UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): December 18, 2020

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**0-17999**	**04-2726691**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 895-0600

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	IMGN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 8.01 - Other Events.

In connection with the filing of a registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC"), ImmunoGen, Inc. (the "Company") is updating the risk factor disclosure contained in its prior public filings, including the risk factor disclosure included under the heading "Risk Factors" included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 11, 2020, principally as a result of amendments to Item 105 of Regulation S-K adopted by the SEC which became effective on November 9, 2020. The updated risk factor disclosure is filed herewith as Exhibit 99.1 to the Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Updated Risk Factors of ImmunoGen, Inc as of December 18,2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ImmunoGen, Inc.

Date: December 18, 2020

By: /s/ David G. Foster
David G. Foster
Vice President, Finance

Unless the context otherwise requires in this Exhibit 99.1, "ImmunoGen," "the Company," "we," "us," "our" and similar names refer to ImmunoGen, Inc. and our subsidiaries. Our trademarks include, without limitation, our name and corporate logo. Other service marks, trademarks and trade names contained in this Exhibit 99.1 are the property of their respective owners.

RISK FACTORS

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. BEFORE DECIDING WHETHER TO INVEST IN OUR COMMON STOCK, YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW. THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY AND IF ANY OF THESE RISKS ACTUALLY OCCURS, OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, OR CASH FLOW COULD BE SERIOUSLY HARMED. ADDITIONAL RISKS AND UNCERTAINTIES THAT WE ARE UNAWARE OF OR THAT WE CURRENTLY DEEM IMMATERIAL ALSO MAY BECOME IMPORTANT FACTORS THAT AFFECT OUR COMPANY AND MAY MATERIALLY IMPAIR OUR BUSINESS.

Risks Related to our Financial Condition

We have a history of operating losses and expect to incur significant additional operating losses and may never be profitable.

We have generated operating losses since our inception. As of September 30, 2020, we had an accumulated deficit of $1.4 billion. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our development, preclinical testing, clinical trials, and collaborator support activities continue. We intend to continue to invest significantly in our product candidates. We may encounter technological or regulatory difficulties as part of this development and commercialization process that we cannot overcome or remedy. Our revenues to date have been primarily from upfront and milestone payments, research and development support, and clinical materials reimbursement from our collaborators, and from royalties received from the commercial sales of Kadcyla (which we sold partial cash rights to 2015 and the remainder in 2019). Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, our expenses could increase beyond expectations if we are required by the Food and Drug Administration, or FDA, or foreign regulatory agencies, to perform studies and clinical trials in addition to those that we currently anticipate, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. We do not expect to generate revenues from the commercial sale of our internal product candidates in the near term, and we may never generate revenues from the commercial sale of internal products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment.

If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.

We will continue to expend substantial resources developing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing products, establishing marketing and sales capabilities to commercialize our product candidates, as well as providing certain support to our collaborators in the development of their products. We believe that our current working capital and expected future collaborator payments will be sufficient to meet our current and projected operating and capital requirements for at least the next 12 months. Conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that can take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that may not be commercially available for several years, if ever. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives.

In addition, we cannot provide assurance that anticipated collaborator payments will, in fact, be received. Should such future collaborator payments not be received, we expect we could seek additional funding from other sources. We may elect or need to seek additional financing sooner due to a number of other factors as well, including:

- if either we incur higher than expected costs or we or any of our collaborators experience slower than expected progress in developing product candidates and obtaining regulatory approvals; and

- acquisition of technologies and other business opportunities that require financial commitments.

Additional funding may not be available to us in sufficient amounts, on favorable terms, or at all. We may raise additional funds through public or private financings, collaborative arrangements, or other arrangements. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Volatility in the financial markets has generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. Debt financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back, or eliminate expenditures for some of our development programs, including restructuring our operations, refinancing or restructuring our debt, or grant rights to develop and market product candidates that we would otherwise prefer to internally develop and market. If we are required to grant such rights, the ultimate value of these product candidates to us may be reduced.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change," is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more shareholders or groups of shareholders who own at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year period. We may have experienced such ownership changes in the past, and we may experience shifts in our stock ownership, some of which are outside ImmunoGen's control. These ownership changes may subject our existing NOLs or credits to substantial limitations under Sections 382 and 383. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. As of December 31, 2019, we had federal NOLs of approximately $471.6 million available to reduce federal taxable income, if any, that begin to expire in 2029 through 2038, $269.2 million of federal NOLs that can be carried forward indefinitely, and $64.4 million of federal credit carryforwards that expire beginning in 2021. Limitations on our ability to utilize those NOLs to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to Our Business and Industry

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business and our financial results.

The spread of COVID-19 has affected segments of the global economy and may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. The current outbreak of COVID-19 has spread worldwide, including countries where we are currently conducting our clinical trials, including our SORAYA and MIRASOL trials. The COVID-19 pandemic is still evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions, and other public health safety measures, as well as reported adverse impacts on healthcare resources, facilities, and providers across the United States, and in other countries worldwide. The continued impact of COVID-19 may result in a period of business disruption, including delays in our clinical trials or delays or disruptions in our supply chain.

The continued impact of COVID-19 globally could adversely affect our clinical trial operations in the United States and elsewhere, including our ability to recruit and retain patients, principal investigators, and site staff who, as healthcare providers, may have heightened exposure to COVID-19. For example, COVID-19 has slowed site activation and patient enrollment for SORAYA, which we believe will result in a limited delay of six- to eight-weeks in the availability of top-line data from this trial from mid-2021 to the third quarter of 2021, and MIRASOL, from which we now expect top-line data in 2022. Even with the approval of vaccines for COVID-19, the pandemic may further delay enrollment in trials due to prioritization of hospital resources toward the pandemic, restrictions on travel, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out our clinical trials. Although we entered the pandemic with ample supply of our drug candidates and we believe we have sufficient inventory on hand for all of our ongoing mirvetuximab monotherapy and combination trials, IMGN632 expansion studies, and activities to support the Phase 1 study for IMGC936, the continuation of the COVID-19 pandemic, or the spread of another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates if we need additional materials. Additionally, although our supply partners have taken prospective measures that we believe will ensure our currently activated trial sites have sufficient safety stock of our drug candidates to weather disruptions in transportation or supply, interruption in the manufacture and/or global shipping affecting the transport of clinical trial materials, such as patient samples, product candidates, and other supplies used in our clinical trials may negatively affect our trials.

In addition, in response to the pandemic and in accordance with direction from state and local government authorities, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring most employees to work remotely (which in turn increases our threat to cyber security, data accessibility, and communication matters), and suspending all non-essential travel worldwide for our employees. In addition, industry events and in-person work-related meetings have been canceled, the continuation of which could negatively affect our business.

The trading prices for our common stock and other biotechnology companies have also been highly volatile as a result of the COVID-19 pandemic. We, therefore, may face difficulties raising capital through sales of our common stock or equity linked to our common stock, or such sales may be on unfavorable terms or unavailable.

We cannot presently predict the scope and severity of any additional potential business shutdowns or disruptions as a result of the COVID-19 pandemic. If we or any of the third parties with whom we engage, however, were to experience further 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 affected, which could have a material adverse impact on our business and our results of operation and financial condition.

If our Antibody-Drug Conjugate technology does not produce safe, effective, and commercially viable products or if such products fail to obtain or maintain FDA approval, our business will be severely harmed.

Our Antibody-Drug Conjugate, or ADC, technology yields novel product candidates for the treatment of cancer. To date, only one ADC using our technology, Kadcyla, has obtained marketing approval. Our ADC product candidates and/or our collaborators' ADC product candidates may not prove to be safe, effective, or commercially viable treatments for cancer and as a result, our ADC technology may not result in any future meaningful benefits to us or for our current or potential collaborators. Furthermore, we are aware of only a limited number of other compounds that are based on technology similar to our ADC technology that have obtained marketing approval by the FDA. If our ADC technology fails to generate product candidates that are safe, effective, and commercially viable treatments for cancer or such product candidates fail to obtain or maintain FDA approval, our business will be severely harmed. In March of 2019, we announced that our FORWARD I Phase 3 clinical trial evaluating mirvetuximab soravtansine compared to chemotherapy in women with FRα-positive, platinum-resistant ovarian cancer, did not meet the primary endpoint in either the entire treatment population or the pre-specified high FRα expression population. Based on post hoc exploratory analyses of the FORWARD I results and consultations with the FDA, we are conducting two new trials of mirvetuximab soravtansine, SORAYA and MIRASOL, to support the potential approval of mirvetuximab soravtansine as a monotherapy. We are also continuing FORWARD II to assess mirvetuximab soravtansine as a combination therapy. Negative results in any of these ongoing clinical trials could cause us to discontinue further development of mirvetuximab soravtansine as a monotherapy, as combination therapy, or both, and may significantly harm our business and future prospects.

Clinical trials for our product candidates and those of our collaborators will be lengthy and expensive, and their outcome is uncertain.

Before obtaining regulatory approval for the commercial sale of any product candidates, we and our collaborators must demonstrate through clinical testing that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time-consuming, expensive, and uncertain process and typically requires years to complete. In our industry, the results from preclinical studies and early clinical trials often are not predictive of results obtained in later-stage clinical trials. Some compounds that have shown promising results in preclinical studies or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. For example, despite encouraging results from earlier clinical trials of mirvetuximab soravtansine, our FORWARD I Phase 3 clinical trial evaluating mirvetuximab soravtansine compared to chemotherapy in women with FRα-positive, platinum-resistant ovarian cancer, did not meet the primary endpoint in either the entire treatment population or the pre-specified high FRα expression population. Based on post hoc exploratory analyses of the FORWARD I results and consultations with the FDA, we are conducting two new trials of mirvetuximab soravtansine, SORAYA and MIRASOL, to support the potential approval of mirvetuximab soravtansine as a monotherapy. The results of SORAYA and/or MIRASOL may not show positive results consistent with our post hoc exploratory analyses of the FORWARD I results or earlier successful trials of mirvetuximab soravtansine as monotherapy which would cause significant harm to our business and future prospects.

At any time during the clinical trials, we, our collaborators, or the FDA or other regulatory authority might delay or halt any clinical trials of our product candidates for various reasons, including:

- occurrence of unacceptable toxicities or side effects;
- ineffectiveness of the product candidate;
- insufficient drug supply, including delays in obtaining supplies/materials necessary for manufacturing such drugs;
- negative or inconclusive results from the clinical trials, or results that necessitate additional nonclinical studies or clinical trials;
- delays in obtaining or maintaining required approvals from institutions, review boards, or other reviewing entities at clinical sites;
- delays in patient enrollment;
- insufficient funding or a reprioritization of financial or other resources;
- our or our collaborators' inability to develop and obtain approval for any companion *in vitro* diagnostic devices that the FDA or other regulatory authority may conclude must be used with such product candidates to ensure their safe use; or
- other reasons that are internal to the businesses of our collaborators and third-party suppliers, which they may not share with us.

Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates or our collaborators' product candidates could severely harm our business.

If our product candidates or those of our collaborators do not gain market acceptance, our business will suffer.

Even if clinical trials demonstrate the safety and efficacy of our and our collaborators' product candidates and the necessary regulatory approvals are obtained, our and our collaborators' products may not gain market acceptance among physicians, patients, healthcare payers, and other members of the medical community. The degree of market acceptance of any products that we or our collaborators develop will depend on a number of factors, including:

- their level of clinical efficacy and safety;
- their advantage over alternative treatment methods;
- our/the marketer's and our collaborators' ability to gain acceptable reimbursement and the reimbursement policies of government and other third-party payers; and
- the quality of the distribution capabilities of the party(ies) responsible to market and distribute the product(s).

Physicians may not prescribe any of our future products until such time as clinical data or other factors demonstrate the safety and efficacy of those products as compared to conventional drugs and other treatments. Even if the clinical safety and efficacy of our products are established, physicians may elect not to recommend the therapies for any number of other reasons, including whether the physicians are already using competing products that satisfy their treatment objectives. If our products do not achieve significant market acceptance and use, we will not be able to recover the significant investment we have made in developing such products and our business will be severely harmed.

We face product liability risks and may not be able to obtain adequate insurance.

While we secure waivers from all participants in our clinical trials, the use of our product candidates during testing or after approval entails an inherent risk of adverse effects, which could expose us to product liability claims. Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We may not have sufficient resources to satisfy any liability resulting from these claims. While we currently have product liability insurance for products that are in clinical testing, our coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance or obtain general product liability insurance on reasonable terms and at an acceptable cost if we or our collaborators begin commercial production of our proposed product candidates. This insurance, even if we can obtain and maintain it, may not be sufficient to provide us with adequate coverage against potential liabilities.

We currently do not have the direct sales, marketing, or distribution capabilities necessary to successfully commercialize our products on a large scale and may be unable to establish such capabilities.

We hold the worldwide rights to commercialize mirvetuximab soravtansine, and currently intend to commercialize mirvetuximab soravtansine ourselves in the United States and the European Union. Alternatively, we may choose to rely on third parties to market and sell mirvetuximab soravtansine in different territories, either through distributor or outlicensing arrangements. At this time, we do not have any significant direct sales, marketing or distribution capabilities. In addition, co-promotion or other marketing arrangements with third parties to commercialize mirvetuximab soravtansine or other future potential products could significantly limit the revenues we derive from these compounds, and these third parties may fail to commercialize our compounds successfully.

We may be unable to compete successfully.

The markets in which we compete are well established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in lower volume sold, pricing reductions, reduced gross margins, and failure to achieve market acceptance for our potential products. Our competitors include research institutions, pharmaceutical companies, and biotechnology companies, such as Pfizer, Seattle Genetics, Roche, Astellas, AstraZeneca/MedImmune, Daiichi Sankyo, GlaxoSmithKline, and AbbVie. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, human, and other resources than we do. As a result, they may:

- develop products that are safer or more effective than our product candidates;
- obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;
- devote greater resources to market or sell their products;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licensing and collaboration arrangements; and
- take advantage of acquisitions or other opportunities more readily than we can.

A number of pharmaceutical and biotechnology companies are currently developing products targeting the same types of cancer that we target, and some of our competitors' products have entered clinical trials or already are commercially available.

Our product candidates, if approved and commercialized, will also compete against well-established, existing, therapeutic products that are currently reimbursed by government healthcare programs, private health insurers, and health maintenance organizations. In addition, if our product candidates are approved and commercialized, we may face competition from biosimilars. The ACA, which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the Public Health Service Act to create an abbreviated approval pathway for two types of "generic" biologics —biosimilars and interchangeable biologic products. The BPCIA establishes a pathway for the FDA approval of follow-on biologics and provides twelve years data exclusivity for reference products and an additional six months exclusivity period if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions, and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments surrounding antibody-based therapeutics for cancer continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

Risks Related to Our Dependence on Third Parties

If our collaborators fail to perform their obligations under our agreements with them, or determine not to continue with clinical trials for particular product candidates, our business could be severely affected.

The development and commercialization of our product candidates depends, in part, upon the formation and maintenance of collaborative arrangements. Collaborations provide an opportunity for us to:

- generate cash flow and revenue;
- fund some of the costs associated with our internal research and development, preclinical testing, clinical trials, and manufacturing;
- seek and obtain regulatory approvals faster than we could on our own;
- successfully commercialize existing and future product candidates; and
- secure access to targets which, due to intellectual property restrictions, would otherwise be unavailable to our technology.

If we fail to secure or maintain successful collaborative arrangements, the development and marketing of compounds that use our technology may be delayed, scaled back, or otherwise may not occur. In addition, we may be unable to negotiate other collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. We cannot control the amount and timing of resources our collaborators may devote to our product candidates. Our collaborators may separately pursue competing product candidates, therapeutic approaches, or technologies to develop treatments for the diseases targeted by us or our collaborative efforts, or may decide, for reasons not known to us, to discontinue development of product candidates under our agreements with them. Any of our collaborators may slow or discontinue the development of a product candidate covered by a collaborative arrangement for reasons that can include, but are not limited to:

- a change in the collaborative partner's strategic focus as a result of merger, management changes, adverse business events, or other causes;
- a change in the priority of the product candidate relative to other programs in the collaborator's pipeline;
- a reassessment of the patent situation related to the compound or its target;
- a change in the anticipated competition for the product candidate;
- preclinical studies and clinical trial results; and
- a reduction in the financial resources the collaborator can or is willing to apply to the development of new compounds.

Even if our collaborators continue their collaborative arrangements with us, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our collaborators may fail to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our collaborators can terminate our collaborative agreements under certain conditions. The decision to advance a product that is covered by a collaborative agreement through clinical trials and ultimately to commercialization is, in some cases, at the discretion of our collaborators. If any collaborative partner were to terminate or breach our agreements, fail to complete its obligations to us in a timely manner, or decide to discontinue its development of a product candidate, our anticipated revenue from the agreement and the development and commercialization of the products could be severely limited or eliminated. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, or at all, our continued development, manufacture, and commercialization of our product candidates could be delayed or scaled back as we may not have the funds or capability to continue these activities. If our collaborators fail to successfully develop and commercialize ADC compounds, our business prospects could be severely harmed.

If our product requirements for clinical trials are significantly higher than we estimated, the inability to procure additional antibody production, conjugation, or fill/finish services in a timely manner could impair our ability to initiate or advance our clinical trials.

We rely on third-party suppliers to manufacture antibodies used in our own proprietary compounds. Due to the specific nature of the antibody and availability of production capacity, there is significant lead time required by these suppliers to provide us with the needed materials. If our antibody requirements for clinical materials to be manufactured are significantly higher than we estimated, we may not be able to readily procure additional antibody which would impair our ability to advance our clinical trials currently in process or initiate additional trials. We also rely on third parties to manufacture bulk drug substance and convert it into filled and finished vials of drug product for clinical use. If our product requirements are significantly higher than we estimated, we may not be able to readily procure slots to manufacture bulk drug substance or to convert drug substance into filled and finished vials of drug product for clinical use. There can be no assurance that we will not have supply problems that could delay or stop our clinical trials or otherwise could have a material adverse effect on our business.

We are currently contractually required to obtain all of the DM4 used in mirvetuximab soravtansine from a single third-party manufacturer, and any delay or interruption in such manufacturer's operations could impair our ability to advance preclinical and clinical trials and commercialization of our product candidates and our collaborators' products candidates.

We rely on a sole third-party supplier, Società Italiana Corticosteroidi S.r.l, to manufacture the DM4 used in mirvetuximab soravtansine. Any delay or interruption in the operations of our sole third-party supplier and/or our supply of DM4 could lead to a delay or interruption in our manufacturing operations, preclinical studies, clinical trials, and commercialization of our product candidates and our collaborators' product candidates, which could negatively affect our business.

We currently rely on, and expect to continue to rely on, third-party manufacturers to produce our antibodies, linkers, payloads, drug substance, and drug product, and any delay or interruption in such manufacturers' operations could impair our ability to advance clinical trials and commercialization of our product candidates.

We rely on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. We have established relationships with third-party manufacturers to provide materials for our clinical trials, and are developing relationships with these and other third-party manufacturers that we believe will be necessary to continue the development of our product candidates and to supply commercial quantities of these product candidates, if they are approved. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity, or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of applications for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

The facilities used to manufacture our product candidates (drug substance and drug product) must be approved by the FDA (and other similar regulatory agencies outside the United States depending on where marketing authorizations are filed) before marketing authorizations are approved. Often, but not always, these inspections are triggered by marketing authorization submissions. We are completely dependent on our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or others, we will not be able to use the products produced at their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or a comparable foreign regulatory authority finds that these facilities do not comply with cGMP, 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. Further, our failure, or the failure of our third-party manufacturers, to comply with these or other applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We depend on a small number of collaborators for a substantial portion of our revenue. The loss of, or a material reduction in activity by, any one of these collaborators could result in a substantial decline in our revenue.

We have and will continue to have collaborations with a limited number of companies. As a result, our financial performance depends on the efforts and overall success of these companies. Also, the failure of any one of our collaborators to perform its obligations under its agreement with us, including making any royalty, milestone, or other payments to us, could have an adverse effect on our financial condition. Further, any material reduction by any one of our collaborators in its level of commitment of resources, funding, personnel, and interest in continued development under its agreement with us could have an adverse effect on our financial condition. If a present or future collaborator of ours were to be involved in a business combination, the collaborator's continued pursuit and emphasis on our product development program could be delayed, diminished, or terminated.

We depend on our collaborators for the determination of royalty payments. We may not be able to detect errors and payment calculations may call for retroactive adjustments.

The royalty payments we may receive are determined by our collaborators based on their reported net sales. Each collaborative partner's calculation of the royalty payments is subject to and dependent upon the adequacy and accuracy of its sales and accounting functions, and errors may occur from time to time in the calculations made by a collaborative partner. Our agreement with Genentech provides us the right to audit the calculations and sales data for the associated royalty payments related to sales of Kadcyla; however, such audits may occur many months following our recognition of the royalty revenue, may require us to adjust our royalty revenues in later periods and generally require audit-related costs on our part.

Royalty rates under our license agreements with our collaborators may vary over the royalty term depending on our intellectual property rights and the existence of certain third-party competing products.

Most of our license agreements with our collaborators provide that the royalty rates are subject to downward adjustment in the absence of ImmunoGen patent rights covering various aspects of the manufacture, use, or sale of the products developed under such licenses, or if certain third-party products compete with the particular product covered by the license agreement.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights adequately, the value of our technology and our product candidates could be diminished.

Our success depends in part on obtaining, maintaining, and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and in foreign countries that cover our novel product candidates and their uses, pharmaceutical formulations and dosages, and processes for the manufacture of them. Our patent portfolio currently includes both patents and patent applications. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving, is surrounded by a great deal of uncertainty, and involves complex legal, scientific, and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, our pending patent applications may not result in issued patents or in patent claims as broad as in the original applications. Although we own numerous patents, the issuance of a patent is not conclusive as to its validity or enforceability. Through litigation, a third party may challenge the validity or enforceability of a patent after its issuance. In addition, the patent prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Patents and patent applications owned or licensed by us may become the subject of interference, opposition, nullity, or other proceedings in a court or patent office in the United States or in a foreign jurisdiction to determine validity, enforceability, or priority of invention, which could result in substantial cost to us. An adverse decision in such a proceeding may result in our loss of rights under a patent or patent application. It is unclear how much protection, if any, will be given to our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. A competitor may successfully invalidate our patents or a challenge could result in limitations of the patents' coverage. In addition, the cost of litigation or interference proceedings to uphold the validity of patents can be substantial. If we are unsuccessful in these proceedings, third parties may be able to use our patented technology without paying us licensing fees or royalties. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In an infringement proceeding, a court may decide that a patent of ours is not valid. Even if the validity of our patents were upheld, a court may refuse to stop the other party from using the technology at issue on the ground that its activities are not covered by our patents.

The Leahy-Smith America Invents Act became fully effective in 2013. In general, the legislation attempts to address issues surrounding the enforceability of patents and the increase in patent litigation by, among other things, moving to a first inventor-to-file system, establishing new procedures for challenging patents, and establishing different methods for invalidating patents. Governmental rule-making implementing the new statute is evolving and will continue to introduce new substantive rules and procedures, particularly with regard to post-grant proceedings such as *inter partes* review and post-grant review. In due course, the courts will interpret various aspects of the law and related agency rules in ways that we cannot predict, potentially making it easier for competitors and other interested parties to challenge our patents, which, if successful, could have a material adverse effect on our business and prospects. In addition, the U.S. Supreme Court has become increasingly active in reviewing U.S. patent law in recent years, and the extent to which recent decisions will affect our ability to enforce certain types of claims under our U.S. patents or obtain future patents in certain areas is difficult to predict at this time.

Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

In addition to our patent rights, we also rely on unpatented technology, trade secrets, know-how, and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets, know-how, and confidential information. We require each of our employees, consultants, and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting, or collaborative relationship with us. Further, we require that all employees enter into assignment of invention agreements as a condition of employment. However, these agreements may not provide effective protection of our information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies. If we are unable to prevent material disclosure of the trade secrets and other intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, adversely affecting our market position and business and operational results.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights held by third parties and we may be unable to protect our rights to, or to commercialize, our product candidates.

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products, or other matters. From time to time, we have received correspondence from third parties alleging that we infringe their intellectual property rights. Any claims that might be brought against us alleging infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation would be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing, or selling potential products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. There may be third-party patents, patent applications, and other intellectual property relevant to our potential products that may block or compete with our products or processes of which we are currently unaware with claims that cover the use or manufacture of our drug candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our drug candidates may infringe. In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third-party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain such license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

Any inability to license proprietary technologies or processes from third parties that we use in connection with the development and manufacture of our product candidates may impair our business.

Other companies, universities, and research institutions have or may obtain patents that could limit our ability to use, manufacture, market, or sell our product candidates or impair our competitive position. As a result, we would have to obtain licenses from other parties before we could continue using, manufacturing, marketing, or selling our potential products. Any necessary licenses may not be available on commercially acceptable terms, if at all. If we do not obtain the required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign products or methods that are found to infringe the patents held by others.

Risks Related to Government Regulation

We and our collaborators are subject to extensive government regulations and we and our collaborators may not be able to obtain necessary regulatory approvals.

We and our collaborators may not receive the regulatory approvals necessary to commercialize our product candidates, which would cause our business to be severely harmed. Pharmaceutical product candidates, including those in development by us and our collaborators, are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of pharmaceutical products. If our potential products or our collaborators' potential products are marketed outside of the United States, they will also be subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, complex, expensive, and uncertain. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the authorities for each indication to establish the product candidate's safety and efficacy. Data obtained from preclinical and other nonclinical studies and clinical trials are susceptible to varying interpretation, which may delay, limit, or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other regulatory approvals of our or our collaborators' product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

- delay marketing of potential products for a considerable period of time;
- limit the indicated uses for which potential products may be marketed;
- impose costly requirements on our activities; and
- place us at a competitive disadvantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in regulatory policy during the period of product development, clinical trials, and regulatory review. Failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. In addition, we are, or may become, subject to various federal, state, and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions, and civil and criminal penalties.

Our and our collaborators' product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we or our collaborators fail to comply with regulations applicable to approved products, these approvals could be lost and the sale of our or our collaborators' products could be suspended.

Even if we or our collaborators receive regulatory approval to market a particular product candidate, the approval could be conditioned on us or our collaborators conducting costly post-approval studies or could limit the indicated uses included in product labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us or our collaborators to withdraw it from the market, or impede or delay our or our collaborators' ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to regulatory review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record-keeping related to the product remain subject to extensive regulatory requirements. We do not have prior experience complying with regulations pertaining to products that have already received marketing approval and, therefore, we may be unable or slow to comply with existing regulations, including changes in existing regulatory requirements, or new regulations. Furthermore, our collaborators may be slow to adapt, or may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements pertaining to products that have already received approval.

If we or our collaborators fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or if previously unknown problems with our or our partners' products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Any one of these could have a material adverse effect on our business or financial condition.

Unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives applicable to our product candidates could limit our potential product revenue.

Regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sales price of a drug before it can be marketed. Some countries restrict the physicians that can authorize the use of more expensive medications. Some countries establish treatment guidelines to help limit the use of more expensive therapeutics and the pool of patients that receive them. In some countries, including the United States, third-party payers frequently seek discounts from list prices and are increasingly challenging the prices charged for medical products. Because our product candidates are in the development stage, we do not know the level of reimbursement, if any, we will receive for any products that we are able to successfully develop. If the reimbursement for any of our product candidates is inadequate in light of our development and other costs, our ability to achieve profitability would be affected.

We believe that the efforts of governments and third-party payers to contain or reduce the cost of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory proposals to change the healthcare system in the United States and other major healthcare markets have been proposed and adopted in recent years. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 created a limited prescription drug benefit for Medicare beneficiaries. While the program established by this statute may increase demand for any products that we are able to successfully develop, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than prices we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. The ACA, which became effective in 2010, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and institute additional health policy reforms. It also requires discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers. The financial impact of these discounts, increased rebates and fees, and the other provisions of the ACA on our business is unclear and there can be no assurance that our business will not be materially adversely affected by the ACA. The ACA has been under scrutiny by the U.S. Congress almost since its passage, and certain sections of the ACA have not been fully implemented or have effectively been repealed, for example, as part of the Tax Cuts and Jobs Act, the U.S. Congress eliminated the ACA's individual mandate. The longevity of other key provisions of the ACA continues to be uncertain. In addition, ongoing initiatives in the United States have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product candidate that we may successfully develop.

In 2016, the 21st Century Cures Act was signed into law. This law is intended to enable the acceleration of the discovery, development, and delivery of 21st century cures, among other things. Provisions in that law, such as those applying to precision medicine, technical updates to clinical trial databases, and advancing new drug therapies, could apply directly or indirectly to our activities and those of our collaborators. At this point, however, it is not clear when that law will be fully implemented and what effect it may have on our business.

If we fail to comply with environmental, health, and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous federal, state, and local environmental, health, and safety laws and regulations, including those governing the manufacture and transportation of hazardous materials and pharmaceutical compounds. Although we believe that our contracted research, development, and manufacturer safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future, including civil or criminal fines and penalties, which we may not be able to afford.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations applicable to us. These current or future laws and regulations may impair our research, development, or production efforts or impact the research activities we pursue, particularly with respect to research involving human subjects or animal testing. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions, which could cause our financial condition to suffer.

Failure to comply with the Foreign Corrupt Practices Act and other similar anti-corruption laws and anti-money laundering laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations could subject us to significant penalties and damage our reputation.

We are subject to the Foreign Corrupt Practices Act, or FCPA, which generally prohibits U.S. companies and intermediaries acting on their behalf from offering or making corrupt payments to “foreign officials” for the purpose of obtaining or retaining business or securing an improper business advantage. The FCPA also requires companies whose securities are publicly listed in the United States to maintain accurate books and records and to maintain adequate internal accounting controls. We are also subject to other similar anti-corruption laws and anti-money laundering laws, as well as export control laws, customs laws, sanctions laws, and other laws that apply to our activities in the countries where we operate. Certain of the jurisdictions in which we conduct or expect to conduct business have heightened risks for public corruption, extortion, bribery, pay-offs, theft, and other fraudulent practices. In many countries, health care professionals who serve as investigators in our clinical studies, or may prescribe or purchase any of our product candidates if they are approved, are employed by a government or an entity owned or controlled by a government. Dealings with these investigators, prescribers, and purchasers are subject to regulation under the FCPA. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws, and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties, and other sanctions.

Inadequate funding for the FDA, the Securities and Exchange Commission, 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, 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 U.S. Securities and Exchange Commission, or 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, over the last several years, including December 22, 2018 to January 25, 2019, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough employees and stop critical activities. If a prolonged government shutdown or a series of shutdowns occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to gain access to the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be subject to, or may in the future become subject to, U.S. federal and state and foreign laws and regulations imposing obligations on how we collect, use, disclose, store, and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and adversely affect our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction, and disposal of personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which such data are processed. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

The legislative and regulatory landscape for privacy and data security continues to evolve. For example, the EU General Data Protection Regulation, or GDPR, which was effective as of May 25, 2018, introduced new data protection requirements in the European Union relating to the consent of the individuals to whom the personal data relate, the information provided to the individuals, the documentation we must retain, the security and confidentiality of the personal data, data breach notification, and the use of third party processors in connection with the processing of personal data. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR. However, our ongoing efforts related to compliance with the GDPR may not be successful and could increase our cost of doing business. In addition, data protection authorities of the different EU member states may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union. It is also not yet clear how the United Kingdom’s withdrawal from the European Union, or BREXIT, will affect the approval, distribution and marketing of medicinal products in the United Kingdom.

In the United States, California adopted the California Consumer Privacy Act of 2018, or CCPA, which became effective in January 2020. The CCPA has been characterized as the first “GDPR-like” privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the EU GDPR. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

Risks Related to the Ownership of Our Common Stock

Our stock price may be volatile and fluctuate significantly and results announced by us and our collaborators or competitors could cause our stock price to decline.

Our stock price could fluctuate significantly due to the risks listed in this section, business developments announced by us and by our collaborators and competitors, or as a result of market trends and daily trading volume. The business developments that could affect our stock price include disclosures related to clinical findings with compounds that make use of our ADC technology, new collaborations, and clinical advancement or discontinuation of product candidates that make use of our ADC technology or product candidates that compete with our compounds or those of our collaborators. Our stock price could also fluctuate significantly with the level of overall investment interest in small-cap biotechnology stocks or for other reasons unrelated to our business.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenue is unpredictable and may fluctuate due to the timing of non-recurring licensing fees, decisions of our collaborators with respect to our agreements with them, and the achievement of milestones and our receipt of the related milestone payments under new and existing licensing and collaboration agreements. Revenue historically recognized under our prior collaboration agreements may not be an indicator of revenue from any future collaboration. In addition, our expenses are unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include obligations to manufacture or supply product or payments owed by us under licensing or collaboration agreements. It is possible that our quarterly and/or annual operating results will not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline. We believe that quarter-to-quarter and year-to-year comparisons of our operating results are not good indicators of our future performance and should not be relied upon to predict the future performance of our stock price.

The potential sale of additional shares of our common stock may cause our stock price to decline.

We may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest of existing shareholders will be diluted and the price of our stock may decline. The price of our common stock may also decline if the market expects us to raise additional capital through the sale of equity or convertible debt securities whether or not we actually plan to do so.

We do not intend to declare or pay cash dividends on our common stock in the foreseeable future.

We have not declared or paid cash dividends on our common stock since our inception and do not intend to declare or pay cash dividends in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Therefore, shareholders will have to rely solely on appreciation in our stock price, if any, in order to achieve a gain on an investment.

General Risk Factors

We depend on our key personnel and we must continue to attract and retain key employees and consultants.

We depend on our key scientific and management personnel. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. 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 to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, sales, marketing, distribution, and finance. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel, or, in the event key personnel leave, suitable replacements for such personnel, on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical, and healthcare companies, universities, and non-profit research institutions. Failure to retain our existing key management and scientific personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) laws or regulations in jurisdictions where we are performing activities in relation to our product candidates, including those laws requiring the reporting of true, complete, and accurate information to such authorities; (2) manufacturing regulations and standards; (3) applicable laws prohibiting the promotion of a medical product for a use that has not been cleared or approved; (4) fraud and abuse, anti-corruption, and anti-money laundering laws, as well as similar laws and regulations and other laws; or (5) laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to laws intended to prevent fraud, bias, misconduct, kickbacks, self-dealing, and other abusive practices, and these laws may differ substantially from country to country. Misconduct by these parties could also include the improper use of information obtained in the course of clinical trials or performing other services, which could result in investigations, sanctions, and serious harm to their or our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions and procedures we currently take or may establish in the future as our operations and employee, CRO's, consultant, and collaborator base expands to detect and prevent this type of 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 by these parties to comply with such 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 and results of operations, including the imposition of significant fines or other sanctions. In addition, we have limited experience with respect to laws governing the commercial sale of pharmaceutical products and we will need to implement measures to ensure compliance with these laws before the commercialization of any of our product candidates, if approved. The failure to adequately implement these measures could negatively affect our sales and marketing activities and our business.

Our business and operations could suffer in the event of system failures.

We utilize information technology systems and networks to process, transmit, and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability, and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our internal computer systems and those of our third-party contract research organizations, or CROs, and other contractors and consultants are vulnerable to damage from cyber-attack, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party CROs and other contractors and consultants. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.