control over financial reporting.

An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. In addition, our independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2020, 2019 or 2018 in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed such an evaluation, control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to corporate governance standards.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." Our management and other personnel have devoted and will continue to devote a substantial amount of time and incur substantial expense in connection with compliance initiatives. For example, in anticipation of becoming a public company, we adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the SEC, and Nasdaq, have and will continue to increase legal and financial compliance costs and make some compliance activities more time consuming. We cannot predict or estimate the amount of additional costs we may incur to respond to these requirements or the timing of such costs. We have invested and will continue to invest in resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of Nasdaq, a majority of our board of directors and each member of our audit committee must be an independent director no later than the first anniversary of the completion of our IPO. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common stock from Nasdaq.

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make 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 choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our 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. We will remain an "emerging growth company" until the earliest to occur of: the last day of the fiscal year in which we have more than $1.07 billion in annual revenue, the date we qualify as a "large accelerated filer," with the market value of our common stock held by non-affiliates exceeding $700 million as of June 30, the issuance by us of more than $1.0 billion of non-convertible debt over a three-year period, and the last day of the fiscal year ending after the fifth anniversary of our IPO, or December 31, 2024. Investors could find our common stock less attractive if we choose to rely on these exemptions. In addition, 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. We have elected to use this extended transition period until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates. If some investors find our common stock less attractive as a result of any of our reliance on these exemptions, there may be a less active trading market for our common stock and our share price may be more volatile.

We have never paid and do not anticipate paying cash dividends on our common stock, and accordingly, stockholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. See the section titled "Dividend Policy." As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for certain claims as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court):

- any derivative action or proceeding under Delaware statutory or common law brought on our behalf;
- any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive forum provision will not apply to any causes of action arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in

legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in any action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 68,100 square feet of office, laboratory and manufacturing space in Mountain View, California under three leases which expire in August 2023, September 2024 and April 2025. We believe this space is sufficient to meet our near-term needs and that any additional space we may require will be available on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information for Our Common Stock

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "IGMS" since September 18, 2019. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 18, 2021, there were 9 holders of record of our common stock and 6 holders of record of our non-voting common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

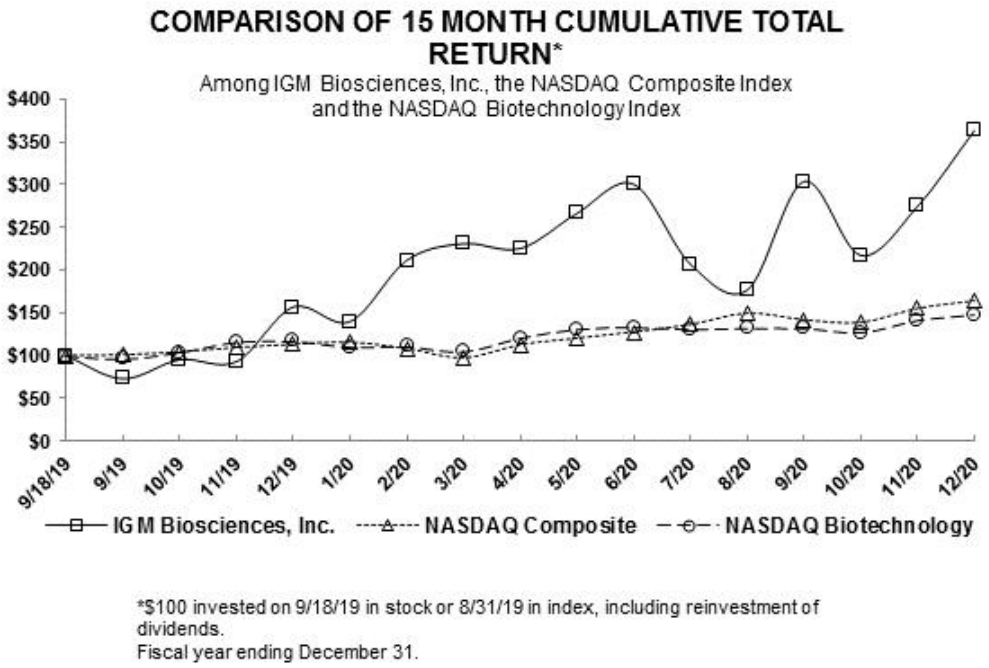
Dividend Policy

We have never declared or paid cash dividends on our capital stock to investors. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, except to the extent that we specifically incorporate this information by reference therein, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and each index on September 18, 2019 (the first day of trading of our common stock with a closing price on that date of $24.30) and its relative performance is tracked through December 31, 2020. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



*$100 invested on 9/18/19 in stock or 8/31/19 in index, including reinvestment of dividends.
Fiscal year ending December 31.

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

On September 17, 2019, our registration statement on Form S-1 (File No. 333-2233365) was declared effective by the SEC for our initial public offering of common stock. We began trading on the Nasdaq Global Select Market on September 18, 2019, and the transaction formally closed on September 20, 2019. In connection with our IPO, we issued and sold an aggregate of 12,578,125 shares of our common stock at a price of $16.00 per share, including 1,640,625 shares issued and sold in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. The aggregate offering price for shares sold in our IPO was $201.3 million. The joint book-running managers for the initial public offering were Jefferies LLC, Piper Jaffray & Co., Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC. After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately $18.4 million, the net proceeds from the offering were approximately $183.0 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on September 18, 2019 pursuant to Rule 424(b)(4). We invested the funds received in interest-bearing investment-grade securities.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data.

Not required.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Overview

We are a biotechnology company pioneering the development of engineered IgM antibodies for the treatment of multiple diseases. IgM antibodies have inherent properties that we believe may enable them to bind more strongly to cells than comparable IgG antibodies. We have created a proprietary IgM antibody technology platform that we believe is particularly well suited for developing T cell engagers, receptor cross-linking agonists and targeted cytokines. Our lead product candidate, IGM-2323, a bispecific T cell engaging IgM antibody targeting CD20 and CD3 proteins, is in an ongoing Phase 1 clinical trial for the treatment of relapsed/refractory B cell Non-Hodgkin's lymphoma (NHL) patients. Our second product candidate, IGM-8444 is an IgM antibody targeting Death Receptor 5 (DR5) proteins which may prove to be useful for the treatment of patients with solid and hematologic malignancies, and in September 2020, we announced the dosing of the first patient in our Phase 1 clinical trial for the treatment of solid cancers and NHL. Our oncology pipeline also includes IGM-7354, a bispecific IgM antibody delivering interleukin-15 (IL-15) cytokines to PD-L1 expressing cells for the treatment of patients with solid and hematologic malignancies.

We believe that we have the most advanced research and development program focused on engineered therapeutic IgM antibodies. We have created a portfolio of patents and patent applications, know-how and trade secrets directed to our platform technology, product candidates and manufacturing capabilities, and we retain worldwide commercial rights to all of our product candidates and the intellectual property related thereto.

Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in-house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have exclusively related to the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform.

We have incurred significant net losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $81.4 million, $43.1 million, and $22.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $188.6 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. In addition, we expect to incur additional costs associated with operating as a public company.

We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance the development of IGM-2323, IGM-8444, IGM-7354 and our COVID-19 antibodies;
- expand our pipeline of IgM antibody product candidates;
- continue to invest in our IgM antibody technology platform;

- build out and expand our in-house manufacturing capabilities;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know-how;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out;
- implement operational, financial and management information systems; and
- attract, hire and retain additional clinical, scientific, management and administrative personnel.

We plan to continue to use third-party service providers, including contract research organizations (CROs) and contract manufacturing organizations (CMOs), to carry out our preclinical and clinical development and manufacture and supply of our preclinical and clinical materials to be used during the development of our product candidates.

We do not have any products approved for sale and have not generated any revenue since inception. We have funded our operations primarily from the sale of convertible preferred stock, the sale of common stock in our public offerings and the issuance of unsecured promissory notes.

In September 2019, we completed our initial public offering (IPO) and sold and issued an aggregate of 12,578,125 shares of common stock, including 1,640,625 shares issued in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock, at $16.00 per share for gross proceeds of $201.3 million. Immediately prior to the closing of our IPO, all shares of convertible preferred stock then outstanding automatically converted into 10,787,861 shares of common stock and 6,431,205 shares of non-voting common stock. The aggregate net proceeds from our IPO, inclusive of the full exercise by the underwriters of their option to purchase additional shares of common stock, were approximately $183.0 million after deducting underwriting discounts and commissions and other offering costs.

On December 11, 2020, pursuant to our registration statement on Form S-3, we completed a public offering of 1,221,224 shares of our common stock, which included the exercise of the underwriters' option to purchase 333,333 shares in full, and pre-funded warrants to purchase an additional 1,334,332 shares of common stock for aggregate gross proceeds of $230.0 million. The public offering price of common stock was $90.00 per share and the public offering price of each pre-funded warrant was $89.99, with each pre-funded warrant having an exercise price of $0.01. After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately $14.6 million, the aggregate net proceeds from our December 11, 2020 public offering were approximately $215.4 million.

We were incorporated in Delaware in 1993 under the name Palingen, Inc. From 1993 to 2010, we were principally engaged in research related to naturally occurring IgM antibodies. In 2010, we received an initial equity investment from Haldor Topsøe Holding A/S, changed our name to IGM Biosciences, Inc. and refocused our research and development efforts toward developing our IgM platform and engineering new IgM antibodies. In December 2017, we established a Danish holding company (IGM Biosciences A/S (Holdco)); in April 2019, we dissolved Holdco. The capitalization information included in this Annual Report on Form 10-K is consistently presented as that of IGM Biosciences, Inc. even during the interim period when we had a holding company structure and our investors held their equity interests in Holdco.

Revenue

To date, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for the discovery and development of product candidates, which include:

Direct expenses consisting of:

- Fees paid to third parties such as consultants, contractors and CROs, for animal studies and other costs related to preclinical studies and clinical trials;
- Costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as CMOs and other vendors;
- Costs related to the preparation of regulatory submissions; and
- Expenses related to laboratory supplies and services;

Indirect expenses consisting of:

- Personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in our research and development functions; and
- Depreciation of equipment and facilities expenses.

We expense research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. All direct research and development expenses are tracked by stage of development. We do not track our indirect research and development costs by product candidate or program.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities to advance our product candidates and our clinical programs, expand our product candidate pipeline and continue to build out and expand our in-house manufacturing capabilities. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. To the extent that our product candidates continue to advance into clinical trials, as well as advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses for personnel in our executive, finance, legal, corporate and other administrative functions, intellectual property, facilities and other allocated expenses, other expenses for outside professional services, including legal, human resources, audit and accounting services, and insurance costs. Personnel-related expenses consist of salaries, benefits and stock-based compensation. We expect our general and administrative expenses to increase for the foreseeable future as we increase our headcount to support our continued research activities and development of product candidates and as a result of operating as a public company, including legal, auditing, additional insurance expenses, investor relations activities, other administrative and professional services, and costs associated with maintaining compliance with exchange listing and Securities and Exchange Commission (SEC) requirements. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Other Income, Net

Other income, net includes interest income earned on our cash and investments, sublease income and interest expense incurred on an unsecured promissory note.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

(in thousands)	Year Ended December 31, 2020	2019	Change
Operating expenses:			
Research and development	$ 65,030	$ 35,257	$ 29,773
General and administrative	18,250	9,241	9,009
Total operating expenses	83,280	44,498	38,782
Loss from operations	(83,280)	(44,498)	(38,782)
Other income, net	1,925	1,365	560
Net loss	$ (81,355)	$ (43,133)	$ (38,222)

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated:

(in thousands)	Year Ended December 31, 2020	2019	Change
Direct expenses			
Clinical stage programs (1)	$ 24,126	$ 10,554	$ 13,572
Preclinical stage programs	15,035	12,095	2,940
Indirect expenses			
Personnel-related	21,184	9,546	11,638
Depreciation and facilities	4,685	3,062	1,623
Total research and development expenses	$ 65,030	$ 35,257	$ 29,773

(1) For the year ended December 31, 2020, includes direct expenses related to: (i) our lead product candidate, IGM-2323, for which we announced the dosing of the first patient in our Phase 1 clinical trial in October 2019; and (ii) our second product candidate, IGM-8444, for which we announced the dosing of the first patient in our Phase 1 clinical trial in September 2020.

Research and development expenses were $65.0 million in 2020 compared to $35.3 million in 2019. The increase of $29.8 million was primarily driven by advancement of our product candidates, including $13.6 million of expenses related to our clinical stage programs, which consisted of clinical and manufacturing expense incurred in the development of our lead product candidate, IGM-2323, and our second product candidate, IGM-8444. Preclinical stage programs expenses increased by $2.9 million primarily driven by a $2.4 million increase in activities related to our infectious disease program, a $2.6 million increase in license and fees, and a $1.7 million increase in expenses related to our discovery and other programs, partially offset by a decrease of $3.8 million for IGM-8444 expenses which are classified within clinical related expenses for 2020. Effective for 2020, expenses for IGM-8444 were classified as clinical stage program expenses due to the dosing of the first patient in our Phase 1 clinical trial in 2020. Personnel-related expenses, including stock-based compensation, increased by $11.6 million due to an increase in headcount, stock option grants, and an increase in the price of our common stock, which resulted in an increase in the stock option grant fair value. Depreciation and facilities increased by $1.6 million primarily due to new lease agreements for additional office, laboratory and manufacturing space in Mountain View, California which commenced in 2019.

General and Administrative Expenses

General and administrative expenses were $18.3 million in 2020 compared to $9.2 million in 2019. The increase of $9.0 million was primarily due to a $5.7 million increase in personnel-related expenses, including stock-based compensation, due to an increase in headcount, stock option grants, combined with an increase in the price of our common stock, which resulted in an increase in stock option grant fair value. In relation to our public company status, administrative expenses increased by $1.8 million primarily due to an increase in directors' and officers' liability insurance and professional services increased by $1.1 million due to legal, accounting and consulting services.

Other Income, Net

Other income, net was $1.9 million in 2020 compared to $1.4 million in 2019. The increase of $0.6 million was primarily due to interest earned from higher cash and investment balances.

Comparison of the Years Ended December 31, 2019 and 2018

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**Change**
Operating expenses:			
Research and development	$ 35,257	$ 18,962	$ 16,295
General and administrative	9,241	3,829	5,412
Total operating expenses	44,498	22,791	21,707
Loss from operations	(44,498)	(22,791)	(21,707)
Other income, net	1,365	80	1,285
Net loss	$ (43,133)	$ (22,711)	$ (20,422)

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated:

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**Change**
Direct expenses			
Clinical stage programs (1)	$ 10,554	$ 7,359	$ 3,195
Preclinical stage programs	12,095	5,394	6,701
Indirect expenses			
Personnel-related	9,546	4,743	4,803
Depreciation and facilities	3,062	1,466	1,596
Total research and development expenses	$ 35,257	$ 18,962	$ 16,295

(1) Includes direct expenses related to our lead product candidate, IGM-2323, for which we announced the dosing of the first patient in our Phase 1 clinical trial in October 2019.

Research and development expenses were $35.3 million in 2019 compared to $19.0 million in 2018. The increase of $16.3 million was driven by advancement of our product candidates, including $3.2 million of expenses related to our clinical stage program, which consisted of preclinical, clinical and manufacturing expense incurred in the development of our lead product candidate, IGM-2323, for which we announced the dosing of the first patient in our Phase 1 clinical trial in October 2019, and $6.7 million related to our preclinical stage programs which consisted of preclinical and manufacturing expenses incurred in the development of our second product candidate, IGM-8444, and expenses related to our discovery programs. Personnel-related expenses, including stock-based compensation, increased by $4.8 million due to an increase in headcount. Depreciation and facilities increased by $1.6 million primarily due to new lease agreements for additional office, laboratory and manufacturing space in Mountain View which commenced in 2019.

General and Administrative Expenses

General and administrative expenses were $9.2 million in 2019 compared to $3.8 million in 2018. The increase of $5.4 million was primarily due to a $2.3 million increase in personnel-related expenses, including stock-based compensation, due to an increase in headcount. Professional services increased by $1.8 million due to legal, accounting, consulting and other services in preparation for our public company status. Administrative expenses increased by $0.9 million primarily due to an increase in directors' and officers' liability insurance. Depreciation and facilities increased by $0.3 million primarily due to new lease agreements for additional office, laboratory and manufacturing space in Mountain View which commenced in 2019.

Other Income, Net

Other income, net was $1.4 million compared to $80,000 in 2018. The increase of $1.3 million was primarily due to higher cash and investment balances.

Liquidity and Capital Resources

Liquidity

Due to our significant research and development expenditures, we have generated operating losses since our inception. We have funded our operations primarily through the sale of convertible preferred stock and common stock and the issuance of unsecured promissory notes. As of December 31, 2020, we had cash and investments of $366.3 million. As of December 31, 2020, we had an accumulated deficit of $188.6 million. We believe that our cash and investments will be sufficient to fund our planned operations for at least one year past the issuance date of these financial statements.

Future Funding Requirements

Our primary uses of cash are to fund operating expenses, which consist primarily of research and development expenditures related to our programs and related personnel costs. The timing and amount of our future funding requirements depends on many factors, including the following:

- the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates, including building out and expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and cost of capital expenditures to support our research, development and manufacturing efforts;
- the number and characteristics of other product candidates that we pursue;
- the costs, timing and outcome of seeking and obtaining U.S. Food and Drug Administration (FDA) and non-U.S. regulatory approvals;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;

- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide related to the COVID-19 pandemic;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

In addition, we will continue to require additional funding in order to complete development of our product candidates and commercialize our products, if approved. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. For example, in December 2020 the Company completed a public offering of common stock and pre-funded warrants for aggregate net proceeds of $215.4 million.

There can be no assurance that, in the event we require additional financing, such financing will be available at terms acceptable to us, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on our ability to achieve our intended business objectives. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs at an earlier stage of development or on less favorable terms than we would otherwise choose or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Net cash used in operating activities	(67,303)	(45,116)	(20,044)
Net cash provided by (used in) investing activities	57,711	(203,238)	(788)
Net cash provided by financing activities	214,781	282,258	22,337

Net Cash Used in Operating Activities

In 2020, net cash used in operating activities was $67.3 million, which consisted primarily of a net loss of $81.4 million, partially offset by $12.0 million in non-cash charges and a net change of $2.0 million in our net operating assets and liabilities. The net change in our operating assets and liabilities was primarily due to an increase in accrued liabilities of $2.8 million and an increase in accounts payable of $2.2 million partially offset by a decrease in lease liabilities of $2.5 million, an increase in prepaid expenses of $0.3 million, and an increase in other assets of $0.3 million. The non-cash charges primarily consisted of stock-based compensation of $8.5 million, non-cash lease expense of $2.6 million, and depreciation expense of $1.0 million.

In 2019, net cash used in operating activities was $45.1 million, which consisted of a net loss of $43.1 million and a net change of $5.0 million in our net operating assets and liabilities, partially offset by $3.0 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to an increase in prepaid expenses of $5.4 million, an increase in other assets of $0.3 million and a decrease in lease liabilities of $1.3 million, partially offset by an increase in accounts payable of $2.0 million. The non-cash charges primarily consisted of non-cash lease expense of $1.7 million, stock-based compensation of $1.0 million and depreciation expense of $0.6 million, partially offset by net amortization of premiums and accretion of discounts on investments of $0.3 million.

In 2018, net cash used in operating activities was $20.0 million, which consisted of a net loss of $22.7 million, partially offset by a net change of $2.2 million in our net operating assets and liabilities and $0.5 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to an increase in accrued liabilities of $2.8 million resulting from an increase in research and development activities. This was partially offset by an increase in prepaid expenses of $0.3 million primarily associated with prepayments made for ongoing research and development activities conducted by third-party service providers. The non-cash charges primarily consisted of depreciation expense of $0.3 million and stock-based compensation of $0.2 million.

Net Cash Provided by (Used in) Investing Activities

In 2020, net cash provided by investing activities was $57.7 million, which consisted of $283.8 million in maturities of investments, offset by $208.6 million in purchases of investments and $17.5 million in purchases of property, plant, and equipment for research and development activities.

In 2019, net cash used in investing activities was $203.2 million, which consisted of $208.9 million in purchases of investments and $2.3 million in purchases of lab equipment for research and development activities, partially offset by $8.0 million in maturities of investments.

Net cash used in investing activities was $0.8 million in 2018, related to the purchase of property and equipment.

Net Cash Provided by Financing Activities

In 2020, net cash provided by financing activities was $214.8 million, which consisted primarily of $215.7 million of net proceeds from our public offering of common stock and pre-funded warrants as well as $0.8 million of proceeds received from purchases under our employee stock purchase plan (ESPP) and from the exercise of stock options under our equity plans. These proceeds were offset by $1.7 million related to payments of employee taxes and exercise costs for shares withheld in connection with stock option exercises.

In 2019, net cash provided by financing activities was $282.3 million, which consisted primarily of $182.8 million of net proceeds from our IPO, $81.7 million of net proceeds from the issuance of shares of our Series C convertible preferred stock, $15.0 million of proceeds from the issuance of an unsecured promissory note to a related party which was subsequently settled as Series C convertible preferred stock in June 2019, the receipt of a $2.6 million receivable that was due from a related party, and $0.2 million from the issuance of common stock and exercise of stock options under our equity plans.

In 2018, net cash provided by financing activities was $22.3 million, which consisted primarily of $17.3 million of net proceeds from the issuance of shares of our Series B convertible preferred stock and $5.0 million of proceeds from the issuance of an unsecured promissory note.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and other commitments as of December 31, 2020:

	Payments Due by Period				
(in thousands)	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Contractual obligations:					
Operating lease obligations (1)	$ 3,086	$ 6,433	$ 3,741	$ —	$ 13,260

(1) Payments due for our lease of office, laboratory and manufacturing spaces in Mountain View, California. The payments represent gross operating lease obligations.

In addition, we enter into agreements in the normal course of business with CROs, CMOs and other vendors for research and development services for operating purposes, which are generally cancelable upon written notice. These payments are not included in this table of contractual obligations.

We have not included milestone or royalty payments or other contractual payment obligations in the table above as the timing and amount of such obligations are unknown or uncertain. See Note 5 to our financial statements included elsewhere in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Accrued Research and Development Expenses

We record accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers, CROs and CMOs. Our contracts with the CMOs generally include fees such as initiation fees, reservation fees, costs related to animal studies and safety tests, verification run costs, materials and reagents expenses, taxes, etc. Our contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We accrue the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event we make advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our financial condition and results of operations. Through December 31, 2020, there have been no material differences from our estimated accrued research and development expenses to actual expenses.

Stock-Based Compensation

We account for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees and directors based on estimated grant-date fair values. We use the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period, and estimate the fair value of share-based awards to employees and directors using the Black-Scholes option-pricing valuation model. The Black-Scholes model requires the input of subjective assumptions, including fair value of common stock, expected term, expected volatility, risk-free interest rate and expected dividends, which are described in greater detail below.

Fair Value of Common Stock—Prior to the IPO, as there was no public market for our common stock, the board of directors determined the fair value of our common stock by taking into consideration, among other things, timely valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Given the absence of a public trading market for our common stock prior to our IPO, 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 our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies and the lack of marketability of our common stock. Since the completion of our IPO, the fair value of each share of common stock underlying stock option grants is based on the closing price of our common stock on the Nasdaq Global Select Market as reported on the date of grant.

Expected Term—The expected term of the options represents the average period the stock options are expected to remain outstanding. As we do not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term of options granted is derived from the average midpoint between the weighted average vesting and the contractual term, also known as the simplified method.

Expected Volatility— Since we have only recently become a public company and have only a limited trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. We selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry, and, where applicable, with historical share price information sufficient to meet the expected life of our stock-based awards. We will continue to apply this process until enough historical information regarding the volatility of our own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the yield of zero-coupon U.S. Treasury notes as of the grant date with maturities commensurate with the expected term of the awards.

Expected Dividends—The expected dividends assumption is based on our expectation of not paying dividends in the foreseeable future; therefore, we used an expected dividend yield of zero.

We account for forfeitures as they occur. Disclosures related to stock-based compensation have been included for employee stock-based compensation only. Stock-based compensation awarded to non-employees for the years ended December 31, 2020, 2019, and 2018 was not material. The fair value of each purchase under our ESPP is estimated at the beginning of the offering period using the Black-Scholes option pricing model.

Assumptions we used in applying the Black-Scholes option-pricing model to determine the estimated fair value of our stock options granted involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

Leases

During 2019, we elected to early adopt Accounting Standard Update (ASU) No. 2016-02, *Leases* (ASC 842) and its associated amendments as of January 1, 2019 using the modified retrospective transition approach. There was no cumulative-effect adjustment recorded to accumulated deficit upon adoption.

Under ASC 842, we determine if an arrangement is a lease at inception. In addition, we determine whether leases meet the classification criteria of a finance or operating lease at the lease commencement date considering: (1) whether the lease transfers ownership of the underlying asset to the lessee at the end of the lease term, (2) whether the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (3) whether the lease term is for a major part of the remaining economic life of the underlying asset, (4) whether the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset, and (5) whether the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of December 31, 2020, our lease population consisted of real estate operating leases. As of the date of adoption of ASC 842, and as of December 31, 2020 and 2019, we did not have finance leases.

Operating leases are included in operating lease right-of-use (ROU) assets, lease liabilities, current, and lease liabilities, non-current in our balance sheet. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. We determine the incremental borrowing rate base on an analysis of corporate bond yields with a credit rating similar ours. The determination of our incremental borrowing rate requires management judgment including the development of a synthetic credit rating and cost of debt as we currently do not carry any debt. We believe that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise such options. Operating lease cost is recognized on a straight-line basis over the expected lease term. Lease agreements entered into after the adoption of ASC 842 that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on our balance sheet. For more information about the impact of adoption and disclosures on our leases, refer to “Note 10 – Commitments and Contingencies” in our notes to financial statements included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. There was no material foreign currency risk for the year ended December 31, 2020. We held $366.3 million in cash and investments as of December 31, 2020 which consisted of money market funds, U.S Treasury securities, commercial paper, corporate debt and U.S. agency securities. We held no interest-bearing liabilities as of December 31, 2020. Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of IGM Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of IGM Biosciences, Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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 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. 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/ Deloitte & Touche LLP

San Francisco, California

March 30, 2021

We have served as the Company's auditor since 2019.

IGM Biosciences, Inc.
Balance Sheets
(in thousands, except share and per share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 241,080	$ 35,891
Short-term investments	125,189	188,743
Prepaid expenses and other current assets	7,003	6,431
Income tax receivable	—	35
Total current assets	373,272	231,100
Property, plant and equipment, net	23,226	3,882
Long-term investments	—	11,973
Operating lease right-of-use asset	11,586	14,137
Other assets	548	258
Total assets	$ 408,632	$ 261,350
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	7,924	3,087
Accrued liabilities	6,649	3,305
Lease liabilities, current	2,667	2,483
Total current liabilities	17,240	8,875
Lease liabilities, non-current	9,577	12,244
Total liabilities	26,817	21,119
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock	—	—
Common stock, $0.01 par value; 1,000,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 25,542,931 and 24,053,921 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	255	240
Non-voting common stock, $0.01 par value; 6,431,208 shares authorized as of December 31, 2020 and December 31, 2019; 6,431,205 shares issued and outstanding as of December 31, 2020 and December 31, 2019	64	64
Additional paid-in-capital	570,030	347,089
Accumulated other comprehensive income	26	43
Accumulated deficit	(188,560)	(107,205)
Total stockholders' equity	381,815	240,231
Total liabilities and stockholders' equity	$ 408,632	$ 261,350

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

IGM Biosciences, Inc.
Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,		
	2020	2019	2018
Operating expenses:			
Research and development	$ 65,030	$ 35,257	$ 18,962
General and administrative	18,250	9,241	3,829
Total operating expenses	83,280	44,498	22,791
Loss from operations	(83,280)	(44,498)	(22,791)
Other income, net	1,925	1,365	80
Net loss	$ (81,355)	$ (43,133)	$ (22,711)
Net loss per share, basic and diluted	$ (2.65)	$ (4.80)	$ (51.84)
Weighted-average common shares outstanding, basic and diluted	30,748,280	8,995,410	438,074

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

IGM Biosciences, Inc.
Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (81,355)	$ (43,133)	$ (22,711)
Other comprehensive income:			
Unrealized gain (loss) on investments	(17)	43	—
Comprehensive loss	$ (81,372)	$ (43,090)	$ (22,711)

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

IGM Biosciences, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Non-Voting Common Stock		Additional Paid-In-	Due To (From) Related	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Party	Income	Deficit	Equity (Deficit)
Balance—December 31, 2017	6,384,797	$ 40,783	438,074	$ 4	-	$ -	$ 35,479	$ (34,625)	$ -	$ (41,361)	$ (40,503)
Issuance of Series B convertible preferred stock, net of issuance costs of $0.5 million	3,116,823	20,134	—	—	—	—	(286)	(2,511)	—	—	(2,797)
Related party equity transaction	—	—	—	—	—	—	(34,625)	34,625	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	183	—	—	—	183
Net loss	—	—	—	—	—	—	—	—	—	(22,711)	(22,711)
Balance—December 31, 2018	9,501,620	60,917	438,074	4	—	—	751	(2,511)	—	(64,072)	(65,828)
Exercise of stock options	—	—	184,036	2	—	—	177	—	—	—	179
Issuance of common stock	—	—	7,566	—	—	—	11	—	—	—	11
Related party equity transaction	—	—	—	—	—	—	39	2,511	—	—	2,550
Issuance of Series C convertible preferred stock, net of issuance costs of $0.4 million	7,717,446	101,636	—	—	—	—	—	—	—	—	—
Vesting of restricted stock	—	—	58,259	1	—	—	(1)	—	—	—	—
Conversion of convertible preferred stock into common stock and non-voting common stock	(17,219,066)	(162,553)	10,787,861	108	6,431,205	64	162,381	—	—	—	162,553
Issuance of common stock upon initial public offering, net of issuance costs of $4.3 million	—	—	12,578,125	125	—	—	182,717	—	—	—	182,842
Unrealized gain on investments	—	—	—	—	—	—	—	—	43	—	43
Stock-based compensation expense	—	—	—	—	—	—	1,014	—	—	—	1,014
Net loss	—	—	—	—	—	—	—	—	—	(43,133)	(43,133)
Balance—December 31, 2019	—	—	24,053,921	240	6,431,205	64	347,089	—	43	(107,205)	240,231
Issuance of common stock and pre-funded warrants, net of offering costs of $0.8 million	—	—	1,221,224	12	—	—	215,400	—	—	—	215,412
Exercise of stock options, net of shares withheld for taxes and exercise costs	—	—	170,537	2	—	—	(1,595)	—	—	—	(1,593)
Vesting of restricted stock	—	—	58,259	1	—	—	(1)	—	—	—	—
Issuance of common stock upon restricted stock unit settlement	—	—	7,645	—	—	—	—	—	—	—	—
Purchases under employee stock purchase plan	—	—	31,345	—	—	—	683	—	—	—	683
Unrealized gain (loss) on investments	—	—	—	—	—	—	—	—	(17)	—	(17)
Stock-based compensation expense	—	—	—	—	—	—	8,454	—	—	—	8,454
Net loss	—	—	—	—	—	—	—	—	—	(81,355)	(81,355)
Balance—December 31, 2020	—	$ —	25,542,931	$ 255	6,431,205	$ 64	$ 570,030	$ —	$ 26	$ (188,560)	$ 381,815

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

IGM Biosciences, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (81,355)	$ (43,133)	$ (22,711)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,025	597	278
Stock-based compensation expense	8,454	1,014	183
Accrued interest on related party loan	—	—	27
Net amortization of premiums and accretion of discounts on investments	(23)	(306)	—
Non-cash lease expense	2,551	1,736	—
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(252)	(5,412)	(262)
Other long-term assets	(290)	(258)	8
Income tax receivable	35	—	(35)
Accounts payable	2,198	1,961	(61)
Accrued liabilities	2,837	(25)	2,791
Income tax payable	—	—	(128)
Deferred rent	—	—	(134)
Lease liabilities	(2,483)	(1,254)	—
Other current liabilities	—	(9)	9
Other long-term liabilities	—	(27)	(9)
Net cash used in operating activities	(67,303)	(45,116)	(20,044)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(17,502)	(2,337)	(788)
Purchases of investments	(208,564)	(208,901)	—
Maturities of investments	283,777	8,000	
Net cash provided by (used in) investing activities	57,711	(203,238)	(788)
Cash flows from financing activities:			
Proceeds from new investors for issuance of Series B convertible preferred stock	—	—	17,337
Proceeds from new investors for issuance of Series C convertible preferred stock	—	72,000	—
Proceeds from related party for issuance of Series C convertible preferred stock	—	10,000	—
Payment of issuance costs for Series C convertible preferred stock	—	(324)	—
Proceeds from related party capital contribution	—	2,550	—
Proceeds from loan from related party	—	15,000	5,000
Proceeds from common stock issuance	—	11	—
Proceeds from exercise of stock options and purchases under the employee stock purchase plan	821	179	—
Payment of employee taxes and exercise costs for shares withheld	(1,731)	—	—
Proceeds from issuance of initial public offering, net of underwriters' commission	—	187,162	—
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	216,186	—	—
Payment of issuance costs for public offerings	(495)	(4,320)	—
Net cash provided by financing activities	214,781	282,258	22,337
Net increase in cash, cash equivalents and restricted cash	205,189	33,904	1,505
Cash, cash equivalents, and restricted cash, beginning of year	35,891	1,987	482
Cash, cash equivalents, and restricted cash, end of year	$ 241,080	$ 35,891	$ 1,987
Cash, cash equivalents, and restricted cash, end of year			
Cash and cash equivalents	241,080	35,891	1,887
Restricted cash	—	—	100
Cash, cash equivalents, and restricted cash, end of year	$ 241,080	$ 35,891	$ 1,987
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ —	$ —	$ 167
Cash paid for interest on related party loan	$ —	$ 297	$ —
Supplemental disclosure of non-cash investing and financing activities:			
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	$ 3,829	$ 962	$ 292
Issuance costs for public offerings in accounts payable and accrued liabilities	$ 279	$ —	$ —
Issuance costs for Series C convertible preferred stock in accounts payable and accrued liabilities	$ —	$ 40	$ —
Settlement of related party loan through issuance of Series C convertible preferred stock	$ —	$ 20,000	$ —
Receivable from related party for Series B convertible preferred stock	$ —	$ —	$ 2,511
Related party equity transaction	$ —	$ —	$ 34,625
Conversion of convertible preferred stock into common stock and non-voting common stock	$ —	$ 162,553	$ —

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

IGM Biosciences, Inc.
Notes to Financial Statements

Note 1. Organization

IGM Biosciences, Inc. (the Company) was incorporated in the state of Delaware in August 1993 under the name Palingen, Inc. and the name was subsequently changed to IGM Biosciences, Inc. in 2010. The Company's headquarters are in Mountain View, California. The Company is a biotechnology company engaged in the development of IgM antibody therapeutics for the treatment of multiple diseases.

In December 2017, the Company established a holding company (Holdco); in April 2019, Holdco was subsequently dissolved and equity interests in Holdco were converted into equity interests in the Company. The information included in these financial statements is consistently presented as if it is that of the Company, even during the interim period when investors held their equity interests in Holdco. Haldor Topsøe Holding A/S is a significant investor in the Company either through its direct equity ownership or indirectly as the majority owner of Holdco, until Holdco was dissolved in April 2019. Haldor Topsøe Holding A/S and Holdco represent a combined entity (Significant Investor) as referenced herein.

Basis of Presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Reverse Stock Split

In August 2019, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock, non-voting common stock and convertible preferred stock, each on a 6.6084-for-1 basis (Reverse Stock Split). The Reverse Stock Split also applied to any outstanding securities or rights convertible into, or exchangeable or exercisable for, common stock, non-voting common stock or convertible preferred stock. The par value of the common stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, non-voting common stock, restricted stock, options to purchase common stock, share data, per share data, convertible preferred stock and related information contained in the financial statements and related footnotes have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on August 30, 2019.

Public Offerings

On September 17, 2019, the Company's registration statement on Form S-1 (File No. 333-233365) relating to its initial public offering (IPO) of common stock became effective. The IPO closed on September 20, 2019 at which time the Company issued an aggregate of 12,578,125 shares of its common stock at a price of $16.00 per share, including 1,640,625 shares issued in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. In addition, immediately prior to the closing of the IPO, all outstanding shares of the Company's convertible preferred stock automatically converted into 10,787,861 shares of common stock and 6,431,205 shares of non-voting common stock. Proceeds from the IPO, net of underwriting discounts and commissions and offering costs, were approximately $183.0 million.

On November 12, 2020, the Company's registration statement on Form S-3 (File No. 333-249863) was declared effective by the Securities and Exchange Commission (the SEC). On December 11, 2020, pursuant to the Form S-3 that was filed, the Company completed a public offering (2020 Public Offering) of 1,221,224 shares of its common stock, which included the exercise of the underwriters' option to purchase 333,333 shares in full, and pre-funded warrants to purchase an additional 1,334,332 shares of common stock (Pre-funded Warrants). The Pre-funded Warrants were issued to two separate related party affiliates. The public offering price of common stock was $90.00 per share and the public offering price of each pre-funded warrant was $89.99, with each pre-funded warrant having an exercise price of $0.01. After deducting underwriting discounts and commissions and offering costs paid or payable by the Company of approximately $14.6 million, the net proceeds from the Company's 2020 Public Offering were approximately $215.4 million.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $188.6 million as of December 31, 2020. As of December 31, 2020, the Company had cash and investments of $366.3 million. Management believes that the existing financial resources are sufficient to continue operating activities at least one year past the issuance date of these financial statements. The Company has historically financed its operations primarily through the sale of convertible preferred stock and common stock and the issuance of unsecured promissory notes. To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue since inception. Management expects operating losses to continue and increase for the foreseeable future, as the Company progresses into clinical development activities for its lead product candidates. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed below. While the Company has been able to raise multiple rounds of financing, there can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates, including, but not limited to, those related to investments, manufacturing accruals, accrued research and development expenses, fair value of common stock, stock-based compensation, operating lease right-of-use (ROU) assets and liabilities, income tax uncertainties and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing engineered IgM antibodies for the treatment of multiple diseases. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States of America.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and investments. The Company invests in money market funds, U.S. Treasury securities, corporate bonds, commercial paper, and U.S. government agency securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and issuers of investments to the extent recorded on the balance sheets. The Company's investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, corporate debt, commercial paper, and places restrictions on the credit ratings, maturities and concentration by type and issuer. The Company has not experienced any losses on its deposits of cash and investments.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, the Company's early stages of clinical drug development; uncertainties related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; the Company's ability to advance product candidates into, and successfully complete, clinical trials on the timelines it projects; the Company's ability to adequately demonstrate sufficient safety and efficacy of its product candidates; the Company's ability to enroll patients in its ongoing and future clinical trials; the Company's ability to successfully manufacture and supply its product candidates for clinical trials; the Company's ability to obtain additional capital to finance its operations; uncertainties related to the projections of the size of patient populations suffering from the diseases the Company is targeting; the Company's ability to obtain, maintain, and protect its intellectual property rights; developments relating to the Company's competitors and its industry, including competing product candidates and therapies; general economic and market conditions; and other risks and uncertainties, including those more fully described in the "Risk Factors" section of this Annual Report on Form 10-K.

The Company's product candidates will require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash and cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and are stated at fair value. Restricted cash consisted of a money market account, which was closed during 2019, that served as collateral for a credit card agreement at one of the Company's financial institutions.

Investments

The Company's investments have been classified and accounted for as available-for-sale securities. Fixed income securities consist of U.S. Treasury securities, U.S. government agency securities, corporate debt, and commercial paper. The specific identification method is used to determine the cost basis of fixed income securities sold. These securities are recorded on the balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive income. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income, net. Realized gains and losses and declines in fair value judged to be other-than-temporary, if any, are also included in other income, net. The Company evaluates securities for other-than-temporary impairment at the balance sheet date. Declines in fair value determined to be other-than-temporary are also included in other income, net. The Company classifies its investments as short or long term primarily based on the remaining contractual maturity of the securities.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful economic lives of the related assets.

Upon retirement or sale of the assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss are recorded to the statements of operations. Repairs and maintenance are charged to operations as incurred.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company evaluates the carrying amount of its long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. There was no impairment of long-lived assets in 2020, 2019 and 2018.

Research and Development Expenses

The Company expenses research and development costs as they are incurred. Research and development expenses consist primarily of: (i) personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in the Company's research and development functions; (ii) fees paid to third parties such as contractors, consultants and contract research organizations (CROs) for conducting clinical trials, animal studies, and other costs related to clinical and preclinical testing; (iii) costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as contract manufacturing organizations (CMOs), and other vendors; (iv) costs related to the preparation of regulatory submissions; (v) expenses related to laboratory supplies and services; and (vi) depreciation of equipment and facilities expenses.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, CROs and CMOs. The Company's contracts with CROs generally include pass-through fees such as costs related to animal studies and safety tests, regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The Company's contracts with the CMOs generally include fees such as initiation fees, reservation fees, verification run costs, materials and reagents expenses, taxes, etc. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from the Company's estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations. Through December 31, 2020, there have been no material differences from the Company's estimated accrued research and development expenses to actual expenses.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Stock-Based Compensation

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees, non-employees and directors based on estimated grant-date fair values. The Company uses the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period, and estimates the fair value of share-based awards to employees and directors using the Black-Scholes option-pricing model. If the service inception date precedes the grant date, the Company accrues for the stock-based compensation based on the fair value at the reporting date. The Company accounts for forfeitures as they occur. The fair value of each purchase under the employee stock purchase plan (ESPP) is estimated at the beginning of the offering period using the Black-Scholes option pricing model and recorded as expense over the service period using the straight-line method.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock (including non-voting common stock and Pre-funded Warrants) outstanding during the period, without consideration for common stock equivalents. Shares of common stock into which the Pre-funded Warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, and filing fees directly relating to the Company’s equity offerings, are capitalized and offset against the proceeds upon the completion of the offering.

There were no deferred offering costs as of December 31, 2020 and 2019.

Leases

During 2019, the Company elected to early adopt Accounting Standard Update (ASU) No. 2016-02, *Leases* (ASC 842) and its associated amendments as of January 1, 2019 using the modified retrospective transition approach. There was no cumulative-effect adjustment recorded to accumulated deficit upon adoption.

Under ASC 842 and its associated amendments, the Company determines if an arrangement is a lease at inception. In addition, the Company determines whether leases meet the classification criteria of a finance or operating lease at the lease commencement date considering: (1) whether the lease transfers ownership of the underlying asset to the lessee at the end of the lease term, (2) whether the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (3) whether the lease term is for a major part of the remaining economic life of the underlying asset, (4) whether the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset, and (5) whether the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of December 31, 2020, the Company's lease population consisted of real estate. As of the date of adoption of ASC 842, and as of December 31, 2020 and 2019, the Company did not have finance leases.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Operating leases are included in operating lease right-of-use (ROU) assets, lease liabilities, current, and lease liabilities, non-current in the Company's balance sheet. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. The Company determines the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to the Company. The determination of the Company's incremental borrowing rate requires management judgment including the development of a synthetic credit rating and cost of debt as the Company currently does not carry any debt. The Company believes that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Operating lease cost is recognized on a straight-line basis over the expected lease term. Variable lease costs represent payments that are dependent on usage, a rate or index. Variable lease cost primarily relates to common area maintenance charges. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on the Company's balance sheet. For more information about the impact of adoption and disclosures on the Company's leases, refer to "Note 10 – Commitments and Contingencies."

Income Taxes

The Company accounts for income taxes using the liability method, whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance when it is more likely than not that some portion, or all of the Company's deferred tax assets will not be realized.

The Company accounts for income tax contingencies using a benefit recognition model. If it considers that a tax position is more likely than not to be sustained upon audit, based solely on the technical merits of the position, it recognizes the benefit. The Company measures the benefit by determining the amount that is greater than 50% likely of being realized upon settlement, presuming that the tax position is examined by the appropriate taxing authority that has full knowledge of all relevant information. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Recently Adopted Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which amends ASC 820, Fair Value Measurement. This ASU modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The effective date was the first quarter of fiscal year 2020, with early adoption permitted for the removed disclosures and delayed adoption until fiscal year 2020 permitted for the new disclosures. The Company adopted this ASU as of January 1, 2020 and the adoption did not have a material impact on its financial statements and related disclosures. The removed and modified disclosures were adopted on a retrospective basis and the new disclosures were adopted on a prospective basis.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

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*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. This ASU also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. This ASU is effective for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact of this standard on its financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2021. The Company is currently assessing the impact of this standard on its financial statements and related disclosures.

Note 3. Fair Value Measurement

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

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.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Financial instruments classified within Level 2 of the fair value hierarchy are valued based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers. To validate the fair value determination provided by its investment managers, the Company reviews the pricing movement in the context of overall market trends and trading information from its investment managers. In addition, the Company assesses the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy. As of December 31, 2020 and 2019, there were no financial instruments classified as Level 3.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

The following tables set forth the fair value of the Company's financial assets, which consist of investments measured and recognized at fair value (in thousands):

		December 31, 2020			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets					
Financial assets included within cash and cash equivalents:					
Money market funds	Level 1	$ 135,257	$ —	$ —	$ 135,257
U.S. Treasury securities	Level 1	73,494	1	—	73,495
U.S. government agency securities	Level 2	30,783	—	(1)	30,782
Financial assets included within short-term investments:					
U.S. Treasury securities	Level 1	71,795	2	—	71,797
Corporate bonds	Level 2	6,876	1	—	6,877
Commercial paper	Level 2	2,997	—	—	2,997
U.S. government agency securities	Level 2	43,495	23	—	43,518
Total		$ 364,697	$ 27	$ (1)	$ 364,723

		December 31, 2019			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets					
Financial assets included within cash and cash equivalents:					
Money market funds	Level 1	$ 12,854	$ —	$ —	$ 12,854
Commercial paper	Level 2	21,677	—	(2)	21,675
Financial assets included within short-term investments:					
U.S. Treasury securities	Level 1	66,244	48	—	66,292
Corporate bonds	Level 2	39,953	3	—	39,956
Commercial paper	Level 2	74,507	—	(9)	74,498
U.S. government agency securities	Level 2	7,995	2	—	7,997
Financial assets included within long-term investments:					
U.S. government agency securities	Level 2	11,974	—	(1)	11,973
Total		$ 235,204	$ 53	$ (12)	$ 235,245

The following table presents the contractual maturities of the Company's cash and investments as of December 31, 2020 (in thousands):

	December 31, 2020
Due in less than one year	$ 364,723
Due in more than one year	—
Total	$ 364,723

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Note 4. Balance Sheet Components

Property, Plant and Equipment, Net

Property, plant and equipment, net consists of the following (in thousands):

	December 31, 2020	December 31, 2019
Laboratory equipment	$ 7,125	$ 3,800
Office equipment	212	150
Leasehold improvement	253	78
Construction in progress	17,925	1,118
Total property, plant and equipment, gross	25,515	5,146
Less: Accumulated depreciation	(2,289)	(1,264)
Total property, plant and equipment, net	$ 23,226	$ 3,882

Depreciation expense was approximately $1.0 million, $0.6 million and $0.3 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Accrued research and development materials and services	$ 1,509	$ 906
Accrued professional services	163	360
Accrued compensation	4,925	2,030
Other	52	9
Total accrued liabilities	$ 6,649	$ 3,305

Note 5. License Agreements

Adimab Agreement

In January 2017, the Company entered into an option and license agreement with Adimab LLC (Adimab) pursuant to which the Company acquired a non-exclusive license to conduct research to evaluate certain Adimab antibodies in the context of the Company's proprietary platform constructs directed to selected targets, and an option to be granted a non-exclusive license to develop and commercialize antibody products incorporating or derived from such Adimab antibodies. The Company may exercise such option on a research program-by-research program basis during a specified period after the expiration of the discovery and evaluation term. The Company is obligated to pay license fees of up to approximately $1.0 million in the aggregate to Adimab under this agreement during the evaluation term. Upon exercise of the Company's option for an antibody covered by the agreement, it will be required to pay additional amounts aggregating up to either $7.4 million or $16.0 million per product incorporating each such antibody upon the option exercise and subsequent achievement of specified development and regulatory milestones, depending on the nature of the Adimab antibody incorporated in such product. In addition, the Company is obligated to pay Adimab either low or mid single-digit royalties based on net sales of each optioned antibody by the Company and its affiliates and sublicensees, subject to specified reductions. During the years ended December 31, 2020, 2019 and 2018, the Company recognized $0.2 million, $0.1 million and $0.3 million, respectively, in research and development expenses incurred under this agreement in its statements of operations.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

LakePharma Agreement

In May 2018, the Company and LakePharma, Inc. (LakePharma) entered into an agreement for screening services aimed towards discovering certain antibodies. If the Company elects to enter into a license to develop and commercialize one or more of the antibodies discovered under this agreement, the Company will be obligated to make payments to LakePharma aggregating up to $10.3 million based on achieving specified development and regulatory milestones for each such antibody. During the years ended December 31, 2020, 2019 and 2018, the Company recognized $0.3 million, $0.1 million and $0.3 million, respectively, in research and development expenses incurred under this agreement in its statements of operations.

AbCellera Agreement

In September 2020, the Company entered into a multi-year, multi-target strategic research and license agreement with AbCellera Biologics Inc. (AbCellera) to facilitate the discovery and development of novel IgM antibodies. The Company may exercise an option to obtain ownership of all rights, title, and interests in the antibodies discovered and developed under the agreement for a selected target. Upon exercise of the option, the Company may be required to pay research and development fees, amounts related to achievement of downstream milestones, and royalties on net sales.

University of Texas Agreement

In October 2020, the Company entered into a multi-year patent and materials license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas Health Science Center at Houston for certain antibodies against the SARS-CoV-2 virus. Under the terms of the agreement, the Company is obligated to pay an upfront payment of $0.1 million, an annual license fee of up to $0.1 million, research and development fees aggregating up to $2.8 million upon the achievement of clinical and regulatory milestones and single digit royalties on future net sales of antibody products stemming from this agreement. During the year ended December 31, 2020, the Company recognized $0.1 million in research and development expenses incurred under this agreement in its statements of operations.

AvantGen Agreement

In December 2020, the Company entered into a multi-year patent and license agreement with AvantGen Inc. for certain antibodies against the SARS-CoV-2 virus. Under the terms of the agreement, the Company is obligated to pay an upfront payment of $0.2 million, an annual fee of up to $0.3 million upon the first and second anniversaries of the agreement, research and development fees aggregating up to $8.4 million upon the achievement of clinical and regulatory milestones and single digit royalties on future net sales of antibody products stemming from this agreement. During the year ended December 31, 2020, the Company recognized $0.2 million in research and development expenses incurred under this agreement in its statements of operations.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Note 6. Common Stock and Non-Voting Common Stock

As of December 31, 2020 and 2019, the Company's certificate of incorporation authorized the Company to issue 1,006,431,208 shares of common stock (including 6,431,208 shares of non-voting common stock) and 200,000,000 shares of preferred stock, respectively, at a par value of $0.01 per share. Each share of common stock (excluding non-voting common stock) is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Company's Board of Directors, subject to prior rights of the preferred stockholders. As of December 31, 2020 and 2019, no dividends have been declared.

The Company had reserved common stock, on an as-converted basis, for future issuance as follows:

	December 31, 2020	December 31, 2019
Stock options, issued and outstanding	2,926,560	2,289,209
Restricted stock units	667	—
Restricted stock, issued and outstanding	—	58,259
Stock options and restricted stock units, future issuance	3,054,127	2,669,264
Employee stock purchase plan, available for future grants	554,088	280,000
Pre-funded warrants	1,334,332	—
Total	7,869,774	5,296,732

Note 7. Pre-Funded Warrants

On December 11, 2020, the Company completed an underwritten public offering of 1,221,224 shares of its common stock, which included the exercise of the underwriters' option to purchase 333,333 shares in full, and Pre-funded Warrants to purchase an additional 1,334,332 shares of common stock. The Pre-funded Warrants were issued to two separate related party affiliates. The public offering price of common stock was $90.00 per share and the public offering price of each Pre-funded Warrant was $89.99, with each Pre-funded Warrant having an exercise price of $0.01. After deducting underwriting discounts and commissions and offering costs paid or payable by the Company of approximately $14.6 million, the aggregate net proceeds from the 2020 Public Offering were approximately $215.4 million.

The public offering price for the Pre-funded Warrants was equal to the public offering price, less the $0.01 exercise price of each warrant. The Pre-funded Warrants were recorded as a component of stockholders' equity within additional paid-in-capital and will expire on the date any such warrant is exercised in full.

Subject to applicable law, upon exercise of a Pre-funded Warrant, a holder may elect to receive the same number of shares of non-voting common stock as the shares of common stock for which the Pre-funded Warrant is exercisable, provided that (i) at the time of such election there is a sufficient number of authorized but unissued and otherwise unreserved shares of non-voting common stock and (ii) the Company consents to such election.

The outstanding Pre-funded Warrants to purchase shares of common stock are exercisable at any time after their original issuance. However, the Company may not effect the exercise of any Pre-funded Warrants, and a holder will not be entitled to exercise any portion of any Pre-funded Warrants that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of the Company's common stock beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of the Company's securities beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of the Company's securities outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-funded Warrants. However, any holder of a Pre-funded Warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at

least 61 days' prior notice from the holder to the Company. As of December 31, 2020, no shares underlying the Pre-funded Warrants had been exercised (see "Note 12 Net Loss Per Share Attributable to Common Stockholders").

Note 8. Stock-Based Compensation

2018 Omnibus Incentive Plan (as Amended and Restated)

The Company's Board of Directors adopted and the Company's stockholders approved, effective on the day prior to the effectiveness of the registration statement on Form S-1 related to the IPO, an amendment and restatement of the 2018 Omnibus Incentive Plan (the 2018 Plan) which provides for the grant of incentive stock options, within the meaning of Section 422 of the Code to employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units (RSUs), stock appreciation rights, performance units, and performance shares to employees, directors, and consultants of the Company.

Options granted under the 2018 Plan expire no later than 10 years from the date of grant. The exercise price of options granted under the 2018 Plan must at least be equal to the fair market value of the Company's common stock on the date of grant. With respect to any participant who owns more than 10% of the voting power of all classes of the Company's outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. Employee stock options generally vest 25% upon one year of continued service to the Company, with the remainder in monthly increments over three additional years.

Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 4,384,000 shares of the Company's common stock for issuance pursuant to awards under the 2018 Plan. The 2018 Plan is administered by the Compensation Committee of the Company's Board of Directors. The number of shares of the Company's common stock available for issuance under the 2018 Plan will also include an annual increase on the first day of each fiscal year beginning with the 2020 fiscal year, equal to the least of (i) 8,768,800 shares, (ii) 4% of the Company's common stock and non-voting common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Company's Board of Directors.

On July 30, 2020, the Company's Board of Directors adopted and the Company's stockholders approved an amendment and restatement of the 2018 Plan which clarified the number of outstanding shares of common stock used to calculate the annual evergreen provision to include both voting and non-voting shares of common stock. Upon adoption of the amended and restated 2018 Plan, the number of shares of common stock available under the 2018 Plan increased by 257,248 shares.

As of December 31, 2020, 3,054,127 shares of common stock remained available for issuance under the 2018 Plan. Effective January 1, 2021, the number of shares of common stock available under the 2018 Plan increased by 1,278,965 shares pursuant to the evergreen provision of the 2018 Plan.

2010 Stock Plan (as Amended and Restated)

The 2010 Stock Plan (the 2010 Plan) was originally adopted by the Company's Board of Directors and approved by the Company's stockholders in November 2010. The 2010 Plan was amended and restated in December 2017 and April 2019. The 2010 Plan allowed the Company to provide incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options and stock purchase rights to eligible employees, consultants and directors and any parent or subsidiary of the Company. The 2010 Plan was terminated in 2019 and the Company will not grant any additional awards under the 2010 Plan. However, the 2010 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2010 Plan.

2019 Employee Stock Purchase Plan

The Company's Board of Directors adopted and the Company's stockholders approved, effective on the day prior to the effectiveness of the registration statement on Form S-1 related to the IPO, the 2019 Employee Stock Purchase Plan (ESPP). However, no offering period or purchase period under the ESPP will begin unless and until determined by the Company's Board of Directors. The ESPP is intended to have two components: a component that is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code (the 423 Component) and a component that is not intended to qualify (the Non-423 Component). The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock at the beginning of the offering period or at the end of each applicable purchase period.

Subject to adjustment in the case of certain capitalization events, a total of 280,000 common shares of the Company were available for purchase at adoption of the ESPP. Pursuant to the ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 560,000 shares, (ii) 1% of the Company's common stock and non-voting common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Company's Board of Directors.

On July 30, 2020, the Company's Board of Directors adopted and the Company's stockholders approved an amendment and restatement of the ESPP which clarified the number of outstanding shares of common stock used to calculate the annual evergreen provision to include both voting and non-voting shares of common stock. Upon adoption of the amended and restated ESPP, the number of shares of common stock available under the ESPP was increased by 64,312 shares. During the year ended December 31, 2020, the Company issued 31,345 shares of common stock under the ESPP.

As of December 31, 2020, 554,088 shares of common stock remained available for issuance under the ESPP. Effective January 1, 2021, the number of shares of common stock available under the ESPP increased by 319,741 shares pursuant to the evergreen provision of the ESPP.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded related to the 2010 Plan, 2018 Plan, and ESPP was recorded in the statements of operations and allocated as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 4,160	$ 522	$ 51
General and administrative	4,294	492	132
Total stock-based compensation expense	$ 8,454	$ 1,014	$ 183

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Stock Options

The following table summarizes stock option activity:

	Outstanding Options			
	Shares	Weighted-Average Exercise	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance—December 31, 2019	2,289,209	$ 3.36	8.1	$ 79,656
Granted	893,875	$ 44.66		
Exercised	(203,192)	$ 2.27		
Cancelled	(53,332)	$ 31.44		
Balance—December 31, 2020	2,926,560	$ 15.54	7.8	$ 212,906
Exercisable—December 31, 2020	1,462,376	$ 6.60	6.8	$ 119,459

The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected term in years	6.0	6.0	5.9
Expected volatility	84.3%	79.3%	77.5%
Risk-free interest rate	1.0%	2.2%	2.9%
Expected dividend yield	—	—	—
Weighted average fair value of share-based awards granted per share	$ 31.70	$ 4.36	$ 0.94

As of December 31, 2020, there was $23.6 million of total unrecognized compensation cost related to stock options under the Plans. The unrecognized stock-based compensation cost is expected to be recognized over a weighted-average period of 2.5 years. The aggregate intrinsic value of options exercised for the years ended December 31, 2020 and December 31, 2019 was $12.5 million and $0.3 million, respectively. Intrinsic values are calculated as the difference between the exercise price of the underlying options and the fair value of the common stock on the date of exercise.

The fair value of ESPP was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected term in years	0.5	0.7	—
Expected volatility	85.5%	74.3%	—
Risk-free interest rate	0.1%	1.9%	—
Expected dividend yield	—	—	—

Restricted Stock

During December 2018, the Company issued 116,518 shares of common stock to an executive officer under a restricted stock agreement at a grant date fair value of $1.39 per share that vested over two years. Any unvested shares were subject to forfeiture in the case that the grantee's service terminated. As of December 31, 2020, all

shares of restricted stock were vested. For the years ended December 31, 2020 and 2019, the related stock-based compensation was not material.

Restricted Stock Units

During the year ended December 31, 2020, the Company granted 8,312 shares of RSUs, of which 7,645 shares were issued upon vesting. These RSUs were granted to a consultant and certain members of the Company's Board of Directors under the Company's Outside Director Compensation Policy, as amended, and had a weighted-average fair value of $69.30 per share. The stock-based compensation expense related to these awards was $0.5 million, which was recognized over the service period of the awards. As of December 31, 2020, the remaining amount of unrecognized stock-based compensation related to these awards was not material. During the years ended December 31, 2020 and 2019, there were no RSUs cancelled.

Note 9. Income Taxes

Income Taxes

The Company had no income tax expense for the years ended December 31, 2020, 2019 and 2018. The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	Year Ended December 31,		
	2020	2019	2018
Federal tax (benefit) at statutory rate	21.0%	21.0%	21.0%
State tax (benefit), net of federal benefit	9.4	6.7	5.5
Permanent differences and other	(0.0)	(0.4)	(0.8)
Research and development credits	4.8	4.3	5.4
Provision to return adjustments	—	(2.8)	—
Stock-based compensation	1.7	—	—
Change in valuation allowance	(36.9)	(28.8)	(31.1)
Effective income tax rate	—%	—%	—%

Deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 38,739	$ 15,650
Accrued liabilities and reserves	1,623	716
Stock-based compensation	1,434	253
Intangible assets	9,792	10,435
Operating lease liability	3,427	4,121
Research and development credits	10,471	4,991
Total deferred tax assets	65,486	36,166
Deferred tax liabilities:		
Property and equipment	(269)	(167)
Right-of-use assets	(3,243)	(3,956)
Total deferred tax liabilities	(3,512)	(4,123)
Valuation allowance	(61,974)	(32,043)
Net deferred tax assets	$ —	$ —

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Notes to Financial Statements — Continued

The provisions of ASC Topic 740, Accounting for Income Taxes (ASC 740), require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. For the years ended December 31, 2020 and 2019, based on all available objective evidence, including the existence of cumulative losses, the Company determined that it was not more likely than not that the net deferred tax assets were fully realizable. Accordingly, the Company established a full valuation allowance against its deferred tax assets. The Company intends to maintain a full valuation allowance on net deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. During the years ended December 31, 2020 and 2019, the valuation allowance increased by $29.9 million and $12.4 million, respectively.

At December 31, 2020, the Company had net operating loss carryforwards available to reduce future taxable income, if any, for federal and California income tax purposes of approximately $141.2 million and $129.4 million, respectively. Of the federal net operating loss carryforwards at December 31, 2020, $4.4 million begins expiring in 2030 and $136.8 million can be carried forward indefinitely, subject to an annual limitation of 80% of taxable income. The California net operating loss carryforward begins expiring in 2037.

At December 31, 2020, the Company also had federal and California research and development tax credit carryforwards of $8.3 million and $5.4 million, respectively, available to offset future income tax, if any. The federal credit carryforwards begins expiring in 2032, and the California credits can be carried forward indefinitely.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change attributes, such as research tax credits, to offset its post-change income may be limited. In general, an “ownership change” will occur if there is a cumulative change in the Company's ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Therefore, certain of the Company's carryforward tax attributes may be subject to an annual limitation regarding their utilization against taxable income in future periods. The Company has completed a Section 382 study and believes it has experienced two changes in ownership. As a result, some of the federal and California NOL carryforwards and tax credit carryforwards may expire before being applied to reduce future income tax liabilities.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Securities Act (CARES Act) was signed into law in the US in March 2020. The CARES Act adjusted a number of provisions in the tax code that could impact a business entity’s income taxes, including the calculation and eligibility of certain deductions and the treatment of net operating losses and tax credits. The enactment of the CARES Act did not result in any material adjustments to our income tax provision for the year ended December 31, 2020, or to our net deferred tax assets as of December 31, 2020. The CARES Act also provides for other non-income tax related benefits to assist those impacted by the COVID-19 pandemic, such as, Paycheck Protection Program loans, deferral of the employer portion of social security taxes, and employee retention credits (“ERC”). The Company elected to defer its portion of social security taxes and it claimed the Employee Retention Credit (“ERC”) as its operations were impacted by a Shelter in Place order issued by a governmental authority (Santa Clara County). The Company utilized approximately $548K of ERC’s during 2020 which will result in a cash benefit. The Company continues to monitor and evaluate the regulatory and interpretive guidance related to the CARES Act.

California Assembly Bill 85 (AB 85) was signed into law in June 2020. The legislation suspends the use of California Net Operating Loss deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation on the use of certain California Tax Credits for 2020, 2021, and 2022. The carryover periods for Net Operating Loss deductions disallowed by this provision will be extended. Given the Company’s net operating loss position in the

current year, the new legislation will not impact the current year provision. The Company will continue to monitor possible California net operating loss and credit limitations in future periods.

Uncertain Tax Positions

The Company adopted the provisions of ASC 740, which requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits (in thousands):

	December 31,		
	2020	2019	2018
Beginning balance	$ 1,820	$ 1,113	$ 665
Decreases for tax positions related to prior years	(495)	—	—
Additions for tax positions related to current year	1,104	707	448
Ending balance	$ 2,429	$ 1,820	$ 1,113

The decrease in balance for tax positions taken in prior years relates to the completion of a research and development tax credit study for the years 2016-2019.

The unrecognized tax benefits, if recognized, would not affect the effective income tax rate due to the valuation allowance that currently offsets deferred tax assets. Interest and penalties were zero. The Company does not expect the unrecognized tax benefits to change significantly over the next twelve months.

The Company files federal and state income tax returns. All periods since inception are subject to examination by federal and state authorities, where applicable. There are currently no pending income tax examinations.

Note 10. Commitments and Contingencies

Operating Leases

The Company leases its headquarters with its main offices and laboratory facilities in Mountain View, California under two lease agreements that end in September 2024 and April 2025. During the three months ended December 31, 2019, the Company entered into a sub-lease agreement for additional office and laboratory space in Mountain View, California, which commenced on December 1, 2019 and expires in September 2024. The Company determined the incremental borrowing rate for this sub-lease agreement based on an analysis of corporate bond yields with a credit rating similar to the Company.

Variable lease cost primarily relates to common area maintenance charges for its real estate leases, which is dependent on usage. Because the rate implicit in each lease is not readily determinable, the Company uses its incremental borrowing rate to determine the present value of the lease payments. As noted in "Note 11 - Related Party Transactions," the Company entered into an agreement with the Significant Investor in February 2019 whereby the Significant Investor lent its credit and creditworthiness to the Company which applied to the Company's leases that transitioned upon the adoption of ASC 842. At the time of adoption, the Company determined the incremental borrowing rates for its leases by adjusting the observable risk-free interest rate with a credit risk premium corresponding to the Significant Investor's credit rating.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

The following table summarizes the cash paid for operating lease liabilities and the lease costs recognized in the statements of operations:

	Year Ended December 31,	
	2020	2019
Cash paid for operating lease liabilities	$ 3,002	$ 1,527
Operating lease cost	3,069	1,396
Variable lease cost	216	683

Information related to the Company's ROU assets and related lease liabilities was as follows (in thousands except for remaining lease term and discount rate):

	December 31, 2020	December 31, 2019
Current operating lease liabilities	$ 2,667	$ 2,483
Non-current operating lease liabilities	9,577	12,244
Weighted average remaining lease term in years	4.1	5.1
Weighted average discount rate	3.8%	3.8%

Maturities of lease liabilities as of December 31, 2020 were as follows (in thousands):

Year Ending December	Operating Lease Commitments
2021	$ 3,086
2022	3,172
2023	3,261
2024	3,008
2025	733
Thereafter	—
Total	13,260
Less imputed interest	(1,016)
Total lease liabilities	$ 12,244

Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its employees. This plan provides for tax-deferred salary deductions for all employees. Employee contributions are voluntary. Employees may contribute up to 100% of their annual compensation to this plan, as limited by an annual maximum amount as determined by the IRS. The Company does not make matching contributions under its 401(k) plan.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the years ended December 31, 2020 and 2019, and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

Indemnification

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the fair value of these agreements is not material.

The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

Note 11. Related Party Transactions

The following are transactions that occurred between the Company and related parties, including the Significant Investor, as defined in Note 1.

Lease Guarantee

In February 2019, the Significant Investor entered into an agreement to lend its credit and creditworthiness to the Company by providing a guarantee in the form of a letter of credit to allow the Company to enter into the lease agreement for its facilities in Mountain View, California. The Company did not draw on the guarantee and in December 2019, the Company exercised its rights to substitute a security deposit in lieu of the letter of credit pursuant to the lease agreement. Accordingly, the letter of credit was returned to the Significant Investor and the guarantee was no longer outstanding as of December 31, 2019.

Settlement of Related Party Receivable

In April 2019, the Company received $2.5 million in cash from the Significant Investor in settlement of the outstanding note receivable as of December 31, 2018.

Related Party Loan

In January, February and April 2019, the Company issued an unsecured promissory note to the Significant Investor for proceeds of $15.0 million. In June 2019, the outstanding unsecured promissory note, amounting to $20.0 million, issued by the Significant Investor was settled as shares of Series C convertible preferred stock (see below). During the year ended December 31, 2019, the Company paid $0.3 million in interest related to the unsecured promissory note issued to the Significant Investor.

2019 Series C Issuance

In June 2019, the Company issued 2,269,838 shares of Series C convertible preferred stock to the Significant Investor for $30.0 million. A portion of the shares of Series C convertible preferred stock was issued to satisfy the settlement of the unsecured promissory note amounting to $20.0 million issued by the Significant Investor.

Public Offerings

Immediately prior to the closing of the IPO, all outstanding shares of the Company's convertible preferred stock held by the Significant Investor automatically converted into common stock and non-voting common stock. In September 2019, the Significant Investor purchased an additional 1,250,000 shares of common stock in connection with the IPO. In December 2020, the Significant Investor purchased an additional 111,111 shares of common stock in connection with the Company's public offering. As a result of these events, the Significant Investor owned 10,400,564 shares of common stock and 2,269,838 shares of non-voting common stock upon the closing of the December 2020 Public Offering.

Additionally, in connection with the 2020 Public Offering the Company issued Pre-funded Warrants to two separate related party affiliates. (See "Note 7 Pre-Funded Warrants").

Note 12. Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock and Pre-funded Warrants outstanding for the period. Shares of common stock into which the Pre-funded Warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date.

The following table sets forth the computation of the basic and diluted net loss per share (in thousands except share and per share data):

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net loss	$ (81,355)	$ (43,133)	$ (22,711)
Denominator:			
Weighted average common shares outstanding used to compute net loss per share, basic and diluted (1)	30,748,280	8,995,410	438,074
Net loss per share attributable to common stockholders	$ (2.65)	$ (4.80)	$ (51.84)

(1) Includes shares of common stock into which Pre-Funded Warrants may be exercised. See Note 7 to our financial statements included in this Form 10-K.

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all common stock equivalents outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	December 31,	
	2020	2019
Stock options	2,926,560	2,289,209
Estimated shares issuable under the employee stock purchase plan	3,054	10,187
Restricted stock units	667	—
Restricted stock	—	58,259
Total	2,930,281	2,357,655

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

13. Selected Quarterly Financial Data (Unaudited)

The following tables provide the selected quarterly financial data for the years ended December 31, 2020 and 2019 (in thousands, except share and per share data):

	2020			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 14,583	$ 15,019	$ 15,829	$ 19,599
General and administrative	3,990	4,388	4,732	5,140
Total operating expenses	18,573	19,407	20,561	24,739
Loss from operations	(18,573)	(19,407)	(20,561)	(24,739)
Other income (expense), net	949	568	291	117
Net loss	$ (17,624)	$ (18,839)	$ (20,270)	$ (24,622)
Net loss per share, basic and diluted	$ (0.58)	$ (0.62)	$ (0.66)	$ (0.79)
Weighted-average common shares outstanding, basic and diluted	30,491,463	30,551,736	30,646,729	31,298,264

	2019			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 5,912	$ 8,303	$ 8,279	$ 12,763
General and administrative	1,445	2,228	2,394	3,174
Total operating expenses	7,357	10,531	10,673	15,937
Loss from operations	(7,357)	(10,531)	(10,673)	(15,937)
Other income (expense), net	(113)	(145)	501	1,122
Net loss	$ (7,470)	$ (10,676)	$ (10,172)	$ (14,815)
Net loss per share, basic and diluted	$ (16.86)	$ (19.08)	$ (2.41)	$ (0.49)
Weighted-average common shares outstanding, basic and diluted	443,118	559,671	4,222,259	30,478,980

Note 14. Subsequent Events

In January 2021, the Company entered into an exclusive license agreement with Medivir AB (Medivir) through which the Company received global, exclusive development and commercialization rights for birinapant, a clinical-stage Second Mitochondrial-derived Activator of Caspases (SMAC) mimetic. Under terms of the agreement, the Company made an upfront payment of $1.0 million upon signing the agreement, to be followed by an additional $1.5 million payment when birinapant is included by the Company in its clinical Phase I studies. Under the terms of the agreement, should birinapant be successfully developed and approved, the Company is obligated to make milestone payments up to a total of approximately $350.0 million, plus tiered royalties from the mid-single digits up to mid-teens on net sales.

In March 2021, the Company entered into a lease agreement for additional office and laboratory space in Mountain View, California which commenced in March 2021 and expires in August 2023. Total future rent payments under the agreement amount to approximately $1.9 million.

IGM Biosciences, Inc.
Notes to Financial Statements — Continued

In March 2021, the Company entered into a license agreement with Ablexis, Inc. through which the Company received rights to use AlivaMab® Mouse technology for antibody drug discovery. Under terms of the license agreement, the Company will pay annual fees, and per product developed, royalty payments based on a percentage of sales and milestone payments based on milestone events set forth in the agreement.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal financial officer, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that as of such date our disclosure controls and procedures were effective at a reasonable assurance level (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework established in "Internal Control-Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting during the quarter ended December 31, 2020, identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services.

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as a part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements filed as part of this Annual Report on Form 10-K are listed in the “Index to Financial Statements” under Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) Exhibits

The list of exhibits filed with this Annual Report on Form 10-K is set forth in the Exhibit Index preceding the signature page and is incorporated herein by reference or filed with this Annual Report on Form 10-K, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary.

None.

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39045	3.1	September 20, 2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-39045	3.1	June 12, 2020
4.1	Specimen common stock certificate of the Registrant.	S-1/A	333-233365	4.1	September 3, 2019
4.2	Amended and Restated Investor Rights Agreement, by and among the Registrant and certain of its stockholders, dated as of June 28, 2019.	S-1	333-233365	4.2	August 19, 2019
4.3	Description of Securities				
4.4	Form of Pre-Funded Warrant	8-K	001-39045	4.1	December 9, 2020
4.5	Form of Registration Rights Agreement, by and between the Registrant and certain securityholders.	8-K	001-39045	10.1	December 7, 2020
10.1+	Amended and Restated 2010 Stock Plan and forms of agreements thereunder.	S-1	333-233365	10.1	August 19, 2019
10.2+	2018 Omnibus Incentive Plan and forms of agreements thereunder.	S-1/A	333-233365	10.2	September 3, 2019
10.3+	Amended and Restated 2018 Omnibus Incentive Plan, amended July 30, 2020, and forms of agreements thereunder.	10-Q	001-39045	10.2	November 5, 2020
10.4+	Amended and Restated 2019 Employee Stock Purchase Plan, amended July 30, 2020, and forms of agreements thereunder.	10-Q	001-39045	10.1	November 5, 2020
10.5+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1/A	333-233365	10.5	September 3, 2019
10.6+	Confirmatory Employment Letter, by and between Fred Schwarzer and the Registrant, effective as of August 19, 2019.	S-1	333-233365	10.6	August 19, 2019
10.7+	Employment Agreement, by and between Daniel Chen and the Registrant, dated as of July 12, 2018.	S-1	333-233365	10.7	August 19, 2019
10.8+	Restricted Stock Grant Agreement, by and between Daniel Chen and the Registrant, dated as of December 30, 2018.	S-1	333-233365	10.8	August 19, 2019
10.9+	Confirmatory Employment Letter, by and between Bruce Keyt and the Registrant, effective as of August 19, 2019.	S-1	333-233365	10.9	August 19, 2019
10.10+	Confirmatory Employment Letter, by and between Misbah Tahir and the Registrant, effective as of August 19, 2019.	S-1	333-233365	10.10	August 19, 2019
10.11+	Change in Control and Severance Policy.	S-1	333-233365	10.11	August 19, 2019
10.12+	Outside Director Compensation Policy (as amended and restated on February 19, 2021).				
10.13+	Executive Incentive Compensation Plan.	S-1	333-233365	10.13	August 19, 2019
10.14	Lease by and between Real Property Investments, LLC and the Registrant, dated February 27, 2019.	S-1	333-233365	10.14	August 19, 2019
10.15	Nominating Agreement, by and among 667, L.P., Baker Brothers Life Sciences, L.P. and the Registrant, dated as of June 28, 2019.	S-1	333-233365	10.15	August 19, 2019
10.16	Nominating Agreement, by and between Haldor Topsøe Holding A/S and the Registrant, dated as of June 28, 2019.	S-1	333-233365	10.16	August 19, 2019
10.17	Nominating Agreement, by and among Redmile Biopharma Investments II, L.P., RAF, L.P., Redmile Strategic Master Fund, LP and the Registrant, dated as of June 28, 2019.	S-1	333-233365	10.17	August 19, 2019

23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (reference is made to the signature page hereto).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	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

+ Indicates management contract or compensatory plan.
† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

IGM Biosciences, Inc.

Date: March 30, 2021 By: /s/ Fred Schwarzer

Fred Schwarzer
Chief Executive Officer and President
(Principal Executive Officer)

Date: March 30, 2021 By: /s/ Misbah Tahir

Misbah Tahir
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Fred Schwarzer and Misbah Tahir and each of them as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Fred Schwarzer Fred Schwarzer	Chief Executive Officer, President and Director (Principal Executive Officer)	March 30, 2021
/s/ Misbah Tahir Misbah Tahir	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2021
/s/ Michael Loberg, Ph.D. Michael Loberg, Ph.D.	Chair of the Board of Directors	March 30, 2021
/s/ Felix Baker, Ph.D. Felix Baker, Ph.D.	Director	March 30, 2021
/s/ M. Kathleen Behrens, Ph.D. M. Kathleen Behrens, Ph.D.	Director	March 30, 2021
/s/ Julie Hambleton, M.D. Julie Hambleton, M.D.	Director	March 30, 2021
/s/ Michael Lee Michael Lee	Director	March 30, 2021
/s/ William Strohl, Ph.D. William Strohl, Ph.D.	Director	March 30, 2021
/s/ Christina Teng Topsøe Christina Teng Topsøe	Director	March 30, 2021
/s/ Jakob Haldor Topsøe Jakob Haldor Topsøe	Director	March 30, 2021

DESCRIPTION OF SECURITIES

Description of Capital Stock

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to our amended and restated certificate of incorporation and amended and restated bylaws. Copies of these documents were filed with the SEC and incorporated by reference as exhibits to our Annual Report on Form 10-K of which this Exhibit 4.3 is a part.

General

Our amended and restated certificate of incorporation authorizes preferred stock and two classes of common stock: voting common stock and non-voting common stock. The rights of the two classes of common stock are identical, except as described below.

Our authorized capital stock consists of 1,206,431,208 shares, $0.01 par value per share, of which:

- 1,000,000,000 shares are designated as voting common stock;
- 6,431,208 shares are designated as non-voting common stock; and
- 200,000,000 shares are designated as preferred stock.

Common Stock and Non-Voting Common Stock

Holders of our common stock and our non-voting common stock have identical rights, provided that, (i) except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the right to convert each share of our non-voting common stock into one share of common stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 4.99% of our common stock immediately prior to and following such conversion, unless otherwise as expressly provided for in our amended and restated certificate of incorporation. However, this ownership limitation may be increased or decreased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to us.

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock and non-voting 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. In the event of our liquidation, dissolution or winding up, the holders of our common stock and non-voting 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 to the prior rights of any preferred stock then outstanding. Holders of our common stock and non-voting common stock have no preemptive rights or other subscription rights and there are no redemption or sinking funds provisions applicable to our common stock and non-voting common stock. All outstanding shares of our common stock and non-voting common stock are duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock and non-voting common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Voting Rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a plurality of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

Dividends

Subject to preferences that may apply to any outstanding shares of convertible preferred stock, holders of our common stock and our non-voting common stock are entitled to receive dividends, if any, that our board of directors may declare from time to time out of funds legally available for that purpose on a non-cumulative basis and shared ratably.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock and our non-voting common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of convertible preferred stock.

Rights and Preferences

Holders of our common stock and our non-voting common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock and our non-voting common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of convertible preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors has the authority, without further action by the stockholders, to issue up to 200,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in our control or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended (the Securities Act). These registration rights are contained in the Amended and Restated Investors' Rights Agreement dated June 28, 2019 (the IRA), which was filed with the SEC and incorporated by reference as an exhibit to our Annual Report on Form 10-K. We will pay the registration expenses (other than underwriting discounts and commissions) of the holders of the shares registered pursuant to the

registrations described below. Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

Demand Registration Rights

Certain holders of shares of our common stock are entitled to certain demand registration rights. At any time before the 5 year anniversary of the date of the IRA, the holders of at least 72% of these shares in the aggregate may, on not more than two occasions, request that we register all or a portion of their shares. Such request for registration must cover shares with an anticipated aggregate offering price, net of underwriting discounts and expenses, of at least $10.0 million.

Piggyback Registration Rights

Certain holders of shares of our common stock are entitled to certain piggyback registration rights. In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, the holders of these shares are entitled to notice of the registration and have the right to include their shares in the registration, subject to limitations that the underwriters may impose on the number of shares included in the offering.

S-3 Registration Rights

Certain holders of shares of our common stock are entitled to certain Form S-3 registration rights. The holders of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate gross proceeds of the shares offered would equal or exceed $5,000,000. We will not be required to effect more than two registrations on Form S-3 within any consecutive 12-month period.

Registration Rights Agreement

Any holder who may be deemed to be an “affiliate” as defined under Rule 144 of the Securities Act and holds at least 756,612 shares of our common stock (including common stock issuable upon conversion of non-voting common stock) is entitled to bind us into entering into a registration rights agreement, through which these holders who enter into the agreement with us would be, subject to certain limitations, entitled to certain registration rights. We have entered into registration rights agreements with these holders. These registration rights include the right to demand that we file with the SEC a Form S-3 registration statement covering the registration of their common stock for resale, as well as certain rights related to underwritten public offerings, subject to certain conditions. These registration rights require us to pay expenses relating to such registrations and indemnify these holders against certain liabilities. Our registration obligations under these registration rights continue in effect until the earliest of (i) ten years after the date we enter into any such agreement; (ii) when the applicable registrable securities have been resold by the holders pursuant to an effective registration statement; (iii) when the applicable registrable securities have been resold pursuant to Rule 144 (or other similar rule); or (iv) at any time after the holders of such registrable securities become an affiliate of the Company, when the applicable registrable securities may be resold pursuant to Rule 144 without limitations as to volume or manner of sale.

Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws

Certain provisions of Delaware law and certain provisions in our amended and restated certificate of incorporation and amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

Preferred Stock

Our amended and restated certificate of incorporation contains provisions that permit our board of directors to issue, without any further vote or action by the stockholders, shares of convertible preferred stock in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting rights (if any) of the shares of the series and the powers, preferences or relative, participation, optional and other special rights, if any, and any qualifications, limitations or restrictions, of the shares of such series.

Classified Board

Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes, designated Class I, Class II and Class III. Each class has an equal number of directors, as nearly as possible, consisting of one third of the total number of directors constituting the entire board of directors. At each annual meeting of stockholders, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that stockholders may only remove a director for cause by a vote of no less than a majority of the shares present in person or by proxy at the meeting and entitled to vote.

Director Vacancies

Our amended and restated certificate of incorporation authorizes only our board of directors to fill vacant directorships.

No Cumulative Voting

Our amended and restated certificate of incorporation provides that stockholders do not have the right to cumulate votes in the election of directors.

Special Meetings of Stockholders

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, except as otherwise required by law, special meetings of the stockholders may be called only by an officer at the request of a majority of our board of directors, by the Chair of our board of directors or by our Chief Executive Officer.

Advance Notice Procedures for Director Nominations

Our amended and restated bylaws provide that stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders must provide timely notice thereof in writing. To be timely, a stockholder’s notice generally must be delivered to and received at our principal executive offices before notice of the meeting is issued by the secretary of the company, with such notice being served not less than 90 or more than 120 days before the meeting. Although the amended and restated bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, the amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws provide that any action to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by written consent.

Amending Our Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the Delaware General Corporation Law (the DGCL). Our amended and restated bylaws may be adopted, amended, altered or repealed by stockholders only upon approval of at least majority of the voting power of all the then outstanding shares of the common stock, except for any amendment of the above provisions, which would require the approval of a two-thirds majority of our then outstanding common stock. Additionally, our amended and restated certificate of incorporation provides that our bylaws may be amended, altered or repealed by the board of directors.

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and convertible preferred stock are available for future issuances without stockholder approval, except as required by the listing standards of the Nasdaq Stock Market LLC, and can be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and convertible preferred stock could render more difficult or discourage an attempt to obtain control of the company by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Jurisdiction

Our amended and restated bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding under Delaware statutory or common law brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty, (iii) any action asserting a claim arising pursuant to the DGCL, (iv) any action regarding our amended and restated certificate of incorporation or amended and restated bylaws, or (v) any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Exchange Act of 1934, as amended (the Exchange Act), or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated bylaws also provide that the federal district courts of the United States of America are the exclusive forum for resolving any complaint asserting a course of action under the Securities Act. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in our securities is deemed to have notice of and consented to this provision. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings.

Business Combinations with Interested Stockholders

We are governed by Section 203 of the DGCL. Subject to certain exceptions, Section 203 of the DGCL prohibits a public Delaware corporation from engaging in a business combination (as defined in such section) with an "interested stockholder" (defined generally as any person who beneficially owns 15% or more of the outstanding voting stock of such corporation or any person affiliated with such person) for a period of three years following the time that such stockholder became an interested stockholder, unless (1) prior to such time the board of directors of such corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of such corporation at the time the transaction commenced (excluding for purposes of determining the voting stock of such corporation outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares

owned (A) by persons who are directors and also officers of such corporation and (B) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or (3) at or subsequent to such time the business combination is approved by the board of directors of such corporation and authorized at a meeting of stockholders (and not by written consent) by the affirmative vote of at least 66 2/3% of the outstanding voting stock of such corporation not owned by the interested stockholder. These provisions may have the effect of delaying, deferring or preventing a change in control of our company.

Limitation of Liability and Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL. We are expressly authorized to, and do, carry directors' and officers' insurance providing coverage for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive directors.

The limitation on liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "IGMS".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and our non-voting common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

Description of Pre-Funded Warrants

The following description of our pre-funded warrants is a summary and is qualified by reference to the form of pre-funded warrant. A copy of the form of pre-funded warrant is filed with the SEC and incorporated by reference as an exhibit to our Annual Report on Form 10-K of which this Exhibit 4.3 is a part.

Form

The pre-funded warrants were issued as individual warrant agreements to certain purchasers. The form of pre-funded warrant is filed with the SEC and incorporated by reference as an exhibit to our Annual Report on Form 10-K of which this Exhibit 4.3 is a part.

Term

The pre-funded warrants will expire on the date the warrant is exercised in full.

Exercisability

The pre-funded warrants are exercisable at any time after their original issuance. The pre-funded warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full of the exercise price in immediately available funds for the number of shares of common stock purchased upon such exercise. As an alternative to payment in immediately available funds, the holder may, in its

sole discretion, elect to exercise the pre-funded warrant through a cashless exercise, in which the holder would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the pre-funded warrant. No fractional shares of our common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the last closing trading price of our common stock on the exercise date.

Subject to applicable law, upon exercise of the pre-funded warrant, a holder may elect to receive the same number of shares of non-voting common stock as the shares of common stock for which the pre-funded warrant is exercisable, provided that (i) at the time of such election there is a sufficient number of authorized but unissued and otherwise unreserved shares of non-voting common stock and (ii) we consent to such election.

Exercise Limitations

We may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of our common stock beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder of a pre-funded warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price

The exercise price of our common stock purchasable upon the exercise of the pre-funded warrants is $0.01 per share. The exercise price of the pre-funded warrants and the number of shares of our common stock issuable upon exercise of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock, as well as upon any distribution of assets, including cash, stock or other property, to our stockholders.

Transferability

Subject to the restrictions on transfer set forth in the pre-funded warrants and applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

There is no established trading market for the pre-funded warrants, and we do not expect a market to develop. We do not intend to apply for the listing of the pre-funded warrants on the Nasdaq Global Select Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions

Upon the consummation of a fundamental transaction (as described in the pre-funded warrants, and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power of our outstanding common stock), the holders of the pre-funded warrants will be entitled to receive, upon exercise of the pre-funded warrants, the kind and amount of securities, cash or other property that such holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction, without regard to any limitations on exercise contained in the pre-funded warrants.

No Rights as a Stockholder

Except by virtue of such holder's ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises the pre-funded warrant.

Exhibit 10.12

IGM BIOSCIENCES, INC.

OUTSIDE DIRECTOR COMPENSATION POLICY

(as Amended and Restated Effective February 19, 2021)

IGM Biosciences, Inc. (the "**Company**") believes that providing cash and equity compensation to members of the Company's Board of Directors (the "**Board**," and members of the Board, the "**Directors**") represents an effective tool to attract, retain and reward Directors who are not employees of the Company (the "**Outside Directors**"). This Outside Director Compensation Policy (the "**Policy**") is intended to formalize the Company's policy regarding cash compensation and grants of equity to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given such terms in the Company's Amended and Restated 2018 Omnibus Incentive Plan (the "**Plan**"). Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of compensation such Outside Director receives under this Policy.

This Policy was originally adopted and approved August 7, 2019 and was effective as of the effective date of the registration statement in connection with the initial public offering of the Company's securities (the "**Effective Date**"). This Policy, as amended and restated, is effective as of February 19, 2021.

1. CASH COMPENSATION

Annual Cash Retainer

Each Outside Director will be paid an annual cash retainer of $40,000. There are no per-meeting attendance fees for attending Board meetings. This cash compensation will be paid quarterly in arrears on a prorated basis.

Committee Annual Cash Retainer

Each Outside Director who serves as the Board chair or the chair or a member of a committee of the Board will be eligible to earn additional annual fees (paid quarterly in arrears on a prorated basis) as follows:

Board Chair:	$	30,000
Audit Committee Chair:	$	15,000
Audit Committee Member:	$	7,500
Compensation Committee Chair:	$	10,000
Compensation Committee Member:	$	5,000
Corporate Governance and Nominating Committee Chair:	$	10,000
Corporate Governance and Nominating Committee Member:	$	5,000
Research and Clinical Development Committee Chair:	$	10,000
Research and Clinical Development Committee Member:	$	5,000

For clarity, each Outside Director who serves as a committee chair will only receive the additional annual fee as the committee chair and not the additional annual fee as a committee member.

Payment

Except as specified in Section 2, each annual cash retainer under this Policy will be paid quarterly in arrears on a prorated basis to each Outside Director who has served in the relevant capacity at any point during the fiscal quarter, and such payment shall be made on the last business day of such fiscal quarter (or as soon thereafter as practical, but in no event later than 30 days following the end of such fiscal quarter). For purposes of clarification, an Outside Director who has served as an Outside Director and/or as a member of an applicable committee (or chair thereof) during only a portion of the relevant Company fiscal quarter will receive a pro-rated payment of the quarterly payment of the applicable annual cash retainer(s), calculated based on the number of

days during such fiscal quarter such Outside Director has served in the relevant capacities. For purposes of clarification, an Outside Director who has served as an Outside Director and/or as a member of an applicable committee (or chair thereof) from the Effective Date through the end of the fiscal quarter containing the Effective Date (the "Initial Period") will receive a prorated payment of the quarterly payment of the applicable annual cash retainer(s), calculated based on the number of days during the Initial Period that such Outside Director has served in the relevant capacities. In any event, an Outside Director who serves as an Outside Director and/or as a member of an applicable committee (or chair thereof) through the last business day of a quarter shall be deemed to have served in such capacity through to the end of such quarter for purposes of determining the fees or equity payable to him or her under this Policy.

2. ELECTIONS TO RECEIVE RESTRICTED STOCK UNITS IN LIEU OF CASH COMPENSATION

Following the Effective Date, subject to complying with the *Retainer Award Election Mechanics* below, each Outside Director may elect to convert 0%, 50% or 100% of his or her cash compensation with respect to services performed in a future quarter and otherwise scheduled to be paid under Section 1 of this Policy (the "**Retainer Cash Payments**") into a number of Restricted Stock Units ("**Retainer Award**") having a Grant Value equal to the aggregate amount of the elected percentage of the Retainer Cash Payments payable to such Outside Director under this Policy for the applicable quarter (as determined on the applicable date of grant of such Retainer Award), provided that the number of Shares covered by such Retainer Award shall be rounded to the nearest whole Share (such election, a "**Retainer Award Election**"). Quarterly Retainer Awards will be automatic and nondiscretionary and will be granted on the last business day of each quarter with respect to Retainer Cash Payments that would have been paid for such quarter. All Restricted Stock Units underlying such quarterly Retainer Awards will be fully vested upon grant and will be settled in Shares as soon as administratively practicable following each date of grant. For purposes of this Policy, "**Grant Value**" is calculated based on the volume weighted average price of one Share over the Company's fourth quarter of the year immediately preceding the year of the date of grant. For purposes of clarity, the amount of Retainer Cash Payments considered with respect to each quarterly Retainer Award will reflect any changes in committee assignments and any appointment or removal as the chair of committee based on the applicable fees earned during the prior quarter pursuant to Section 1 of this Policy.

Retainer Award Election Mechanics

Each Retainer Award Election must be submitted in the form and manner specified by the Board or Compensation Committee. An individual who fails to make a timely Retainer Award Election shall not receive a Retainer Award for the next calendar year, and instead shall receive the applicable Retainer Cash Payments for such calendar year. Once a Retainer Award Election is validly submitted and becomes effective, it will remain in effect with respect to all subsequent Retainer Cash Payments related to future calendar years unless the applicable Outside Director revokes such election as provided in (ii) below.

Retainer Award Elections must comply with the following timing requirements:

i. Annual Election. Each Outside Director may make a Retainer Award Election with respect to Annual Retainer Cash Payments payable to such Outside Director in the following calendar year (the "**Annual Election**"). The Annual Election must be submitted to the Company's Chief Financial Officer within the Company's fourth quarter open trading window (the "**Fourth Quarter Trading Window**") of the calendar year immediately preceding the calendar year to which the Retainer Cash Payments relate (the last day of such trading window, the "**Annual Election Deadline**"), and, except as provided in (ii) below, the Annual Election shall become irrevocable effective as of the Annual Election Deadline, provided that if such calendar year does not contain a Fourth Quarter Trading Window, Outside Directors will not be eligible to make an Annual Election in such calendar year.

ii. Revocation/Revision. An Outside Director may revoke or revise his or her existing Retainer Award Election during a Fourth Quarter Trading Window by such calendar year's Annual Election Deadline with respect to Retainer Cash Payments related to future calendar years. If a calendar year does not contain a Fourth Quarter Trading Window, Outside Directors will not be eligible to revoke or revise a Retainer Award Election in such calendar year.

3. EQUITY COMPENSATION

Outside Directors will be eligible to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Section 3 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(a) No Discretion. No person will have any discretion to select which Outside Directors will be granted any Awards under this Policy or to determine the number of Shares to be covered by such Awards.

(b) Initial Options. Each individual who first becomes an Outside Director following the Effective Date will be granted a nonstatutory stock option (an "**Initial Option**") having a Fair Value of $650,000. The Initial Option will be automatically granted on the first trading date on or after the date on which such individual first becomes an Outside Director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy. If an individual was a member of the Board and also an employee, becoming an Outside Director due to termination of employment will not entitle the Outside Director to an Initial Option. Each Initial Option will vest as to 1/3rd of the Shares subject to the Initial Option on the one-year anniversary of the date the applicable Outside Director's service as an Outside Director commenced and as to 1/36th of the Shares subject to the Initial Option each month thereafter, in each case subject to the Outside Director continuing to be a Service Provider through the applicable vesting date. Each Initial Option will become fully vested and exercisable immediately prior to a Change in Control, subject to the Outside Director continuing to be a Service Provider at the time of the Change in Control.

(c) Annual Options. Following the Effective Date, each Outside Director will be automatically granted a nonstatutory stock option on the same date as annual equity award grants are made to the Company's executive officers (an "**Annual Option**") having a Fair Value of $400,000. Each Annual Option will vest as to 1/12th of the Shares subject to the Annual Option each month that is completed after the date of the first annual meeting of the Company's stockholders following the date of grant (each, an "**Annual Meeting**") after the date the Annual Option is granted, provided that the Annual Option will vest in full on the earlier of (i) the 12-month anniversary of the first Annual Meeting following the date of grant, or (ii) the date of the second regularly scheduled Annual Meeting after the date of grant, in each case subject to the Outside Director continuing to be a Service Provider through the applicable vesting date.

(d) Additional Terms of Initial Options and Annual Options. The terms and conditions of each Initial Option and Annual Option will be as follows:

i. The term of each Initial Option and Annual Option will be ten years, subject to earlier termination as provided in the Plan.

ii. Each Initial Option and Annual Option will have an exercise price per Share equal to 100% of the Fair Market Value per Share on the grant date.

(e) For purposes of this Policy, "Fair Value" means the grant date fair value of an Award determined in accordance with U.S. generally accepted accounting principles.

4. CHANGE IN CONTROL

In the event of a Change in Control, each Outside Director will fully vest in his or her outstanding Company equity awards immediately prior to a Change in Control, including any Initial Option or Annual Option, provided that the Outside Director continues to be an Outside Director through the date of the Change in Control.

5. ANNUAL COMPENSATION LIMIT

No Outside Director may be paid, issued or granted, in any fiscal year, any cash compensation and Awards with an aggregate value greater than $1,000,000 for an Outside Director's first year of service or $750,000 in any subsequent year. The value of any Award will be based on its Fair Value. Any cash compensation paid or Awards granted to an individual for his or her services as an Employee, or for his or her services as a Consultant (other than as an Outside Director), will not count for purposes of the limitation under this Section 5.

6. TRAVEL EXPENSES

Each Outside Director's reasonable, customary and documented out-of-pocket travel expenses to Board and committee meetings will be reimbursed by the Company.

7. ADDITIONAL PROVISIONS

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors thereunder.

8. ADJUSTMENTS

In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

9. SECTION 409A

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (i) 15th day of the 3rd month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (ii) 15th day of the 3rd month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company or any of its Parent or Subsidiaries have any liability or obligation to reimburse, indemnify, or hold harmless an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

10. STOCKHOLDER APPROVAL

The initial adoption of the Policy will be subject to approval by the Company's stockholders prior to the Effective Date. Unless otherwise required by applicable law, following such approval, the Policy shall not be subject to approval by the Company's stockholders, including, for the avoidance of doubt, as a result of or in connection with an action taken with respect to this Policy as contemplated in Section 11 hereof.

11. REVISIONS

The Board may amend, alter, suspend or terminate this Policy at any time and for any reason. No amendment, alteration, suspension or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed in writing between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Compensation Committee's ability to exercise the powers granted to it under the Plan with respect to Awards granted under the Plan pursuant to this Policy prior to the date of such termination.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-249863 on Form S-3 and Registration Statement Nos. 333-248111, 333-237411 and 333-233826 on Form S-8 of our report dated March 30, 2021 relating to the financial statements of IGM Biosciences, Inc., appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

//s// Deloitte & Touche

San Francisco, California
March 30, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fred Schwarzer, certify that:

1. I have reviewed this Annual Report on Form 10-K of IGM Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2021

By: /s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Misbah Tahir, certify that:

1. I have reviewed this Annual Report on Form 10-K of IGM Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2021

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of IGM Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fred Schwarzer, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2021

By: /s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of IGM Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Misbah Tahir, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2021

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial and Accounting Officer)