Reconciliation of Adjusted Net Income (Loss) attributable to shareholders of Cellectis to Net Income (Loss) attributable to shareholders of Cellectis

	2015	2016	2017	2018	2019
			$ in thousands		
Net Income (Loss) attributable to shareholders of Cellectis	**(22,796)**	**(67,255)**	**(99,368)**	**(78,693)**	**(102,091)**
Adjustment of non-cash stock-based compensation expense:					
Research and development expenses	20,563	33,207	23,832	18,057	12,260
Selling, general and administrative expenses	12,839	25,415	26,586	19,161	14,621
Total non-cash stock-based compensation expense:	33,402	58,622	50,418	37,218	26,881
Non-cash stock-based compensation expense attributable to non controlling interests	—	—	(1,493)	(2,655)	(3,639)
Adjusted Net Income (Loss) attributable to shareholders of Cellectis	**10,606**	**(8,633)**	**(50,443)**	**(44,130)**	**(78,849)**

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business and our industry are subject to significant risks. You should carefully consider all of the information set forth in this Annual Report, including the following risk factors. Our business, financial condition or results of operations could be materially adversely affected by any of these risks.

Risks Related to Our Business and Industry

We and Calyxt have limited operating histories, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.

We are a clinical-stage biopharmaceutical company and, as of December 31, 2019, we own 68.9% of Calyxt, Inc., a U.S. technology company focused on deliverying plant-based solutions that are healthy and sustainable, each with a limited operating history. Investment in biopharmaceutical and plant-based technology development is a highly speculative endeavor. Biopharmaceutical and plant-based technology product development entails substantial upfront capital expenditures and there is significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, to gain any required regulatory approvals or to become commercially viable. In our therapeutics business, we are focused on developing products using our gene-editing platform to develop genetically modified T-cells that express a CAR and are designed to target and kill cancer cells. While there have been significant advances in cell-based immunotherapy, our gene-editing platform and T-cell and CAR technologies are new and unproven. Several of the product candidates that we are developing or co-developing are in pre-clinical stages. We are sponsoring three clinical studies in the United States. We have started Phase I clinical trials in the United States for UCART123 targeting acute myeloid leukemia (AML), UCART22 targeting B-cell acute lymphoblastic leukemia (B-ALL), and UCARTCS1 targeting Multiple Myeloma (MM). In addition, UCART19, which we exclusively license to Les Laboratories Servier S.A.S., or Servier, is currently the subject of clinical development through two clinical studies being sponsored by Servier both targeting Acute Lymphoblastic Leukemia (ALL), and one clinical study being sponsored by Allogene Therapeutics, Inc., or Allogene, targeting Diffuse Large B-cell lymphoma (DLBCL) and follicular lymphoma (FL), which are subtypes of Non-Hodgkin Lymphoma (NHL). We have not yet generated any revenue from biopharmaceutical product sales to date. In Calyxt's plant-based technology business, Calyxt is utilizing patented plant breeding technology to develop plant-based solutions that are healthy and sustainable. Although Calyxt has achieved commercialization of its high oleic soybean oil and meal in the first quarter of 2019, it has not yet generated significant revenues from sales of its plant products.

Our limited operating history may make it difficult to evaluate our current business and our future prospects. We have encountered, and will continue to encounter, risks and difficulties frequently experienced by growing companies in rapidly developing and changing industries, such as the biopharmaceutical and plant-based technology industries, including challenges in forecasting accuracy, determining appropriate investments of our limited resources, gaining market acceptance of the products created using our gene-editing platform, managing a complex regulatory landscape and developing new product candidates. Our current operating model may require changes in order for us to scale our operations efficiently. You should consider our business and prospects in light of the risks and difficulties we face as an early-stage company focused on developing products in the fields of immunotherapy gene editing and plant-based technology.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We devote most of our financial resources to research and development relating to our CAR T-cell immunotherapy product candidates. We finance our current immuno-oncology operations primarily through strategic alliances with pharmaceutical companies, including Servier and Allogene (pursuant to assets transferred from Pfizer in April 2018), as well as through the sale of equity securities and, to a lesser extent, obtaining public funding in support of innovation, reimbursements of research tax credit claims, and royalties on our licensed technology. For the year ended December 31, 2019, we received $7.5 million in payments pursuant to our principal collaboration agreements.

In the year ended December 31, 2019, our research and development expenses were $92.0 million.

We currently have no commercial biopharmaceutical products. Notwithstanding the commencement of several clinical studies, it will be several years, if ever, before we obtain regulatory approval for, and are ready for commercialization of, a biopharmaceutical product candidate. Even if we or our collaborators successfully commence and complete clinical studies and obtain regulatory approval to market a product candidate, any future revenues will depend upon the size of any markets in which the product candidates are approved for sale as well as the market share captured by such product candidates, market acceptance of such product candidates and levels of reimbursement from third-party payors.

Although Calyxt’s first commercial sales from its high oleic soybean products occurred in the first quarter of 2019, Calyxt’s sales will be limited to a single product and may be limited until Calyxt achieves operating scale.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect our losses and our cash utilization to increase in the near term as we conduct our clinical studies, file IND and/or foreign equivalent filings for additional product candidates, conduct research and development for product candidates invest in and develop our manufacturing capabilities, seek regulatory and marketing approvals, and establish necessary infrastructure for the commercialization of any products for which we obtain marketing approval.

The net losses we incur may fluctuate significantly from year to year and 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. In any particular period or periods, our operating result could be below the expectations of securities analysts or investors which could cause the price of our ADSs to decline.

We may need to raise additional funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently sponsoring three clinical studies. In addition, we are preparing to file additional IND and/or foreign equivalent filings with respect to new clinical studies for certain of our product candidates and/or to extend the number of investigational sites. We are also advancing additional product candidates to and through pre-clinical testing. The process of developing and manufacturing CAR T-cell product candidates and conducting clinical studies is expensive, lengthy and risky, and we expect our research and development expenses to increase substantially in connection with our ongoing activities. In addition, subject to obtaining regulatory approval of any biopharmaceutical product candidates, we expect to incur significant commercialization expenses.

As of December 31, 2019, we had cash and cash equivalents and current financial assets of approximately $360.9 million. We believe our cash and cash equivalents and our cash flow from operations (including payments we expect to receive pursuant to our collaboration agreements) and government funding of research programs will be sufficient to fund Cellectis’ operations into

2022 and Calyxt's operations through mid 2021. Also, our operating plan, including our product development plans, may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. To commercialize our products, if approved, we will require significant working capital to operate our business and maintain our operations.

Our ability to raise additional capital may be limited. To the extent that we raise additional capital through the sale of additional equity or convertible securities, current ownership interests may be diluted and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights. Debt financing, if available, would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends. To the extent we raise additional funds through arrangements with collaborators or otherwise, we may be required to relinquish some of our technologies, product candidates or revenue streams, license our technologies or product candidates on unfavorable terms, or otherwise agree to terms unfavorable to us.

In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or in light of specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or product candidate development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, operating results and prospects.

We are limited in our ability to raise additional share capital, which may make it difficult for us to raise capital to fund our operations.

Under French law, our share capital generally may be increased with the approval of a two-thirds majority vote of the shareholders present, represented by proxy, or voting by mail obtained at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in the share capital. Accordingly, our board of directors may be precluded from issuing additional share capital if the prior approval of the shareholders is not duly obtained.

Risks Related to the Discovery, Development and Commercialization of Our Therapeutic Product Candidates

Our therapeutic product candidate development programs are in various phases of development and may be unsuccessful.

We are currently sponsoring three clinical studies, and four clinical studies are being sponsored by Allogene and Servier, pursuant to exclusive licenses. Further, several additional therapeutic product candidates are still in discovery or pre-clinical proof of concept stages of development and have only undergone limited testing in animals. Even if certain of our product candidates progress through clinical studies, these product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive preliminary clinical data and/or results in animal studies. The results from animal studies are not necessarily predictive of results in current or future clinical studies.

Because some of our current product candidates are in the early stages of development, there can be no assurance that our research and development activities will result in product candidates we can advance through clinical development. The results of clinical studies are subject to a variety of factors and considerations, and we cannot assure you that we or our collaborators will achieve the applicable targets in these studies.

Because of the early stage of development of our product candidates, we have not yet demonstrated the safety, specificity and clinical benefits of our product candidates in humans, and we cannot assure you that the results of any human trials will demonstrate the value and efficacy of our platform. Moreover, there are a number of regulatory requirements that we must satisfy before additional clinical studies may be commenced in the United States or the European Union with respect to our product candidates. Satisfaction of these requirements will entail substantial time, effort and financial resources. Any time, effort and financial resources we expend on our early-stage product candidate development programs may adversely affect our ability to continue development and commercialization of our more advanced product candidates, and we may never commence additional clinical studies despite expending significant resources in pursuit of their development. Further, our clinical studies may not be successful and such product candidates may never be approved by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or any other regulatory agency.

Even if a product candidate successfully completes clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before regulatory approval may be obtained. Although there are a large number of drugs and biologics in development globally, only a small percentage obtain regulatory approval, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance.

If the results of our clinical trials are inconclusive or if there are safety concerns or adverse events associated with the product candidates we develop, we may:

- lose any competitive advantages that such product candidates may have;
- be delayed in obtaining marketing approval for the subject product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as initially intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions, contraindications or safety warnings;
- be subject to changes with the way the product is administered;
- be required to perform additional clinical trials or broaden current clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- need to modify or terminate contractual relationships with third parties with regard to the performance of said clinical trials;
- be sued;
- experience damage to our reputation; or
- not reach the milestones triggering payments from our collaborators.

Early data from compassionate use treatment and from clinical trials are not predictive of success in later clinical trials.

In December 2016, during a meeting with the National Institutes of Health’s Office of Biotechnology Activities’ Recombinant DNA Advisory Committee, or the RAC, Pfizer and Servier presented preliminary clinical study data for UCART19 and data from three clinical uses of UCART19 on a compassionate basis. These three compassionate use patients have been treated under U.K. “specials” licenses from the Medicines & Healthcare products Regulatory Agency (MHRA) to administer the UCART19 product candidate to a patient on compassionate use basis. Compassionate use refers to the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. More recently, in December 2018, during the American Society of Hematology (ASH) Conference, Servier presented intermediate results from its current pediatric and adult clinical studies on UCART19 in the United Kingdom, the United States, Belgium and France. These preliminary results from the pediatric and adult UCART19 Clinical Studies showed that 82% of patients (14/17) who received a lymphodepletion regimen (consisting of fludarabine, cyclophosphamide and alemtuzumab, an anti-CD52 monoclonal antibody) achieved a complete remission (CR) or complete remission with incomplete blood cell recovery (CRi) by day 28 or day 42 after infusion. Within the 14 responder patients, 71% showed a “minimal residual disease” (MRD) negative (MRD- stands for less than 1 leukemic cell among 10E4 normal cells) assessed by flow or qPCR. When considering all treated patients (lymphodepleted or not), 67% (14/21) achieved CR/CRi. Regarding safety considerations, there were no serious adverse events (grade ^{3}3) for graft versus host disease (GvHD) and neurological events. Grade 3-4 toxicities were events of cytokine release syndrome (14%, 3/21), prolonged cytopenia (29%, 6/21) and viral infections (24%, 5/21).

We cannot assure you that the administration of UCART19 to other patients will have results that are similar to those reported by Servier. Such results are preliminary in nature, do not bear statistical significance and should not be viewed as predictive of ultimate success. It is possible that such results will not continue or may not be repeated in other potential compassionate uses or in ongoing or future clinical trials on UCART19 or other UCART product candidates.

We have limited experience in conducting or managing clinical trials for potential therapeutic products.

We are currently sponsoring clinical studies at three sites for the BALLI-01 Study, at four sites for the AMELI-01 Study and at three sites for the MELANI-01 Study. We anticipate expanding these existing clinical studies to additional sites and commencing additional clinical studies. We have limited experience in conducting or managing the clinical trials necessary to obtain regulatory approvals for any product candidate. We rely on a clinical research organization, or CRO, medical institutions and clinical investigators to conduct our clinical studies. Our reliance on third parties for clinical development activities reduces

our control over these activities. Third-party contractors may not complete activities on schedule, or may not conduct clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet required performance standards or expected deadlines, we might be required to replace them or the data that they provide could be rejected by the FDA or comparable foreign regulatory bodies, all of which may result in a delay of the affected trial and additional program costs.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Pre-clinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. For example, in September 2017, a clinical hold was placed on our UCART123 clinical studies and remained in place until the FDA permitted these clinical studies to restart in November 2017 according to revised protocols, and in 2018, manufacturing events slowed down the advancement of our UCART123 clinical studies and the commencement of our UCART22 Clinical Study.

We cannot guarantee that any pre-clinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years to complete the pre-clinical testing and clinical development necessary to commercialize a product candidate, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials, including a number of patient deaths in CAR-T trials conducted in the United States. We cannot be certain that our product candidates will not face similar setbacks. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more clinical trials would be a major setback for our product candidates and for us and may require us or our collaborators to delay, reduce or re-define the scope of, or eliminate one or more product candidate development programs, any of which could have a material adverse effect on our business, financial condition and prospects.

In addition, a number of events, including any of the following, could delay the completion of our current and future clinical trials and negatively impact the ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us or our collaborators by the FDA or any foreign regulatory authority regarding the scope or design of clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- changes in regulatory requirements and guidance that necessitate amendments to clinical trial protocols;
- insufficient supply or deficient quality of the product candidates or other materials necessary to conduct the clinical trials;
- delays in obtaining regulatory agency approval for the conduct of the clinical trials;
- lower-than-anticipated enrollment and retention rate of subjects in clinical trials for a variety of reasons, including size of patient population, sites selection, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- serious and unexpected drug-related side effects experienced by patients in clinical trials (including clinical studies for similar side effects reported in third parties' product candidate); or
- failure of our or our collaborators' third-party contractors to meet their contractual obligations in a timely manner.

Data obtained from pre-clinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Clinical trials may be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unfavorable interpretations by FDA or similar foreign regulatory authorities of data, where clinical study plans call for interim data analysis;
- FDA or similar foreign regulatory authorities determine the plan or protocol for the investigation is deficient in design to meet its stated objectives;

- lack of, or failure to, demonstrate efficacy;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval.

We have concentrated our research and development efforts on our CAR T-cell immunotherapy product development, including our gene-editing technologies, and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our UCART product candidates' platform and there can be no assurance that any development problems we experience in the future related to our gene-editing technologies will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Currently, only a very limited number of gene therapy products have been approved in the United States and Europe. Approvals by the EMA and FDA for existing gene therapy products may not be indicative of what these regulators may require for approval of further gene therapy products. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Because we are developing novel CAR T-cell immunotherapy product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing requirements have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies (OTAT, formerly known as the Office of Cellular, Tissue and Gene Therapies, or OCTGT) within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, review processes and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the EU a special committee called the Committee for Advanced Therapies (CAT) was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products (ATMPs) to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. In this regard, on May 28, 2014, the EMA issued a recommendation that Cellectis' UCART19 be considered a gene therapy product under Regulation (EC) No 1394/2007 on ATMPs. We believe this recommendation is likely to be applicable to our UCART product candidates; however, this recommendation is not definitive until such products obtain regulatory approval for commercialization.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product

candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our CAR T-cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

As we or our collaborators advance product candidates, we and they will be required to consult with these regulatory groups and comply with all applicable guidelines, rules and regulations. Because the clinical studies for UCART19 and are being sponsored by Servier and Allogene, they are directly interacting with the relevant regulatory agencies and we are not able to direct such interactions. Some of the discussions among our commercial collaborators and relevant regulatory agencies could generate additional unexpected requirements from regulatory agencies that may apply to our wholly-controlled UCART product candidates, including UCART123, UCARTCS1 and UCART22 and could lead to potential delays or additional requirements, such as additional studies or modifications to our controlled clinical studies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

The United Kingdom's withdrawal from the European Union may have a negative effect on our business, results of operations and financial condition.

The United Kingdom's membership in the European Union ended on January 31, 2020. During the current transition period, negotiations between the United Kingdom and the European Union will be conducted to determine terms relating to their future relations, including trade, financial and legal agreements.

The full political and economic effects of this "Brexit" remain quite uncertain to this date. Depending on the outcome of the negotiations, a certain number of risks could materialize, including:

- a deterioration or stagnation of the United Kingdom's economic conditions,
- volatility in the exchange rate between the euro and the pound sterling, which may have a negative impact on our results,
- a rise in inflation in the United Kingdom,
- legal and regulatory uncertainty, in particular regarding the interaction between local and European regulations, regarding taxation or regarding importation or exportation of goods,
- legal and regulatory uncertainty regarding the conduct of clinical trials and/or the approval of our product candidates in the United Kingdom, which may affect our ability to conduct clinical trials and obtain regulatory approvals in the United Kingdom,
- Any delay in the completion of our United Kingdom clinical trials or in obtaining any regulatory approvals in the United Kingdom and/or the European Union,
- increased difficulties in finding financing opportunities in the United Kingdom or finding financing opportunities secured in whole or in part by assets located in the United Kingdom.

The occurrence of such events or risks could adversely affect our business, our prospects, our ability to achieve our objectives, generate revenue and achieve and sustain profitability.

Our gene-editing technology is relatively new, and if we are unable to use this technology in all of our intended applications, our revenue opportunities will be limited.

Even if the use of gene editing technologies increases, our technology involves a relatively new approach to gene editing, using sequence-specific DNA-cutting enzymes, or nucleases, to perform precise and stable modifications in the DNA of living-cells and organisms. Although we have generated nucleases for many specific gene sequences, we have not created nucleases for all gene sequences that we may seek to target, and we may not be able do so, which could limit the usefulness of our technology.

The expected value and utility of our nucleases is, in part, based on our belief that the targeted modification of genes or specific regulation of gene expression may enable us to develop a new therapeutic approach. There is only a limited understanding of the role of specific genes in these applications. Life sciences companies have only been able to successfully develop or commercialize a few products in this biopharmaceutical space. We or our collaborators may not be able to use our technology to develop commercial products.

In addition, the industry is rapidly developing, and our competitors may introduce new technologies that render our technology obsolete, uneconomical or less attractive. New technology could emerge at any point in the development cycle of our product candidates. As competitors use or develop new technologies, we may be placed at a competitive disadvantage, and

competitive pressures may force us to implement new technologies at a substantial cost. In addition, our competitors have greater financial, technical and personnel resources that allow them to enjoy technological advantages and may in the future allow them to implement new technologies before we can. We cannot be certain that we will be able to implement technologies on a timely basis or at a cost that is acceptable to us. If we are unable to maintain technological advancements consistent with industry standards, our operations and financial condition may be adversely affected.

We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, the product candidates that are central to our business.

Our business depends primarily on the successful clinical development, regulatory approval and commercialization of our CAR T-cell immunotherapy product candidates. Notwithstanding our ongoing clinical studies, we may never be able to develop products that will be approved or commercialized.

Our therapeutic product candidates will require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence their commercialization. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate, with substantial evidence gathered in well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA or, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use in each target indication. In the United States, we expect that the requisite regulatory submission to seek marketing approval for our gene therapy products will be a Biologic License Application, or BLA, and the competent regulatory authority is the FDA. In the EU, the requisite approval is a Marketing Authorization, or MA, which for products developed by the means of recombinant DNA technology, gene or cell therapy products as well as tissue engineered products, is issued through a centralized procedure involving the EMA. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Despite our efforts, our product candidates may not:

This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond our existing cash on hand. Of the large number of drugs in development globally, only a small percentage successfully completes the regulatory approval process and even fewer are commercialized. Furthermore, we have not marketed, distributed or sold any products. Our success will, in addition to the factors discussed above, depend on the successful commercialization of the product candidates we develop on our own and our collaborators' successful commercialization of the products they develop, which may, in each case, require:

- establishing commercial manufacturing arrangements with third-party manufacturers;
- collaborating with third-parties to market and sell any approved drug; or
- acceptance of such commercial products by the medical community and by patients and third-party payors.

Many of these factors are beyond our control. We do not expect any of the product candidates we or our collaborators develop to be commercially available for many years and some or all may never become commercially available. We may never generate revenues through the sale of products.

We face substantial competition from companies many of which have considerably more resources and experience than we have.

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid innovation, and many companies apply significant resources toward developing novel and proprietary therapies for the treatment of cancer, which often incorporate novel technologies and valuable intellectual property. We compete with companies in the immunotherapy space, as well as companies developing novel targeted therapies for cancer. In addition, our product candidates, if approved, will compete with existing standards of care for the diseases that our product candidates target as well as new compounds, drugs or therapies, some of which may achieve better results than our product candidates. We anticipate that we will face intense and increasing competition from many different sources, including new and established biotechnology and pharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions.

Immunotherapy is being pursued by both biotech companies and large-cap pharmaceutical companies. We face competition from gene-editing companies, autologous and allogeneic CAR T-cell companies and cell-therapy companies. We also face competition from non-cell based treatments offered by global biopharmaceutical companies. Many of our competitors, either alone or with their collaboration partners, have substantially greater financial, technical and other resources, such as larger research and development staff and/or greater expertise in research and development, manufacturing, pre-clinical testing and conducting clinical trials. In addition, smaller or early-stage companies may compete with us through collaborative arrangements

with more established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these enterprises. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our competitors, either alone or with collaborators, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Even if we obtain regulatory approval of our product candidates, we may not be the first to market and that may affect the price or demand for our product candidates. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for the commercialization of any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain such regulatory approval.

The FDA or other regulatory authority, as applicable, may delay, limit or deny approval of our product candidates for many reasons, including disagreement with clinical trial design or implementation, determinations that a product candidate is not sufficiently safe or efficacious, objections to the statistical significance of data or our interpretation of data, objections to the production, formulation or labeling of our product candidates, and any other discretionary factors such regulators deem relevant.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market the product candidates we develop, which would significantly harm our business, results of operations and prospects. In addition, even if we or our collaborators were able to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for the product candidates we develop.

We expect several of the product candidates we develop will initially be available as treatment for patients with advanced disease, or with a rare disease with no other treatment option, which could limit the size of the market for these product candidates.

We expect that, if approved, several of the product candidates we develop will initially receive regulatory approval as treatment for advanced or rare diseases. This could limit the initial size of the market for these product candidates, and we cannot predict when, if ever, such product candidates would receive regulatory approval for indications treating a more expansive patient population.

Any issues that arise in the high complex manufacturing process for our product candidates could have an adverse effect on our business, financial position or prospects.

Our product candidates undergo a complex, highly-regulated manufacturing process that is subject to multiple risks. As a result of the complexities of this process, the cost to manufacture our CAR T-cell immunotherapy products is generally higher than traditional small molecule chemical compounds, and the manufacturing process requires very minimal batch-to-batch variability, which is expensive to ensure. Our manufacturing process is susceptible to product loss or failure due to issues associated with the collection of white blood cells from healthy third-party donors, manufacturing or supply of raw material or

starting material, shipping such material to the manufacturing site, ensuring standardized production batch-to-batch in the context of mass production, freezing the manufactured product, shipping the final product globally, and infusing patients with the product. In addition, we may face manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, shortage of raw material or starting material and other procurement issues, changes in regulation, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. 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, the manufacturing may be stopped or such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Further, as our product candidates are developed through pre-clinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results or adapt to the regulatory agencies' requirements. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Currently, the product candidates we develop are manufactured using processes intended for pre-clinical and clinical stage production by third-party contract manufacturing organizations, or CMOs. Although we work with CMOs to ensure that commercially viable processes will be available for mass production, there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up and/or scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may ultimately be unable to reduce the cost of goods for the product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

Our manufacturing strategy for the product candidates we develop contemplates the continued use of one or more CMOs as well as our own manufacturing facility, which we are establishing in Raleigh, North Carolina, and Paris, France. However, we have no experience as a company in developing a manufacturing infrastructure that complies with all standards applicable to the manufacturing of a product to be used by or administered to patients, and may never be successful in developing such in-house manufacturing capabilities. We may engage additional CMOs or establish additional manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we successfully develop our own manufacturing capabilities our manufacturing processes could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, regulatory issues and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval processes for the jurisdictions in which we or our collaborators will seek marketing approval for commercialization as well as ongoing compliance requirements. If the manufacturing process is changed during the course of product development, FDA or foreign regulatory authorities could require us to repeat some or all previously conducted trials or conduct additional bridging trials, which could delay or impede our ability to obtain marketing approval. If we or our CMOs are unable to reliably produce product candidates or products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to further develop, conduct clinical trials for, and commercialize such products in the relevant territories. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Negative publicity and increased regulatory scrutiny of genetic research and therapies involving gene editing may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Our gene-editing technologies are relatively novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates. Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates. For example, there have been patient deaths in recent CAR-T trials conducted in the United States by our competitors as well as in our UCART123 clinical studies, which have led to clinical trial holds. Adverse events in clinical studies for the product candidates we develop or those of our competitors, even if not ultimately attributable to our or their product candidates, respectively (such as the many adverse events that typically arise from the transplant process), and any resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stronger labeling for those product candidates that are approved and a decrease in demand for any such product candidates.

We or our collaborators may find it difficult to enroll patients in clinical studies on the product candidates we develop, which could delay or prevent clinical studies of the product candidates.

Identifying and qualifying patients to participate in clinical studies is critical to the success of the relevant product candidate. The timing of clinical studies depends, in part, on the speed of recruitment of patients to participate in testing such product candidates as well as completion of required follow-up periods. We or our collaborators may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete the clinical studies for our respective product candidates in a timely manner. If patients are unable or unwilling to participate in such studies, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our technology or termination of the clinical studies altogether.

In addition, clinical trials for the product candidates we or our collaborators develop will compete with other clinical trials for product candidates that are in the same therapeutic areas as such product candidates, and this competition may reduce the number and types of patients available to us and our collaborators. Because the number of qualified clinical investigators is limited, we expect to conduct some of the clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of patients who are available for our clinical trials at such clinical trial sites. Certain of our competitors may have greater success than us in enrolling patients as a result of a variety of factors. Moreover, because the product candidates we develop represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and stem cell transplants, rather than enroll patients in our future clinical trial or clinical trial of our collaborators.

Patient enrollment is affected by a variety of factors, including:

- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial, including relative to other available therapies;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- patient referral practices of physicians; and
- our ability to monitor patients adequately during and after treatment.

If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct clinical studies as planned, we or our collaborators may need to delay, limit or terminate ongoing or planned clinical studies, any of which could have a material adverse effect on our business and financial condition. Even if we are able to enroll a sufficient number of patients in our clinical 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 the product candidates we develop.

Our product candidates may fail safety studies in clinical trials or may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Our gene-editing technologies may not be sufficiently specific for their target sites, or they may not target unique sites within the genome of interest, which may result in random DNA recombination events. For example, off-target cleavage may lead to the production of double-strand breaks that overwhelm the cell’s repair machinery and, as a consequence, yield chromosomal rearrangements and/or cell death. Off-target cleavage events also may result in random integration of donor DNA. As a result, off-target cleavage in T-cells may lead to undesirable side effects for patients, and consequently could cause delays, interruptions or suspensions of clinical trials and delays or denial of regulatory approval by the FDA or other regulatory authorities. Because the products we develop have had only very limited clinical application, we do not yet have sufficient information to know whether any of our product candidates will cause undesirable side effects.

Any undesirable side effects could cause us, our collaborators or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Further, if the product candidates we develop receive marketing approval and we or others identify undesirable side effects caused by the products or any other similar products after the approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the products or require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we or our collaborators may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we or our collaborators may be required to perform additional post marketing safety studies or post marketing safety registries;
- we or our collaborators may be required to change the way the products are distributed or administered or conduct additional clinical trials;
- we or our collaborators may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products or products developed with our technologies; and
- our reputation may suffer.

Any of these events could prevent the affected products from achieving or maintaining market acceptance and could substantially increase the costs of commercializing such products and significantly impact the ability of such products to generate revenues. In addition, with respect to product candidates developed by our collaborators, such events could prevent the affected products from reaching milestones that would trigger payments to Cellectis.

If the product candidates we develop do not achieve projected development and commercialization in the announced or expected timeframes, the further development or commercialization of our product candidates may be delayed, and our business may be harmed.

We sometimes estimate, or may in the future estimate, for planning purposes, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, the receipt of marketing approval or commercialization objectives. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources and constraints, progress of development activities, and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates.

If we or our collaborators fail to achieve announced milestones in the expected timeframes, the commercialization of the product candidates may be delayed, our credibility may be undermined, and our business and results of operations may be harmed.

Further development and commercialization of our own product candidates will depend, in part, on strategic alliances with our collaborators. If our collaborators do not diligently pursue product development efforts, the advance of our own programs progress may be delayed and our revenues may be deferred.

We expect to continue to rely, to some extent, on our collaborators to provide funding in support of our own independent research and pre-clinical and clinical testing. Our technology is broad based, and we do not currently possess the financial resources necessary to fully develop and commercialize potential products that may result from our technologies or the resources or capabilities to complete the lengthy marketing approval processes that may be required for such products. Therefore, we plan to rely on strategic alliances to help us finance the development and commercialization of our own biopharmaceutical products. As a result, our success depends, in part, on our ability to collect milestone and royalty payments from our collaborators. To the extent our collaborators do not aggressively pursue product candidates for which we are entitled to such payments or pursue such product candidates ineffectively, we will fail to realize these significant revenue streams, which could have an adverse effect on our business and future prospects.

If collaborators with whom we currently have alliances, such as Allogene and Servier, or future collaborators with whom we may engage, are unable or unwilling to advance their programs, or if they do not diligently pursue product development and product approval, this may slow our progress and defer or negatively impact our revenues. Such failures would have an adverse effect on our ability to collect key revenue streams and, for this reason, would adversely impact our business, financial position and prospects. Our collaborators may assign, sublicense or abandon product candidates or we may have disagreements with our collaborators, which would cause associated product development to slow or cease. There can be no assurance that our current strategic alliances will continue or be successful, and we may require significant time to secure new strategic alliances because we need to effectively market the benefits of our technology to these future alliance partners, which may direct the attention and resources of our research and development personnel and management away from our primary business operations. Further, each strategic alliance arrangement will involve the negotiation of unique terms, and such negotiation efforts may not result in a strategic alliance or may result in unfavorable arrangements.

The loss of existing or future collaboration agreements would not only delay or potentially terminate the possible development or commercialization of products derived from our technologies, but it may also delay or terminate our ability to test target candidates for specific genes. If any collaborator fails to conduct the collaborative activities successfully and in a timely manner, the pre-clinical or clinical development or commercialization of the affected product candidates or research programs would be delayed or could be terminated.

Under typical collaboration agreements, we would expect to receive revenue with respect to a CAR T-cell immunotherapy product based on achievement of specific milestones, as well as royalties based on a percentage of sales of the commercialized products. Achieving these milestones will depend, in part, on the efforts of our collaborator as well as, in most cases and for a limited period of time, our own. If we, or any collaborator, fails to meet specific milestones, then the strategic alliance may be terminated, which could reduce our revenues.

In addition, our collaboration agreements are generally terminable at will upon specified prior notice. If one or more collaborators terminates a collaboration agreement, this could have an adverse effect on our revenues. See “Item 4. Information on the Company – B. Business Overview – Our Strategic Alliances.

Even if we or our collaborators successfully complete clinical trials of product candidates, those candidates may not be commercialized successfully for other reasons.

Even if we or our collaborators successfully complete clinical trials for one or more of the product candidates, those candidates may not be commercialized for other reasons, including:

- failing to receive regulatory approvals required to market them as drugs;
- being subject to proprietary rights held by others;
- failing to comply with GMP requirements;
- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable;
- being inferior to existing approved drugs or therapies;
- failing to compete effectively with existing or new products or treatments commercialized by competitors; or
- failing to show long-term benefits sufficient to offset associated risks.

In addition, for any product candidates we develop through our strategic alliances, we will depend entirely upon the other party for marketing and sales of that product. These collaborators may not devote sufficient time or resources to the marketing and commercialization, or may determine not to pursue marketing and commercialization at all. Our business and results of operations will be negatively impacted by any failure of our collaborators to effectively market and commercialize an approved product.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to ongoing regulatory requirements.

Even if we obtain regulatory approval in a jurisdiction for the product candidates we develop, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety and other post-market information. Any regulatory approvals received for the product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. For example, the holder of an approved BLA in the United States is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. Similarly, in the EU, pharmacovigilance obligations are applicable to all medicinal products. In addition to those, holders of a marketing authorization for gene or cell therapy products must detail, in their application, the measures they envisage to ensure follow-up of the efficacy and safety of these products. In cases of particular concern, marketing authorization holders for gene or cell therapy products in the EU may be required to design a risk management system with a view to identifying, preventing or minimizing risks, and may be obliged to carry out post-marketing studies. In the United States, the holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar provisions apply in the EU. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Similarly, in the EU any promotion of medicinal products is highly regulated and, depending on the specific jurisdiction involved, may require prior vetting by the competent national regulatory authority.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory agency disagrees with the promotion, marketing or labeling of that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our collaborators fail to comply with applicable regulatory requirements following approval of any of the product candidates we develop, national competent authorities may:

- issue a warning letter asserting a violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our collaborators;
- restrict the marketing, distribution or manufacturing of the product;
- seize or detain product or otherwise require the withdrawal or recall of product from the market;
- refuse to permit the import or export of products; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any of the foregoing regulatory actions could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit the ability to commercialize products and generate revenues. In addition, the FDA's policies, and policies of foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. 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 or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, marketing approval that has been obtained may be lost and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, to establish an abbreviated pathway for the approval of products that are biosimilar to or interchangeable with an FDA-approved biological product. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Similarly in Europe, a biosimilar is defined as a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Developers of biosimilars are required to demonstrate through comprehensive comparability studies with the reference medicine that:

- their biological medicine is highly similar to the reference medicine, notwithstanding natural variability inherent to all biological medicines;
- there are no clinically meaningful differences between the biosimilar and the reference medicine in terms of safety, quality and efficacy.

Biosimilars can only be authorized once the period of data exclusivity on the reference medicine has expired. In general, this means that the biological reference medicine must have been authorized for at least eight years before another company can apply for approval of a similar biological medicine.

Even if we or our collaborators obtain and maintain approval for product candidates in the United States or another jurisdiction, we or our collaborators may never obtain approval for the same product candidates in other jurisdictions, which would limit market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The approval process varies among countries and may limit our or our collaborators' ability to develop, manufacture, promote and sell our product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell the product candidates in the EU and many other jurisdictions, we and our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional pre-clinical studies or clinical trials both before and post approval. In many countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for the product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or our collaborators fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, the target market will be reduced and the ability to realize the full market potential of the subject product candidates will be harmed and our business may be adversely affected.

Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we or our collaborators may decide to first seek regulatory approvals of a product candidate in countries other than the United States, or we or our collaborators may simultaneously seek regulatory approvals in the United States and other countries, in which case we or our collaborators will be subject to the regulatory requirements of health authorities in each country in which we seek approvals. Obtaining regulatory approvals from health authorities in countries outside the United States and the EU is likely to subject us or our collaborators to risks in such countries that are substantially similar to the risks associated with obtaining approval in the United States or the EU described herein.

We plan to seek orphan drug status for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with such status, which may cause our revenue, if any, to be reduced.

We plan to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we intend to seek orphan product designation for some or all of our product candidates, we may never receive such designations.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a 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 product exclusivity or if 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. Even if we obtain orphan drug designation for a product candidate, we may not be the first to obtain marketing approval for any particular orphan

indication due to the uncertainties associated with developing pharmaceutical products. Exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective, the disease or condition exceeded the population threshold, 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. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would unlikely generate sufficient return in the EU to justify the necessary investment. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition.

In the EU, orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the EU can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies (Article 37, Regulation 1901/2006). However, the 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation—for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the first applicant consents to a second orphan medicinal product application; or
- the first applicant cannot supply enough orphan medicinal product.

Although we may seek fast-track designation from the FDA for some or all of our product candidates, there is no assurance that such designation will be granted or, if granted that it will lead to a faster development or regulatory review or approval process.

We may seek fast-track designation and review for some or all of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition or disease, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation. Thus, even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Moreover, even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures and such designation does not assure ultimate approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Although we may seek a regenerative medicine advanced therapy (RMAT) designation, a breakthrough therapy designation and/or priority medicines (PRIME) designation for our product candidates, there is no assurance that such designations will be granted or, if granted that they will lead to a faster development or regulatory review or approval process.

We may seek a RMAT designation or a breakthrough therapy designation from the FDA for some or all of our product candidates.

A drug is eligible for RMAT designation if, (i) the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations; (ii) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

We may also seek a PRIME designation from the European Medicines Agency (or EMA) for some or all of our product candidates. Through a PRIME designation, the EMA offers support to medicine developers to optimize the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications. This scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by the EMA. To be eligible for a PRIME designation, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data.

For product candidates that obtain a RMAT, PRIME or breakthrough therapy designation, interaction and communication between the FDA or the EMA (as applicable) and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. However, the granting of such designations is within the discretion of the FDA or the EMA, respectively. In any event, the receipt of a RMAT or a PRIME designation or a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional agencies procedures and does not assure ultimate approval. In addition, even if one or more of our product candidates qualify as RMAT or a PRIME or a breakthrough therapy, the FDA or the EMA may later decide that such product no longer meet the conditions for qualification.

Even if any of our product candidates are commercialized, they may not be accepted by physicians, patients, or the medical community in general, and may also become subject to market conditions that could harm our business.

Even if any of our product candidates receive marketing approval, the medical community may not accept such products as adequately safe and efficacious for their indicated use. Moreover, physicians may choose to restrict the use of the product, if, based on experience, clinical data, side-effect profiles and other factors, they are not convinced that the product is preferable to existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives marketing approval, which will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of the product;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our and any collaborator's ability to educate the medical community about the safety and effectiveness of the product;
- the coverage and reimbursement policies of government and commercial third-party payors pertaining to the product; and
- the market price of the product relative to competing treatments.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical products. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient's condition, injury or even death. For example, our liability could be sought by patients participating in the clinical trials for our product candidates as a result of unexpected side effects resulting from the administration of these product candidates. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, our collaborators, biopharmaceutical companies and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees and subcontractors, over which we have little or no control.

In addition, regardless of merit or eventual outcome, product liability claims may result in: impairment of our business reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs due to related litigation; distraction of management's attention from our primary business; substantial monetary awards to trial participants, patients or other claimants; loss of revenue; exhaustion of any available insurance and our capital resources; the inability by us and our collaborators to commercialize our product candidates; and decreased demand for our product candidates, if approved for commercial sale.

We maintain product liability insurance coverage for damages caused by our product candidates, including clinical trial insurance coverage, with coverage limits that we believe are customary for companies in our industry. This coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims by us or our partners, licensees or subcontractors, which could prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval, which could adversely affect our business.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend, in part, on the availability of adequate coverage and reimbursement from third-party payors.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

Policies for coverage and reimbursement for products vary among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us or our collaborators to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our product candidates.

Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates represent new approaches to the treatment of cancer and accordingly, may have a higher cost than conventional therapies and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be elevated.

Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues if we obtain regulatory approval for any of our product candidates.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The continuing efforts of various governments, insurance companies, managed care organizations and other payors to contain or reduce healthcare costs may adversely affect our ability or our collaborators' ability to set a price for our products that we believe is fair, to achieve profitability, and to obtain and maintain market acceptance by patients and the medical community;

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory initiatives to contain healthcare costs. By way of example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was enacted in March 2010.

The ACA expanded health care coverage through Medicaid expansion and the implementation of a tax penalty for individuals who do not maintain mandated health insurance coverage (the so-called 'individual mandate'). The ACA also contains a number of provisions that affect coverage and reimbursement of drug products. Considerable uncertainty remains regarding the implementation and impact of the ACA. Under the Trump administration, there have been ongoing Congressional and judicial efforts to modify or repeal all or certain provisions of the ACA. For example, tax reform legislation was enacted at the end of 2017 that eliminated the individual mandate beginning in 2019. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the ACA unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. In December 2019, a federal appeals court agreed that the individual mandate was unconstitutional, but remanded the case back to the district court to assess more carefully whether any provisions of the ACA were severable and could survive. Pending action by the district court and resolution of any appeals, which could take an extended period of time, the ACA remains operational. We cannot predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts, and there can be no assurance that any such health care reforms will not adversely affect our future business and financial results.

U.S. federal and state governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, waivers from Medicaid drug rebate law requirements, restrictions

on reimbursement and requirements for substitution of generic products for branded prescription drugs. The private sector has also sought to control healthcare costs by limiting coverage or reimbursement or requiring discounts and rebates on products. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures could significantly decrease the available coverage and the price we might establish for our potential products, which would have an adverse effect on our net revenues and operating results.

Moreover, this political and legislative uncertainty could harm our and our collaborators' ability to market any products and generate revenues.

Cost containment measures that healthcare payors and providers are instituting and the effect of further healthcare reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses.

In some countries, the proposed pricing for a biopharmaceutical product must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of a biopharmaceutical product is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the EU do not follow price structures of the United States and generally tend to have significantly lower prices.

We believe that pricing pressures will continue and may increase, which may make it difficult for us to sell our potential products that may be approved in the future at a price acceptable to us or any of our future collaborators.

Our future profitability, if any, depends, in part, on our ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability, if any, will depend, in part, on our ability and the ability of our collaborators to commercialize the product candidates we develop in markets throughout the world. Commercialization of our product candidates in various markets could subject us to additional risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting and legal requirements in each jurisdiction that we pursue;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- country specific requirements related to the cells used as starting material for manufacturing;
- language barriers for technical training, healthcare professionals and patients documents;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- patients' ability to obtain reimbursement for products in various markets.

Sales of the products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are subject to healthcare laws and regulations, which could expose us to the potential for criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our products, if approved. Our arrangements with such persons and third-party payors must be structured in accordance with the broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products, if we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations 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 or lease, order or recommendation of, any item, good, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.
- The federal civil and criminal false claims laws and civil monetary penalties laws, which impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose certain requirements on covered entities and their business associates, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the ACA, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members.
- Analogous laws and regulations in various U.S. states, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than U.S. federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.
- Similar legislation is applicable in other countries such as EU Member States, including by way of example and without limitation: the UK's Bribery Act 2010 or the French Decree No 2013-414 on Transparency of Benefits Given by Companies Manufacturing or Marketing Health and Cosmetic Products for Human Use (*Décret n° 2013-414 du 21 mai 2013 relatif à la transparence des avantages accordés par les entreprises produisant ou commercialisant des produits à finalité sanitaire et cosmétique destinés à l'homme*).

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of any laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Our Reliance on Third Parties

We expect to continue to rely on third parties to conduct some aspects of our development programs and these third parties may not perform satisfactorily.

We do not, and do not expect in the future to, independently conduct all aspects of our product manufacturing, quality control, protocol development, material supply, research and pre-clinical development, translational activities and clinical testing as well as distribution. We rely, and will continue to rely, on third parties for some of these activities. Under certain circumstances, these third parties may be entitled to terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our product development activities.

In addition, in connection with our engagement of third parties, we control only certain aspects of their activities. Our reliance on these third parties for product manufacturing, quality control, protocol development, material supply, research and pre-

clinical development, translational activities and clinical testing and distribution activities reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required regulations and study and trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct their activities in accordance with regulatory requirements and our stated study and trial plans and protocols, or if there are disagreements between us and these third parties, we may not be able to complete, or may be delayed in completing, the pre-clinical studies and clinical trials required to support future regulatory submissions and approval of the product candidates we develop. In some such cases we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay with respect to the approval of our product candidates and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, reliance on third-party manufacturers, suppliers, research organizations and/or distributors entails risks to which we would not be subject if we conducted the above-mentioned activities ourselves, including:

- that our third-party manufacturers, research organizations or distributors may have little or no experience with our or comparable products and may therefore require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture, test or distribute our product candidates;
- that our contract manufacturers, research organizations and distributors are not able to execute our manufacturing, testing or distribution procedures and other logistical support requirements appropriately;
- that our contract manufacturers may not perform as agreed or in compliance with applicable laws and requirements, or may not devote sufficient resources to our products or may not remain in the contract manufacturing business for the time required to supply investigational products for our clinical trials or to successfully produce, store and supply our products once approved;
- that we may not own, have equivalent necessary rights in, or access to the intellectual property rights to, or know how residing in any improvements or developments made by our third-party manufacturers or research organizations in the manufacturing process or testing of our products;
- that such third parties may experience business disruptions, such as bankruptcy, that disrupt their ability to perform their obligations to us.

Any of these events could lead to manufacturing, supply and/or clinical study delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products.

Our existing collaborations, or any future collaboration arrangements, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize our product candidates.

We have entered into strategic alliances with collaborators, such as Allogene and Servier, under which our collaborators have exclusive development and commercialization rights with respect to certain product candidates, and we may in the future enter into additional collaborations. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may not perform or prioritize their obligations as expected;
- the clinical trials conducted as part of such collaborations may not be successful;
- collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to pursue development or commercialization of product candidates based on clinical trial results, changes in the collaborators' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, or abandon a product candidate;
- collaborators could develop, independently or with third parties, products that compete directly or indirectly with our product candidates;
- product candidates developed pursuant to collaboration arrangements may be viewed by our collaborators as competitive with their other own product candidates or products, which may cause them to cease to devote resources to the product candidate's development or commercialization;
- a collaborator may not commit sufficient resources to the commercialization, marketing and distribution of any product candidate;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, may cause delays or termination of the development or commercialization of such product candidates, or may result in time-consuming and expensive legal proceedings;
- collaborators may not properly maintain, protect, defend or enforce intellectual property rights or may improperly use proprietary information;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate third party intellectual property rights, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, the development of product candidates may be delayed or stopped; and
- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive anticipated milestone or royalty payments under the collaborations. If we do not receive anticipated payments, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report apply to the activities of our collaborators.

Significant regulation applies to the manufacturing of our products and the manufacturing facilities on which we rely may not meet regulatory requirements or may have limited capacity.

All entities involved in the preparation of products for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulations. For example, in the United States, components of a finished CAR T-cell immunotherapy product approved for commercial sale or used in clinical studies must be manufactured in accordance with the current Good Manufacturing Practices (cGMP) requirements. Similarly, all investigational medicinal products in the EU must be manufactured in compliance with Good Manufacturing Practices, or GMP. The FDA's cGMP regulations and comparable regulations in other jurisdictions govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of the product candidates we develop that may not be detectable in final product testing. In the United States, we or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's cGMP requirements enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, inspect a manufacturing facility involved with the preparation and/or control of our product candidates as well as the associated quality systems for compliance with the regulations applicable to the activities being conducted.

Similarly, in the EU, Directive 2003/94/EC lays down the principles and guidelines of GMP in respect of medicinal products and investigational medicinal products and requires that products are consistently produced and controlled in accordance with the applicable quality standards. It also requires that medicinal products and investigational medicinal products that are imported from third countries are manufactured in accordance with standards at least equivalent to the GMP standards laid down in the EU. Directive 2003/94/EC, together with the detailed EU Guidelines on GMP, govern the quality management, personnel, premises, documentation, production operations, quality control, outsources activities, complaints and product recall and self-inspection. GMP inspections are performed by the competent authorities of the EU Member States, and are coordinated by the EMA in the case of medicinal products that are authorized through the EU centralized procedure.

If we or any of our third-party manufacturers fail to provide appropriate products or maintain regulatory compliance, the regulator can impose regulatory sanctions including, among other things, the imposition of a hold on clinical trials, the refusal to permit a clinical trial to commence, the refusal to use certain batches of product candidates intended to be used in the clinical trials, the refusal to approve a pending application for a new product, the revocation or non-renewal of a pre-existing approval, or the refusal to accept some non-clinical and/or clinical data generated with material for which that third-party was responsible. As a result, our business, financial condition and results of operations may be materially harmed.

In addition, if supply from one approved manufacturer or supplier is interrupted, there could be a significant disruption in commercial and/or clinical supply of our products. Identifying and engaging an alternative manufacturer or supplier that complies with applicable regulatory requirements could result in further delay. Applicable regulatory agencies may also require additional studies if a new manufacturer or supplier is relied upon in connection with commercial production. Switching manufacturers or

suppliers may involve substantial costs and time and is likely to result in a delay in our desired clinical and commercial timelines. Although we have started construction of two of our own manufacturing facilities, we may never be successful in developing our own manufacturing capabilities. Even if we are successful, developing our own manufacturing capabilities may be costlier than we anticipate or may result in delays.

These factors could cause commercialization of our product candidates, cause us to incur higher costs, or prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

Access to raw materials, starting material and products necessary for the conduct of clinical trials and manufacturing of our product candidates is not guaranteed.

We are dependent on third parties for the supply of various of materials, including biological materials, that are necessary to produce our product candidates. The supply of these materials could be reduced or interrupted at any time. In such case, we may not be able to find other acceptable suppliers or on acceptable terms. If key suppliers or manufacturers are lost or the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture, and market our product candidates in a timely and competitive manner. In addition, biological materials are subject to stringent manufacturing process and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect the ability to complete trials and commercialize our products candidates. In addition, our suppliers or manufacturers may, from time to time, change their internal manufacturing or testing processes and procedures. Such changes may require us to perform or have performed studies to demonstrate equivalence of the materials produced or tested under such new procedures. Such equivalence testing may impose significant delays in the development of our product candidates. Furthermore, our suppliers may face quality issues or findings from regulatory authorities' inspections that could lead to delays or interruption of the supply of our product candidates.

We and our collaborators rely on third parties to conduct, supervise and monitor clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We and our collaborators rely on medical institutions, clinical investigators, contract research organizations, or CROs, contract laboratories, and collaborators to carry out or otherwise assist us in connection with our or their clinical trials and to perform data collection and analysis. While we will and our collaborators have agreements governing their activities, we and they will have limited influence over such third parties' actual performance and will control only certain aspects of such third parties' activities. Nevertheless, we or our collaborators will be responsible for ensuring that each of such clinical trials is conducted in accordance with the applicable protocol, legal, regulatory, ethical and scientific standards, and reliance on the third party does not relieve us or our collaborators of our respective regulatory responsibilities.

We, our collaborators, and our CROs are required to comply with the FDA's and other regulatory authorities' good clinical practices, or GCP, cGMP, good laboratory practices, or GLP, and other applicable requirements for conducting, recording and reporting the results of pre-clinical studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Regulatory authorities around the world, including the FDA and European authorities, enforce these requirements through periodic inspections of study sponsors, CROs, principal investigators and clinical trial sites. If we, our collaborators, our CROs, our investigators or trial sites fail to comply with applicable GCP, GLP, GMP or other applicable regulatory requirements, the clinical data generated in future clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities around the world may require the performance of additional clinical trials before issuing any marketing authorizations for the relevant product candidates. Upon inspection, the FDA or EMA may determine that clinical trials did not comply with GCP, GLP and GMP requirements, which may render the data generated in those trials unreliable or otherwise not usable for the purpose of supporting the marketing authorization applications for the relevant products.

Clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- we are unable to negotiate agreements with third parties under reasonable terms;
- termination or non-renewal of agreements with third parties occurs in a manner or at a time that is costly or damaging to us;
- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory or ethical requirements, or for other reasons.

Third party performance failures may increase our costs, delay our ability to obtain regulatory approval, and delay or prevent starting or completion of clinical trials and delay or prevent commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

We may enter into agreements with third parties to sell, distribute and/or market any of the products candidates we develop for which we obtain regulatory approval, which may adversely affect our ability to generate revenues.

Given our early development stage, we have no experience in sales, marketing and distribution of biopharmaceutical products. However, if any of our product candidates obtain marketing approval, we intend to develop sales and marketing capacity, either alone or with partners, either through contracts or licenses. Outsourcing sales, distribution and marketing may subject us to a variety of risks, including:

- our inability to exercise direct control over sales, distribution and marketing activities and personnel;
- failure or inability of contracted sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products; and
- potential disputes with third parties concerning distribution, sales and marketing expenses, calculation of royalties, and sales and marketing strategies.

If we are unable to partner with a third party that has adequate sales, marketing, and distribution capabilities, we may have difficulty commercializing our product candidates, which would adversely affect our business, financial condition, and ability to generate product revenues.

Our reliance on third parties and our collaborations require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties for the advancement of our products platform, pre-clinical testing, quality control, clinical trials, translational activities and manufacturing activities, we must, at times, share trade secrets with them. The sharing of our trade secrets with certain collaborators and CMOs may arise from our collaborations with Servier and Allogene, any collaborations we may enter into in the future, as well as our agreements with our past, present or future CMOs. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, subcontractors, advisors, employees and consultants prior to beginning research, services or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. In addition, agreements with third parties typically restrict the ability of such third parties to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the strategic alliance. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and product development that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Our collaborators or CMOs may be acquired by competitors, which may increase the risk that these entities may breach their confidentiality obligations and share our confidential information with the acquirer. For example, in April 2019, Novartis announced its acquisition of CellForCure, which serves as a CMO for us.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor’s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Calyxt, Its Business and Operations

Calyxt faces significant competition and many of its competitors have substantially greater financial, technical and other resources than it does.

The market for plant-based technology products is highly competitive, and Calyxt faces significant direct and indirect competition in several aspects of its business. Competition for improving plant genetics comes from conventional and advanced

plant breeding techniques, as well as from the development of advanced biotechnology traits. Competition for providing more nutritious ingredients for food companies come from chemical-based ingredients, additives and substitutes, which are developed by various companies. Mergers and acquisitions in the plant science, specialty food ingredient and agricultural biotechnology, seed and chemical industries may result in even more resources being concentrated among a smaller number of Calyxt's competitors. Most of these competitors have substantially greater financial, technical, marketing, sales, distribution and other resources than Calyxt does, such as larger R&D staff, more experienced marketing and manufacturing organizations and more well-established sales forces. As a result, Calyxt may be unable to compete successfully against its current or future competitors, which may result in price reductions, reduced margins and the inability to achieve market acceptance for its products. We expect Calyxt to continue to face significant competition in the markets in which Calyxt intends to commercialize its products.

Many of Calyxt's competitors engage in ongoing R&D, and technological developments by Calyxt's competitors could render its products less competitive or obsolete, resulting in reduced sales compared to our expectations. Calyxt's ability to compete effectively and to achieve commercial success depends, in part, on Calyxt ability to: control manufacturing and marketing costs; effectively price and market Calyxt's products; successfully develop an effective marketing program and an efficient supply chain; develop new products with properties attractive to customers; and commercialize its products quickly without incurring major regulatory costs. Calyxt may not be successful in achieving these factors and any such failure may adversely affect its business, results of operations and financial condition.

From time to time, certain seed and chemical companies that are potential competitors of Calyxt may seek new traits or trait development technologies and may seek to license its technology. Calyxt has, in the past, entered such licensing arrangements and may continue to enter such arrangements in the future. Some of these companies may have significantly greater financial resources and may even compete with Calyxt's business. In such circumstances, competitors could use its technologies to develop their own products that would compete with Calyxt's product candidates.

Calyxt also anticipates increased competition in the future as new companies enter the market and new technologies become available, particularly in the area of gene editing. Calyxt's technology may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of Calyxt's competitors that are more effective or that enable them to develop and commercialize products more quickly or with lower expense than Calyxt is able to do. At the same time, the expiration of patents covering existing products reduces the barriers to entry for competitors. If for any reason Calyxt's technology becomes obsolete or uneconomical relative to its competitors' technologies, this would prevent or limit Calyxt's ability to generate revenues from the commercialization of Calyxt's products.

Calyxt's business activities are currently conducted at a limited number of locations, which makes Calyxt susceptible to damage or business disruptions caused by natural disasters or acts of vandalism.

Calyxt's current headquarters and R&D facilities, which include an office, labs, greenhouses, field testing acreage, and a demonstration test kitchen, are in Roseville, Minnesota. Calyxt's seed production takes place primarily in the United States and its territories with contra season production also occurring in Argentina. Third party warehousing for seed storage, and Calyxt's limited number of processing partners (*e.g.* storage, transportation, crushers and refiners) are all located in the Upper Midwest region of the United States. Calyxt takes precautions to safeguard its facilities, including insurance, health and safety protocols, and off-site storage of critical research results and computer data. Particularly in the case of insurance, Calyxt's insurance may not cover certain losses, or Calyxt's losses may exceed its coverage limits. A natural disaster, such as a hurricane, drought, fire, flood, tornado, earthquake, or other intentional or negligent acts, including acts of vandalism, could damage or destroy Calyxt's equipment, inventory, development projects, field trials or data, and cause Calyxt to incur significant additional expenses to repair or replace the damaged physical facilities, which in the case of seed production may be the result of years of development work that is not easily or quickly reproduced, and increase the development schedule for Calyxt's product pipeline candidates.

To compete effectively, Calyxt must introduce new products that achieve market acceptance.

In order to remain competitive and increase revenue, Calyxt must introduce new products from its pipeline of product candidates. If Calyxt fails to anticipate or respond to technological developments, market requirements, or consumer preferences, or if Calyxt is significantly delayed in developing and introducing products, Calyxt's revenues will not increase.

Development of successful agricultural products using gene-editing technologies requires significant levels of investment in R&D, including laboratory, greenhouse and field testing, to demonstrate product effectiveness and can take several years or more. Calyxt incurred R&D expenses, including non-cash stock compensation expenses of $12.2 million in the year ended December 31, 2019, $10.4 million in the year ended December 31, 2018, and $11.5 million in the year ended December 31, 2017. Calyxt must commit significant resources and may incur obligations (such as royalty obligations or milestone fees) to develop new products before knowing whether its investments will result in products the market will accept and without knowing the levels of revenue, if any, that may be derived from these products.

Development of new or improved agricultural products involves risks of failure inherent in the development of products based on innovative and complex technologies. These risks include the possibility that:

- Calyxt's products may not perform as expected in the field;
- Calyxt's products may not receive necessary regulatory permits and governmental clearances in the markets in which Calyxt intends to sell them;
- consumer preferences, which are unpredictable and can vary greatly, may change quickly, making Calyxt's products no longer desirable;
- Calyxt's competitors may develop new products that taste better or have other more appealing characteristics than Calyxt's products;
- Calyxt's products may be viewed as too expensive by customers as compared to competitive products;
- Calyxt's products may be difficult to produce on a large scale or will not be economical to grow;
- intellectual property and other proprietary rights of third parties may prevent Calyxt or its collaborators from marketing and selling Calyxt's products;
- Calyxt may be unable to patent or otherwise obtain intellectual property protection for its discoveries in the necessary jurisdictions;
- Calyxt or its customers may be unable to fully develop or commercialize products in a timely manner or at all; and
- third parties may develop superior or equivalent products.

Accordingly, if Calyxt experiences any significant delays in the development or introduction of new products or if its new products do not achieve market acceptance, Calyxt's business, operating results and financial condition would be adversely affected.

Any collaboration arrangements that Calyxt may enter in the future may not be successful, which could adversely affect Calyxt's ability to develop and commercialize its product candidates.

Calyxt may seek collaboration arrangements with third parties for the development or commercialization of its product candidates depending on the merits of retaining commercialization rights for itself as compared to entering collaboration arrangements. Calyxt will face, to the extent that it decides to enter collaboration arrangements, significant competition in seeking appropriate partners. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. Calyxt may not be successful in its efforts to establish and implement collaboration or other alternative arrangements should it so chose to enter such arrangements. The terms of any collaborations or other arrangements that Calyxt may establish may not be favorable to Calyxt or to us.

The success of its collaboration arrangements will depend heavily on the efforts and activities of Calyxt's partners. Collaborations are subject to numerous risks, which may include that:

- partners have significant discretion in determining the efforts and resources that they will apply to R&D partnerships;
- partners may not pursue development and commercialization of Calyxt's product candidates or may elect not to continue or renew development or commercialization programs based on trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- partners may delay trials, provide insufficient funding for a trial program, stop a trial, abandon a product candidate, repeat or conduct new trials or require a new formulation of a product candidate for testing;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with Calyxt's products or product candidates;
- a partner with marketing, manufacturing and distribution rights to one or more products may not commit enough resources to or otherwise not perform satisfactorily in carrying out these activities;
- Calyxt could grant exclusive rights to its partners that would prevent Calyxt from collaborating with others;
- partners may not properly maintain or defend intellectual property rights or may use Calyxt's intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate Calyxt's intellectual property or proprietary information or expose Calyxt to potential liability;
- disputes may arise between Calyxt and a partner that causes the delay or termination of the research, development or commercialization of Calyxt's current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- partnerships may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;

- partners may own or co-own intellectual property covering Calyxt's products that results from it partnering with them, and in such cases, Calyxt would not have the exclusive right to develop or commercialize such intellectual property; and
- a partner's sales and marketing activities or other operations may not follow applicable laws resulting in civil or criminal proceedings.

If ongoing or future field trials are unsuccessful, Calyxt may be unable to complete the development of product candidates on a timely basis or at all.

Calyxt relies on field trials to demonstrate the efficacy of product candidates that it has developed and evaluated in greenhouse conditions. Field trials allow Calyxt to test product candidates in the field as well as to increase seed production, and to measure performance across multiple geographies and conditions. Successful completion of field trials is critical to the success of Calyxt's product development efforts. If Calyxt's ongoing or future field trials are unsuccessful or produce inconsistent results or unanticipated adverse effects on the agronomic performance of Calyxt's crops, or if the field trials do not produce reliable data, Calyxt's product development efforts could be delayed, subject to additional regulatory review or abandoned entirely. In addition, in order to support Calyxt's commercialization efforts, it is necessary to collect data across multiple growing seasons and from different geographies. Even in cases where initial field trials are successful, Calyxt cannot be certain that additional field trials conducted on a greater number of acres or in different geographies will also be successful. Many factors that are beyond Calyxt's control may adversely affect the success of these field trials, including unique geographic conditions, weather and climatic variations, disease or pests, or acts of protest or vandalism. Field trials, which may take up to two to three years, are costly, and any field trial failures that Calyxt may experience may not be covered by insurance and, therefore, could result in increased costs, which may negatively impact Calyxt's business and results of operations. During the first quarter of 2020, Calyxt was notified that a significant portion of its high fiber wheat plants were damaged in field trials due to improper aerial chemical applications by unaffiliated third parties. While Calyxt is continuing to assess the impact of this damage on the overall development process and timeline, Calyxt expects to harvest the remaining field trial crop in spring 2020 and continue Phase II development in 2020. Calyxt's Phase II development activities in 2020 will include testing the product concept in field conditions, completing food application studies and voluntarily consulting with FDA. Depending on the results of the spring 2020 field trial crop harvest and the success of its other activities in Phase II and Phase III, Calyxt's high fiber wheat product may launch as early as 2022.

Calyxt relies on third parties to conduct, monitor, support, and oversee field trials and other research services for product candidates in development, and any performance issues by third parties, or Calyxt's inability to engage third parties on acceptable terms, may impact Calyxt's ability to successfully commercialize such product candidates.

Calyxt currently relies on third parties, such as growers, consultants, contractors and universities, to conduct, monitor, support and oversee these field trials. In some cases, these field trials are conducted outside of the United States, making it difficult for Calyxt to monitor the work being conducted by the third parties that it engages. Although Calyxt provides its third-party contractors with protocols regarding the production and handling of its product candidates, Calyxt has limited control over the execution of field trials. Poor field trial execution or data collection, failure to follow required agronomic practices, protocols or regulatory requirements, or mishandling of product candidates by these third parties could impair the success of Calyxt's field trials. Any such failures may result in delays in the development of Calyxt's product candidates or the incurrence of additional costs. Even if Calyxt's third-party contractors adhere to its suggested protocols, field trials may fail to succeed for a variety of other reasons, including weather, disease or pests, improper timing of planting Calyxt's seeds, or incorrect fertilizer use. Ultimately, Calyxt remains responsible for ensuring that each of its field trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and Calyxt's reliance on third parties does not relieve Calyxt of its responsibilities. Should such third parties fail to comply with these standards, Calyxt's ability to develop its product candidates could be adversely impacted.

Additionally, if Calyxt is unable to maintain or enter into agreements with third-party contractors on acceptable terms, or if engagement is terminated prematurely, Calyxt may be unable to conduct or complete its field trials in the manner Calyxt anticipates. If Calyxt's relationship with any of these third-party contractors is terminated, Calyxt may be unable to enter arrangements with alternative contractors on commercially reasonable terms, or at all. Switching or adding third-party contractors can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when any new third party commences field trial work. As a result, delays may occur, which could materially impact Calyxt's ability to meet its desired development timelines.

The successful commercialization of Calyxt's products depends on Calyxt's ability to produce high-quality plants and seeds cost-effectively on a large scale and to accurately forecast demand for Calyxt's products, and Calyxt may be unable to do so.

The production of commercial-scale quantities of seeds requires the multiplication of the plants or seeds through a succession of plantings and seed harvests. The cost-effective production of high-quality, high-volume quantities of any product candidates Calyxt successfully develops depends on Calyxt's ability to scale its production processes to produce plants and seeds in enough quantity to meet demand. For example, food ingredients such as soybean oil and wheat flour will require optimized

production and commercialization of the underlying plant and seed harvests. Calyxt cannot assure that its existing or future seed production techniques will enable Calyxt to meet its large-scale production goals cost-effectively for the products in its pipeline. Even if Calyxt is successful in developing ways to increase yields and enhance quality, Calyxt may not be able to do so cost-effectively or on a timely basis, which could adversely affect Calyxt's ability to achieve profitability. If Calyxt is unable to maintain or enhance the quality of its plants and seeds as it increases its production capacity, including through the expected use of third parties, Calyxt may experience reductions in customer or farmer demand, higher costs and increased inventory write-offs.

In addition, because of the length of time it takes to produce commercial quantities of marketable seeds, Calyxt will need to make seed production decisions well in advance of product sales. Calyxt's ability to accurately forecast supply can be adversely affected by several factors outside of Calyxt's control, including changes in market conditions, environmental factors, such as pests and diseases, and adverse weather conditions. A shortfall in the supply of Calyxt's products may reduce product revenue, damage our or Calyxt's reputation in the market and adversely affect relationships. Any product surplus Calyxt has on hand may negatively impact cash flows, reduce the quality of Calyxt's inventory and ultimately result in write-offs of inventory. Additionally, we or Calyxt will take financial risk in Calyxt's inventory given that Calyxt will have to keep the inventory at its net realizable value on its balance sheet. Fluctuations in the spot price of Calyxt's crops in inventory could have negative impacts on its consolidated financial statements. Any failure on Calyxt's part to produce enough inventory, or overproduction of a product, could harm its business, results of operations and financial condition. In addition, its customers may cancel orders, request a decrease in quantity, or make returns, which may lead to a surplus of Calyxt's products.

While Calyxt estimates that the potential size of its target markets for its products is significant, that estimate has not been independently verified and is based on certain assumptions that may not prove to be accurate. Calyxt's ability to accurately forecast demand is dependent on the timing of customer decisions, qualification cycles, and other factors outside of its control. As a result, these estimates could differ materially from actual market sizes, which could result in decreased demand for Calyxt's products and therefore adversely impact Calyxt's future business prospects, results of operation and financial condition.

Interruptions in the production or transportation of Calyxt's seeds could adversely affect its operations and profitability.

Calyxt relies on contract seed producers to produce seed for our product candidates. Poor execution, failure to follow required agronomic practices, protocols or regulatory requirements, or mishandling of product candidates by these contract seed producers could adversely affect Calyxt's products. Any such failures may result in delays in Calyxt's ability to obtain seed for its seed production needs in a timely manner. Such delays could adversely affect Calyxt's ability to deliver seed to farmers to meet their planting window. Calyxt's dependency upon timely seed deliveries means that interruptions or stoppages in such deliveries, or delays or limitations with respect to seed production, could adversely affect Calyxt's operations until alternative arrangements could be made. Such a delay would adversely affect our and Calyxt's reputation and revenues. If Calyxt were unable to produce the necessary seed for an extended period for any reason, its business, customer relations, and operating results could suffer.

Calyxt may not be able to identify suitable seed producers to meet its production needs or Calyxt may not be able to enter into cost effective agreements with suitable seed producers on acceptable terms. If any contract seed producers whom Calyxt engages fail to perform their obligations as expected or breach or terminate their agreements with Calyxt, or if Calyxt is unable to secure the services of such third parties when and as needed, it may adversely affect Calyxt's business.

The unintended presence of Calyxt's traits in other products or plants may negatively affect it.

Trace amounts of Calyxt's traits may unintentionally be found in the products of third parties, which may result in negative publicity and claims of liability brought by such third parties or others against us or Calyxt. Furthermore, in the event of an unintended dissemination of Calyxt's gene-edited germplasm into the environment, or the presence of unintended trace amounts of Calyxt's traits in conventional seed, or in the grain or products produced from conventional crops, we or Calyxt could be subject to claims by multiple parties, including environmental advocacy groups, as well as governmental actions such as mandated crop destruction, product recalls, or additional stewardship practices and environmental cleanup or monitoring.

The successful commercialization of Calyxt products may face challenges from public perceptions of gene-edited products and ethical, legal, environmental, health and social concerns.

The successful commercialization of Calyxt's product candidates depends, in part, on public acceptance of gene-edited agricultural products.

Consumers may not understand the nature of Calyxt's technologies or the scientific distinction between Calyxt's non-transgenic gene-edited products and transgenic products of competitors. As a result, they may transfer negative perceptions and attitudes regarding transgenic products to Calyxt's products and product candidates. A lack of understanding of Calyxt's technologies may also make consumers more susceptible to the influence of negative information provided by opponents of biotechnology. Some opponents of biotechnology actively seek to raise public concern about gene editing, whether transgenic or non-transgenic, by claiming that plant products developed using biotechnology are unsafe for consumption or their use, pose a risk of damage to the environment, or creates legal, social and ethical dilemmas. The commercial success of Calyxt's products and product candidates may be adversely affected by such claims, even if unsubstantiated. In addition, opponents of biotechnology

have vandalized the fields of farmers planting biotech seeds and facilities used by biotechnology companies. Any such acts of vandalism targeting the fields of Calyxt's farmer customers, Calyxt field testing sites or Calyxt research, production or other facilities, could adversely affect Calyxt's sales and Calyxt's costs.

Negative public perceptions about gene editing can also affect the regulatory environment in the jurisdictions in which Calyxt is targeting the sale of Calyxt's products and the commercialization of Calyxt's product candidates. Any increase in such negative perceptions or any restrictive government regulations in response thereto, could have a negative effect on Calyxt's business and may delay or impair the sale of Calyxt's products or the development or commercialization of Calyxt's product candidates. Even in light of compliance with regulatory protocols or following receipt of confirmation of non-regulated status in a jurisdiction, public pressure may lead to increased regulation of products produced using biotechnology, further legislation regarding novel trait development technologies, or administrative litigation concerning prior regulatory determinations, each of which could adversely affect Calyxt's ability to sell its product or commercialize its product candidates. In addition, labeling requirements could heighten public concerns and make consumers less likely to purchase food products containing gene-edited ingredients.

Additionally, Calyxt is currently exploring product opportunities in hemp, among other crops. Hemp, as defined in the 2018 Farm Bill as *Cannabis sativa* containing a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis, has been removed from the Controlled Substances Act and is legally distinct from marijuana/cannabis, which is *Cannabis sativa* containing a THC concentration of more than 0.3% on a dry weight basis. Because the hemp plant and the marijuana plant are both part of the same cannabis sativa species of plant, Calyxt's activities with legal hemp may be incorrectly perceived as Calyxt being involved in federally illegal cannabis/marijuana. Also, despite growing support for the cannabis industry and legalization of cannabis in certain states in the United States, many individuals and businesses remain opposed to the cannabis industry. Any negative press resulting from any incorrect perception that Calyxt has entered the cannabis space could result in a loss of current or future business. It could also adversely affect the public's perception of Calyxt and lead to reluctance by new parties to do business with Calyxt or to own its common stock. Business partners, including but not limited to financial institutions and customers, may attempt to end or limit their relationships with Calyxt due to this incorrect perception, which may negatively affect Calyxt's business, financial condition, and results of operations.

If Calyxt's products become adulterated, misbranded, or mislabeled, Calyxt might need to recall those items and may experience product liability claims if consumers or animals are injured.

Calyxt is targeting sale of its high oleic soybean oil as a premium oil in the foodservice, food manufacturing, animal nutrition, and industrial market segments. Calyxt sells its high oleic soybean meal into the animal nutrition market segment. Calyxt may need to recall its High oleic soybean products if they become adulterated, misbranded, or mislabeled. A widespread product recall could result in significant losses due to the costs of a recall, the destruction of product inventory, and lost sales due to the unavailability of product for a period of time. Calyxt could also suffer losses from a significant product liability judgment against it. A significant product recall or product liability case could also result in adverse publicity, damage to Calyxt's reputation, and a loss of consumer or purchaser confidence in Calyxt's products, which could have an adverse effect on Calyxt's business, results of operations and financial condition and the value of Calyxt's brands.

Products that Calyxt develops, and food containing Calyxt's products, may fail to meet standards established by third-party non-GMO verification organizations, which could reduce the value of Calyxt's products to customers.

Certain third-party organizations offer verification programs that seek to identify non-GMO products to consumers. These organizations verify the status of products (such as foods, beverages and vitamins) as non-GMO based on independently developed standards, and often authorize the display of specific markers or labels illustrating such status on the verified product's packaging.

Standards established by such third-party organizations for the verification of non-GMO status may differ from applicable regulatory legal standards applied by regulators in the United States. As a result, notwithstanding a determination as to the non-regulated status of a product pursuant to APHIS's regulatory procedures (or a similar determination in other jurisdictions), Calyxt's products, and third-party products that utilize Calyxt's gene-edited products as ingredients, may fail to meet more restrictive or non-scientific standards imposed by these independent verification organizations.

For example, there are third-party verification organizations that withhold non-GMO certification from products developed using gene editing technology, including a product that does not contain any foreign DNA, such has Calyxt's high oleic soybean. Such a position means that some non-GMO seals or labels are not available for gene edited products, including our high oleic soybean products. This has limited Calyxt's ability to demand non-GMO premiums for its high oleic soybean meal.

If Calyxt is sued for defective products and if such lawsuits were determined adversely, Calyxt could be subject to substantial damages, for which insurance coverage is not available.

Calyxt may be held liable if any product it develops, or any product that uses or incorporates any of Calyxt's technologies is found unsuitable during marketing, sale or consumption. For example, the detection of an unintended trait in a commercial seed variety or the crops and products produced may result in governmental actions such as mandated crop destruction, product recalls or environmental cleanup or monitoring. Concerns about seed quality could also lead to additional regulations being imposed on Calyxt's business, such as regulations related to testing procedures, mandatory governmental reviews of biotechnology advances, or additional regulations relating to the integrity of the food supply chain from the farm to the finished product.

Calyxt may need to raise additional funding, which may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force Calyxt to delay, limit or terminate its product development efforts or other operations.

As of December 31, 2019, Calyxt had cash and cash equivalents of $58.6 million. Calyxt believes its cash and cash equivalents will be enough to fund its operations through at least mid-2021.

Calyxt's business plan is to complete the development and regulatory processes for its product candidates and commercialize additional product candidates. Based on Calyxt's history of losses, Calyxt does not expect that it will be able to fund its longer-term capital and liquidity needs to execute its business plan and pursue its strategic goals through its cash balances and operating cash flow alone. To fund Calyxt's longer-term capital and liquidity needs, Calyxt expects it will need to secure additional capital. Calyxt's business plan and financing needs are subject to change depending on, among other things, success of its product development efforts, its revenue and its efforts to continue to effectively manage expenses. If Calyxt is ultimately unable to generate sufficient revenue to meet its financial targets, become profitable and have sustainable positive cash flows, Calyxt may be required to further reduce expenses, which could have a further negative effect on Calyxt's ability to generate revenue, or Calyxt may be required to raise additional capital more quickly than Calyxt expects or Calyxt may need more capital than it expects.

Calyxt may obtain future additional financing by incurring indebtedness or from an offering of Calyxt's equity or convertible securities or both. To the extent that Calyxt raises additional capital through the sale of additional equity or convertible securities, current ownership interests will be diluted, and new investors may demand rights, preferences or privileges senior to those of existing holders of common stock. Debt financing, if available, would result in increased fixed payment obligations and a portion of Calyxt's operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends. If Calyxt raises capital in the future, Calyxt cannot assure you that additional capital will be available in the amount or at the time Calyxt needs it, or that it will be available on acceptable terms or at all. If Calyxt is unable to obtain sufficient funding on a timely basis, Calyxt may be required to significantly curtail, delay or discontinue one or more of its research or product candidate development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on Calyxt's business opportunities, as desired, which could materially affect Calyxt's business, operating results and prospects and cause the price of its common stock to decline.

Changes in tax laws and regulations could impact Calyxt's financial results and require compliance efforts that could increase Calyxt's cost of doing business.

Calyxt is subject to a variety of tax laws and regulations in the jurisdictions in which it operates. Changes in the tax laws could impact Calyxt's financial results and maintaining compliance with these laws can increase Calyxt's cost of doing business. Most notably, on December 22, 2017, U.S. tax reform legislation known as the Tax Cuts and Jobs Act (the "TCJA") was signed into law. The TCJA makes substantial changes to U.S. tax law, including a reduction in the corporate tax rate, a limitation on deductibility of interest expense, a limitation on the use of net operating losses to offset future taxable income, an allowance of immediate expensing of capital expenditures, the modification or repeal of certain business deductions (including executive compensation) and credits, deemed repatriation of foreign earnings and significant changes to the taxation of foreign earnings going forward, and new rules designed to prevent erosion of the U.S. income tax base (such as a new minimum tax, called the Base Erosion and Anti-abuse Tax, applicable to certain U.S. corporations that make certain payments to related foreign persons). The provisions in the TCJA are subject to additional regulatory or administrative developments, including any regulations or other guidance promulgated by the U.S. Treasury, Internal Revenue Service, and other regulators. Further, there can be no assurance that Calyxt's current interpretations of, and assumptions regarding, the TCJA and any related regulations or guidance will not be reviewed or investigated by regulators in the future.

Calyxt's ability to use its net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2019, Calyxt had approximately $141.4 million of net operating losses, or NOLs, for federal and state income tax purposes, which may be available to offset income tax liabilities in the future. In addition, Calyxt may generate additional NOLs in future years. Under Section 382 of the Internal Revenue Code of 1986 (as amended, the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. For this purpose, an ownership change generally means a more than 50 percentage point change in the ownership of a corporation by one or more stockholders or specified groups of stockholders, each of which owns 5% or more of the corporation (determined after the application of certain attribution and grouping rules) over a three-year period. Although Calyxt does not believe that any of its NOLs are currently subject to limitation under Section 382 of the Code, future changes in its stock ownership, some of which may be outside of its control, could result in an ownership change under Section 382 of the Code, which could limit Calyxt's ability to use its existing or future NOLs to offset future taxable income. In addition, for an NOL that was generated in the 2017 taxable year or in an earlier taxable year, Calyxt is permitted to carry forward the NOL from the taxable year in which it arose only to the succeeding twenty taxable years, and, if Calyxt does not generate sufficient taxable income to utilize the NOL carryforward within this period, it may expire unused. NOLs generated in taxable year 2018 and future years have indefinite carryforward periods.

The TCJA contains significant changes to the rules regarding NOLs. These changes include limiting the deduction of NOLs to 80% of current year taxable income, prohibiting the carryback of NOLs, and allowing NOLs to be carried forward indefinitely. These changes apply to NOLs arising in taxable years beginning after December 31, 2017, and therefore Calyxt's ability to use such NOLs to offset any future taxable income may be significantly limited. In addition, the reduction in the federal corporate tax rate under the TCJA potentially diminishes the value of Calyxt's NOLs to it. Historically, Calyxt has established a full valuation allowance for deferred tax assets due to the uncertainty that enough taxable income will be generated in the taxing jurisdiction to utilize the assets. Therefore, Calyxt does not expect changes to the rules regarding NOLs under the TCJA to have a material impact on its consolidated financial statements for the year ending December 31, 2019, as all net deferred tax assets are fully reserved.

The overall agricultural industry is susceptible to commodity price changes and Calyxt is exposed to market risks from changes in commodity prices.

Changes in the prices of commodities products could result in higher overall cost along the agricultural supply chain, which may negatively affect Calyxt's ability to commercialize its products. Calyxt will be susceptible to changes in costs in the agricultural industry as a result of factors beyond its control, such as general economic conditions, seasonal fluctuations, weather conditions, demand, food safety concerns, product recalls and government regulations. As a result, Calyxt may not be able to anticipate or react to changing costs by adjusting its practices, which could cause its operating results to deteriorate. While Calyxt manages its exposure to changing commodity prices underlying sales contracts and supply agreements for grain and seed production by entering into commodity derivative transactions, those activities may not provide full mitigation of Calyxt's exposure to changes in commodity prices, and as a result Calyxt's results of operations and financial condition may be affected.

Adverse weather conditions, natural disasters, crop disease, pests and other natural conditions can impose significant costs and losses on Calyxt.

The ability to grow Calyxt's plant products is vulnerable to adverse weather conditions, including windstorms, floods, drought and temperature extremes, which are quite common but difficult to predict, the effects of which may be influenced and intensified by ongoing global climate change. Unfavorable growing conditions can reduce both crop size and crop quality. This risk is particularly acute with respect to regions or countries in which Calyxt plans to source a significant percentage of Calyxt's plant products. In extreme cases, entire harvests may be lost in some geographic areas. Such adverse conditions can increase costs, decrease revenues and lead to additional charges to earnings, which may have a material adverse effect on Calyxt's business, financial position and results of operations.

The ability to grow Calyxt's plant products is also vulnerable to crop disease and to pests, which may vary in severity and effect, depending on the stage of production at the time of infection or infestation, the type of treatment applied, climatic conditions and the risks associated with ongoing global climate change. The costs to control disease and other infestations vary depending on the severity of the damage and the extent of the plantings affected. Moreover, there can be no assurance that available technologies to control such infestations will continue to be effective. These infestations can also increase costs, decrease revenues and lead to additional charges to earnings, which may have a material adverse effect on Calyxt's business, financial position and results of operations.

Calyxt expects its business will be highly seasonal and subject to weather conditions and other factors beyond its control, which may cause Calyxt's sales and operating results to fluctuate significantly.

The sale of plant products is dependent upon planting and growing seasons, which vary from year to year, and are expected to result in both highly seasonal patterns and substantial fluctuations in quarterly sales and profitability. Furthermore,

significant fluctuations in market prices for agricultural inputs and crops could also have an adverse effect on the value of Calyxt plant products. Weather conditions and natural disasters, such as heavy rains, hurricanes, hail, floods, tornadoes, freezing conditions, drought or fire, also affect decisions by food manufacturers or farmers about the types and amounts of seeds to plant and the timing of harvesting and planting such seeds, as well as adversely impact the agricultural industry as a whole in various regions. Disruptions that cause delays by food manufacturers or farmers in harvesting or planting can result in the movement of orders to a future quarter. Disruptions that cause delays by Calyxt farmers in harvesting could cause Calyxt to be delayed, or to fail entirely in delivering food ingredients to food manufacturers. Any of those delays or failures would negatively affect the quarter in which they occur and cause fluctuations in Calyxt operating results.

The regulatory environment in the United States for our current and future products is uncertain and evolving.

Changes in applicable regulatory requirements could result in a substantial increase in the time and costs associated with developing Calyxt's products and negatively impact Calyxt's operating results. While the USDA and FDA currently have petition processes that Calyxt has successfully completed in the past, these processes and the manner in which the USDA and FDA interpret their own regulations may change in the future, negatively impacting Calyxt's speed to market and cost to launch product candidates. Calyxt cannot predict whether advocacy groups will challenge existing regulations and USDA or FDA determinations or whether the USDA or FDA will alter the manner in which it interprets its own regulations or institutes new regulations, or otherwise modifies regulations in a way that will subject Calyxt's products to more burdensome standards, thereby substantially increasing the time and costs associated with developing Calyxt's product candidates.

Additionally, Calyxt is currently exploring product opportunities in hemp, among other crops. Hemp, as defined in the 2018 Farm Bill as *Cannabis sativa* containing a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis, has been removed from the Controlled Substances Act. It is legally distinct from marijuana and recognized as an agricultural crop by the United States government. Federal and state laws and regulations on hemp address production, monitoring, manufacturing, distribution, and laboratory testing to ensure that that the hemp has a THC concentration of not more than 0.3% on a dry weight basis. Federal laws and regulations may also address the transportation or shipment of hemp or hemp products. As Calyxt continues to explore hemp as a product candidate, Calyxt may become subject to increasing regulation particular to hemp, which could require Calyxt to incur additional costs associated with compliance requirements.

The regulatory environment outside the United States varies greatly from jurisdiction to jurisdiction and there is less certainty how Calyxt's products will be regulated.

The regulatory environment around gene editing in plants for food ingredients is greatly uncertain outside of the United States and varies greatly from jurisdiction to jurisdiction. Each jurisdiction may have its own regulatory framework regarding genetically modified foods, which may include restrictions and regulations on planting and growing genetically modified plants and in the consumption and labeling of genetically modified foods, and which may encapsulate Calyxt's products. To the extent regulatory frameworks outside of the United States are not receptive to Calyxt's gene-editing technologies, this may limit Calyxt's ability to expand into other global markets.

Complying with the regulatory requirements outside the United States will be costly and time-consuming, and there is no guarantee Calyxt will be able to commercialize its products outside the United States.

Calyxt cannot predict whether or when any jurisdiction will change its regulations with respect to its products. Advocacy groups have engaged in publicity campaigns and filed lawsuits in various countries against companies and regulatory authorities, seeking to halt regulatory approval or clearance activities or influence public opinion against genetically engineered and/or gene-edited products. In addition, governmental reaction to negative publicity concerning Calyxt's products could result in greater regulation of genetic research and derivative products or regulatory costs that render Calyxt's products cost prohibitive.

The scale of the commodity food industry may make it difficult to monitor and control the distribution of Calyxt's products. As a result, Calyxt's products may be sold inadvertently within jurisdictions where they are not approved for distribution. Such sales may lead to regulatory challenges or lawsuits against Calyxt, which could result in significant expenses and management attention.

Government policies and regulations, particularly those affecting the agricultural sector and related industries, could adversely affect Calyxt's operations and profitability.

Agricultural production and trade flows are subject to government policies and regulations. Governmental policies and approvals of technologies affecting the agricultural industry, such as taxes, tariffs, duties, subsidies, incentives and import and export restrictions on agricultural commodities and commodity products can influence the planting of certain crops, the location and size of crop production, and the volume and types of imports and exports. Future government policies in the United States or in other countries may discourage food manufacturers or farmers from using Calyxt's products or encourage the use of products

more advantageous to Calyxt's competitors, which would put Calyxt at a commercial disadvantage and could negatively impact its future revenues and results of operations.

Calyxt may use hazardous chemicals and biological materials in its business and is subject to numerous environmental, health and safety laws and regulations. Compliance with such laws and regulations and any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Calyxt is subject to numerous federal, state, local and foreign environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment, manufacture and disposal of hazardous materials and wastes, discharge of pollutants into the environment and human health and safety matters. Calyxt's research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. Calyxt cannot eliminate the risk of contamination or discharge and any resultant injury from these materials. Calyxt may be sued for any injury or contamination that results from its use or the use by third parties of these materials, or may otherwise be required to remediate such contamination, and Calyxt's liability may exceed any insurance coverage and its total assets. Compliance with environmental, health and safety laws and regulations may be expensive and may impair Calyxt's research and development efforts. If Calyxt fails to comply with these requirements, it could incur substantial costs and liabilities, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, Calyxt cannot predict the impact on its business of new or amended environmental, health and safety laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced. These current or future laws and regulations may impair Calyxt's research, development or production efforts.

Adverse outcomes in future legal proceedings could subject Calyxt to substantial damages, adversely affect Calyxt results of operations, harm our or Calyxt's reputation and result in governmental actions.

We or Calyxt may become party to legal proceedings, including matters involving personnel and employment issues, personal injury, product liability, environmental matters, intellectual property disputes and other proceedings. We or Calyxt may be held liable if Calyxt traits do not perform as anticipated by Calyxt customers, or if any product that Calyxt develops or any product that uses Calyxt's technologies or incorporates any of Calyxt's traits or is found unsuitable during marketing, sale or consumption. Courts could levy substantial damages against us in connection with claims products arising from the use of Calyxt's products.

The detection of unintended traits in Calyxt's seeds could result in governmental actions such as mandated crop destruction, product recalls or environmental cleanup or monitoring. Concerns about seed quality could also lead to additional regulations being imposed on Calyxt's business, such as regulations related to testing procedures, mandatory governmental reviews of biotechnology advances, or the integrity of the food supply chain from the farm to the finished product.

Depending on their nature, certain future legal proceedings could result in substantial damages or payment awards that exceed Calyxt's insurance coverage. Calyxt will estimate its exposure to any future legal proceedings and establish provisions for the estimated liabilities where it is reasonably possible to estimate and where an adverse outcome is probable. Assessing and predicting the outcome of these matters will involve substantial uncertainties. Furthermore, even if the outcome is ultimately in Calyxt's favor, Calyxt's costs associated with such litigation may be material. Adverse outcomes in future legal proceedings or the costs and expenses associated therewith could damage our or Calyxt's market reputation and have an adverse effect on our or Calyxt's results of operations.

Calyxt will be subject to a myriad of different laws and regulations governing hemp and its inability to comply with such laws in a cost-effective manner may have an adverse effect on Calyxt's business and result of operations.

Laws and regulations governing the use of hemp in the United States are broad in scope; subject to evolving interpretations; and subject to enforcement by a myriad of regulatory agencies and law enforcement entities. Under the Agriculture Improvement Act of 2018, also known as the 2018 Farm Bill, a state or Indian tribe that desires to have primary regulatory authority over the production of hemp in the state or territory of the Indian tribe must submit a plan to monitor and regulate hemp production to the Secretary of the United States Department of Agriculture or USDA. The Secretary must then approve the state or tribal plan after determining if the plan complies with the requirements set forth in the Agriculture Improvement Act of 2018. The Secretary may also audit the state or Indian tribe's compliance with the federally approved plan. If the Secretary does not approve the state or Indian tribe's plan, then the production of hemp in that state or territory of that Indian tribe will be subject to a plan established by USDA. USDA has not yet established such a plan. Calyxt anticipates that many states will seek to have primary regulatory authority over the production of hemp. States that seek such authority may create new laws and regulations that limit or restrict the use of hemp.

Federal and state laws and regulations on hemp may address production, monitoring, manufacturing, distribution, and laboratory testing to ensure that that the hemp has a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Federal laws and regulations may also address the transportation or shipment of hemp or hemp products, as the Agriculture Improvement Act of 2018 prohibits states and Indian tribes from prohibiting the transportation or shipment of hemp or hemp products produced in accordance with that law through the state or territory of the Indian tribe, as applicable. Calyxt may be

subject to many different state-based regulatory regimens for hemp, all of which could require Calyxt to incur substantial costs associated with compliance requirements. Calyxt's research and development operations will be restricted to only where such operations are legal on the local, state and federal levels.

In addition, it is possible that additional regulations may be enacted in the future in the United States and globally that will be directly applicable to Calyxt's research and development operations. Calyxt cannot predict the nature of any future laws, regulations, interpretations, or applications, nor can it determine what effect additional governmental regulations or administrative policies and procedures, when and if promulgated, could have on Calyxt's business.

Calyxt has no operating history in the legal hemp industry, which makes it difficult to accurately assess its future growth prospects.

The legal hemp industry is evolving and may not develop as expected. Furthermore, Calyxt's plans continue to evolve Calyxt they assesses new strategic opportunities for its business within this industry. Assessing the prospects of this industry is challenging in light of both known and unknown risks and difficulties Calyxt may encounter. Growth prospects in the legal hemp industry can be affected by a wide variety of factors including:

- competition from other companies;
- regulatory limitations and changes in regulation; and
- changes in underlying consumer behavior, which may affect the demand of Calyxt's legal hemp traits.

Calyxt may not be able to successfully address the above factors, which could negatively impact its intended business plans.

Because Calyxt has only recently begun its legal hemp operations, Calyxt anticipates its operating expenses will increase prior to earning revenue from these operations.

As Calyxt starts to conduct research and development with respect to legal hemp, Calyxt anticipates significant increases in its operating expenses, without realizing significant revenues from such operations. As a result, Calyxt may incur significant financial losses with respect to such operations in the foreseeable future. There is no history upon which to base any assumption as to the likelihood that these operations will prove successful.

Negative press from working with the hemp crop could have a material adverse effect on Calyxt's business, financial condition, and results of operations.

The hemp plant and the cannabis/marijuana plant are both part of the same cannabis sativa genus/species of plant, except that hemp, by definition, has less than 0.3% THC content, but the same plant with a higher THC content is cannabis/marijuana, which is legal under certain state laws, but which is not legal under federal law. The similarities between these plants can cause confusion, and Calyxt's activities with legal hemp may be incorrectly perceived as Calyxt being involved in federally illegal cannabis. Also, despite growing support for the cannabis industry and legalization of cannabis in certain U.S. states, many individuals and businesses remain opposed to the cannabis industry. Any negative press resulting from any incorrect perception that Calyxt has entered the cannabis space could result in a loss of current or future business. It could also adversely affect the public's perception of Calyxt and lead to reluctance by new parties to do business with Calyxt or to own Calyxt common stock. Calyxt cannot assure you that additional business partners, including but not limited to financial institutions and customers, will not attempt to end or curtail their relationships with Calyxt. Any such negative press or cessation of business could have a material adverse effect on Calyxt's business, financial condition, and results of operations.

Risks Related to Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends, in part, on obtaining and maintaining proprietary rights to our and our licensors' intellectual property estate, including with respect to our product candidates, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our product candidates is uncertain due to a number of factors, including:

- we or our licensors may not have been the first to invent the technology covered by our or their pending patent applications or issued patents;
- we cannot be certain that we or our licensors were the first to file patent applications covering our product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing;

- others may independently develop identical, similar or alternative products or compositions or methods of use thereof;
- the disclosures in our or our licensors' patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our or our licensors' pending patent applications may not result in issued patents;
- we or our licensors may not seek or obtain patent protection in countries or jurisdictions that may eventually provide us a significant business opportunity;
- any patents issued to us or our licensors may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties, which may result in our or our licensors' patent claims being narrowed, invalidated or held unenforceable;
- our compositions and methods may not be patentable;
- others may design around our or our licensors' patent claims to produce competitive products that fall outside of the scope of our or our licensors' patents; and
- others may identify prior art or other bases upon which to challenge and ultimately invalidate our or our licensors' patents or otherwise render them unenforceable.

Even if we own, obtain or in-license patents covering our product candidates or compositions, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights or other intellectual property rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop and, if approved, commercialize our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us or our licensors.

Obtaining and maintaining a patent portfolio entails significant expense of resources. Part of such expense includes periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications due over the course of several stages of prosecuting patent applications, and over the lifetime of maintaining and enforcing issued patents. We or our licensors may or may not choose to pursue or maintain protection for particular intellectual property in our or our licensors portfolio. If we or our licensors choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. In some cases, the prosecution and maintenance of our licensed patents is controlled by the applicable licensor. If such licensor fails to properly prosecute and maintain such patents, we could lose our rights to them, which could materially impair any competitive advantage afforded by such patents. Furthermore, we and our licensors employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we and they are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent prosecution and maintenance process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our or our licensors' patents or a finding that they are unenforceable. We or our licensors may or may not choose to pursue litigation or other actions against those that have infringed on our or their patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. In some cases, the enforcement and defense of patents we in-license is controlled by the applicable licensor. If such licensor fails to actively enforce and defend such patents, any competitive advantage afforded by such patents could be materially impaired. In addition, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we or our licensors can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our competitive position.

The patent positions of biotechnology and biopharmaceutical companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of

claims allowed in some patents covering biological and biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, and foreign patent offices are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated, narrowed or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review, *inter partes* review, or other administrative proceedings in the USPTO. Foreign patents as well may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Challenges to our or our licensors' patents and patent applications, if successful, may result in the denial of our or our licensors' patent applications or the loss or reduction in their scope. In addition, such interference, reexamination, post-grant review, *inter partes* review, opposition proceedings and other administrative proceedings may be costly and involve the diversion of significant management time. Accordingly, rights under any of our or our licensors' patents may not provide us with sufficient protection against competitive products or processes and any loss, denial or reduction in scope of any such patents and patent applications may have a material adverse effect on our business.

Furthermore, even if not challenged, our or our licensors' patents and patent applications may not adequately protect our product candidates or technology or prevent others from designing their products or technology to avoid being covered by our or our licensors' patent claims. If the breadth or strength of protection provided by the patents we own or license with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our ability to successfully commercialize, our product candidates. Furthermore, for U.S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO in order to determine who was the first to invent any of the subject matter covered by such patent claims.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any notice or compensation to us, or may limit the scope of patent protection that we or our licensors are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we or our licensors fail to obtain and maintain patent protection and trade secret protection of our product candidates and technology, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and have a material adverse effect on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Our or our licensors' issued patents and pending patent applications will expire on dates ranging from 2020 to 2033, subject to any patent extensions that may be available for such patents. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we or our licensors do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

Developments in patent law could have a negative impact on our business.

From time to time, the United States Supreme Court, or the Supreme Court, other federal courts, the United States Congress, the USPTO and similar foreign authorities may change the standards of patentability and any such changes could have a negative impact on our business.

The Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. As a result of these changes, the patent law in the United States may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO continues to promulgate new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our or our licensors' patent applications and the ability of us and our licensors' to obtain patents and to enforce or defend any patents that may issue from such patent applications, all of which could have a material adverse effect on our business.

In addition, recent Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the Supreme Court, the United States

Congress, the federal courts, the USPTO and similar foreign authorities, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Because we rely on third parties for the advancement of our products platform, pre-clinical testing, quality control, clinical trials, and manufacturing activities, we must, at times, share trade secrets with them, and our collaborations with Servier and Allogene, and any collaborations we may enter into in the future, may also lead to share certain of our trade secrets with our collaborators.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, intellectual property assignment, collaborative research agreements, consulting agreements or other similar agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may be breached or held unenforceable and may not effectively assign intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not provide adequate protection for our proprietary information. For example, our security measures may not prevent an employee, consultant, or collaborators with authorized access from misappropriating our trade secrets and providing them to a competitor, and the recourse we have available against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Furthermore, our proprietary information may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, including our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained 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 or our licensors do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we or our licensors have patent protection, but where the ability to enforce our or our licensors' patent rights is not as strong as in the United States. These products may compete with our products and our intellectual property rights and such rights may not be effective or sufficient to prevent such competition.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we or our licensors may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies, and the requirements for patentability differ, in varying degrees, from country to country, and the laws of some foreign countries do not protect intellectual property rights, including trade secrets, to the same extent as federal and state laws of the United States. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. Such issues may make it difficult for us to stop the

infringement, misappropriation or other violation of our intellectual property rights. For example, many foreign countries, including the EU countries, have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. 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 and our licensors' 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. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Furthermore, proceedings to enforce our and our licensors' patent rights and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly, could put our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our or our licensors' 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.

Third parties may assert rights to inventions we develop or otherwise regard as our own.

Third parties may in the future make claims challenging the inventorship or ownership of our or our licensors' intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our strategic alliances. These agreements provide that we must negotiate certain commercial rights with such collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the strategic alliance. In some instances, there may not be adequate written provisions to address clearly the allocation of intellectual property rights that may arise from the respective alliance. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials when required, or if disputes otherwise arise with respect to the intellectual property developed through the use of a collaborator's samples, we may be limited in our ability to capitalize on the full market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or are in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and could interfere with our ability to capture the full commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property and associated products and technology, or may lose our rights in that intellectual property. Either outcome could have a material adverse effect on our business.

In addition, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the United States government. As a result, the United States government has certain rights to such patent rights and technology, which include march-in rights. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to the United States industry. Any exercise by the government of any of the foregoing rights could have a material adverse effect on our business.

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

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We currently employ, and may in the future employ, individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. Although we are not currently subject to any material pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights.

If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially including treble damages if we are found to have willfully infringed a party’s patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- our or our collaborators’ being required to obtain a license under third-party intellectual property, and such license may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business, including our ability to further develop, commercialize, and sell products.

Any infringement, misappropriation or other violation by us of intellectual property rights of others may prevent or delay our product development efforts and may prevent or increase the costs of our successfully commercializing our product candidates, if approved.

Our success will depend in part on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties.

The biotechnology and biopharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our or our collaborators’ products or product candidates or the use of our or our collaborators’ technologies infringe, misappropriate or otherwise violate patent claims or other intellectual property rights held by them or that we or our collaborators’ are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorneys’ fees if we or our collaborators are found to be willfully infringing another party’s patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. Such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same intellectual property rights or technologies licensed to us. In addition, if any such claim were successfully asserted against us and we could not obtain a license, we or our collaborators may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing our products, product candidates or other infringing technology, or those we develop with our collaborators.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention pursuing these proceedings, which could have a material adverse effect on us. 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. In addition, if securities analysts or investors negatively perceive, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales,

marketing or distribution activities. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. We may not have sufficient resources to advance these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename trademarks we may own, to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Furthermore, third parties may petition courts for declarations of invalidity or unenforceability with respect to our patents or individual claims. If successful, such claims could narrow the scope of protection afforded our product candidates and future products, if any. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no 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 our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We may be unsuccessful in licensing or acquiring intellectual property that may be required to develop and commercialize our product candidates from third parties.

We have rights, through licenses from third parties and under patents that we own, to the intellectual property to develop our product candidates. Because our programs may involve additional product candidates that may require the use of intellectual property or proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license any third-party intellectual property or proprietary rights or to do so on commercially reasonable terms. The licensing and acquisition of third-party intellectual property and proprietary rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property and proprietary rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size and greater capital resources and development and commercialization capabilities.

For example, we sometimes collaborate with academic institutions to accelerate our research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the strategic alliance. Regardless of such option, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us, and the institution may license such intellectual property rights to third parties, potentially blocking our ability to pursue our development and commercialization plans.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license to us intellectual property and proprietary rights. We also may be unable to license or acquire third-party intellectual property and proprietary rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully acquire or in-license rights to required third-party intellectual property and proprietary rights or maintain the existing intellectual property and proprietary rights we have, we may have to cease development of the relevant program, product or product candidate, which could have a material adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market products or product candidates covered by the license.

In addition, disputes may arise regarding the payment of the royalties or other consideration due to licensors in connection with our exploitation of the rights we license from them. Licensors may contest the basis of payments we retained and claim that we are obligated to make payments under a broader basis. In addition to the costs of any litigation we may face as a result, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If such licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing products using such intellectual property. In addition, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and product candidates, which could harm our business significantly. In other cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Moreover, we have obligations under these license agreements, and any failure to satisfy those obligations could give our licensor the right to terminate the agreement. Termination of a necessary license agreement could have a material adverse impact on our business.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

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

If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Risks Related to Our Organization, Structure and Operation

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of December 31, 2019, we had 264 full-time employees (including Calyxt, Inc.) and we expect to increase our number of employees and the scope and location of our operations. To manage our anticipated development and expansion, including the development and the commercialization of our product candidates, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in

weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our 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, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We depend on key management personnel and attracting and retaining other qualified personnel, and our business could be harmed if we lose key management personnel or cannot attract and retain other qualified personnel.

Our success depends to a significant degree upon the technical skills and continued service of certain members of our management team, including Dr. André Choulika, our co-founder and Chief Executive Officer; Dr. David Sourdive, our co-founder and Executive Vice President, Strategic Initiatives; and Eric Dutang, our Chief Financial Officer. Although we maintain “key person” insurance policies on the lives of our co-founders, the loss of the services of our co-founders or other key executive officers could have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, regulatory, medical, technical, and sales and marketing executives and personnel. The failure to attract, integrate, motivate, and retain additional skilled and qualified personnel, or to find suitable replacements upon departures, could have a material adverse effect on our business.

We compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. In addition, failure to succeed in our product candidates’ development may make it more challenging to recruit and retain qualified personnel. There can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

In order to induce valuable employees to remain at Cellectis, we have provided from time to time free shares and stock options to purchase ordinary shares that vest over time. The value to employees of free shares and stock options that vest over time may be significantly affected by movements in the price of our ordinary shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. In addition, our board authority to grant equity incentive instruments is subject to an approval of a two-thirds majority of the shares held by our shareholders. Our shareholders may vote against some or all resolutions giving authority to our board to grant equity.

The requirements of being a U.S. public company require significant resources and management attention and affect our ability to attract and retain executive management and qualified board members.

As a U.S. public company, we incur significant legal, accounting, and other expenses. We are subject to the US Securities Exchange Act of 1934, of the Exchange Act, including the reporting requirements thereunder, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Compliance with these rules and regulations results in substantial legal and financial compliance costs and makes some activities more difficult, time-consuming or costly and increases demand on our systems and resources. These costs and other impacts would increase if we cease to qualify as a foreign private issuer, in which case we would be required to comply with the enhanced reporting and governance requirements applicable to U.S. domestic reporting companies.

In addition, our subsidiary Calyxt is a U.S. public company, and is also subject to the Exchange Act, including the reporting requirements thereunder, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Having a U.S. public company subsidiary has impacted the disclosure of our financial information and has increased our legal and financial compliance costs.

Further, being a U.S. public company and a French public company has impacted the disclosure of information and required compliance with two sets of applicable rules. From time to time, this may result in uncertainty regarding compliance matters and has resulted in higher costs necessitated by legal analysis of dual legal regimes, ongoing revisions to disclosure and adherence to heightened governance practices. As a result of the enhanced disclosure requirements of the U.S. securities laws, business and financial information that we report is broadly disseminated and highly visible to investors, which we believe may increase the likelihood of threatened or actual litigation, including by competitors and other third parties, which could, even if unsuccessful, divert financial resources and the attention of our management from our operations.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business, investor confidence and market price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our disclosure controls and procedures and the effectiveness of our internal control over financial reporting at the end of each fiscal year. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting, and we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit and finance committee be advised and regularly updated on management's review of internal control over financial reporting.

Our compliance with applicable provisions of Section 404 requires that we incur substantial accounting expense and expend significant management attention and time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed. Moreover, if we are not able to comply with the applicable requirements of Section 404 in a timely manner, we may be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Furthermore, if we are unable to conclude that our internal control over financial reporting is effective or if our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities. Failure to implement or maintain effective internal control systems required of public companies could also restrict our access to the capital markets. The occurrence of any of the foregoing would also require additional financial and management resources.

Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our results of operations.

As a French technology company, we have benefited from certain tax advantages, including the French research tax credit (*Crédit d'Impôt Recherche*), or CIR. The CIR is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess (if any) may be refunded at the end of a three fiscal-year period (or, sooner, in certain cases). The Research tax credit receivables as of December 31, 2019 include the accrual for a French research tax credit related to 2019 for $7.9 million and a portion related to 2017 and 2018 for $0.8 million. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France. The French tax authority with the assistance of the Research and Technology Ministry may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in their view for the CIR benefit, in accordance with the French tax code (*code général des impôts*) and the relevant official guidelines.

During December 2018, the French Tax Authority initiated an audit related to the 2014, 2015, 2016 and 2017 French research tax credits. As a result of the audit, the French Tax Authority withheld a portion of the 2018 and 2017 research tax credits payment corresponding to the nature of certain employee costs. We challenged the French Tax Authority's withholding and do not believe that a provision should be recorded at this time. Should the French tax authorities be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, or we may not obtain the refunds for which we have applied, which could have a significant impact on our results of operations and future cash flows.

Furthermore, if the French Parliament decides to eliminate, modify, or reduce the scope of the CIR benefit, which it could decide to do at any time, our results of operations could be adversely affected.

We may be exposed to significant foreign exchange risk, which may adversely affect our financial condition, results of operations and cash flows.

We incur portions of our expenses and may in the future derive revenues in currencies other than the euro, including, in particular, the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. While we are engaged in hedging transactions to minimize the impact of uncertainty in future exchange rates on cash flows, we may not hedge all of our foreign currency exchange rate risk. In addition, hedging transactions carry their own risks and costs, including the possibility of a default by the counterpart to the hedge transaction. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

We may use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, manufacture and disposal of hazardous materials and wastes. Our research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. Federal, state, local or foreign laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur delays, substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced. These current or future laws and regulations may impair our research, development or production efforts.

Our internal computer systems, or those of our third-party contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs or loss of personal data.

Despite the implementation of security measures, our internal computer systems and those of our third-party contractors and consultants are vulnerable to damage from computer viruses, cyber-attacks, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we do not believe that we have experienced any significant 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 significant damages including without limitation 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 regulatory 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.

Data privacy regulations could adversely affect our business, results of operations and financial condition.

We are subject to data privacy and protection laws and regulations that impose requirements relating to the collection, transmission, storage and use of personally-identifying information, including comprehensive regulatory systems in the U.S. and EU. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including regulations promulgated pursuant to HIPAA that establish privacy and security standards for the use and disclosure of individually identifiable health information and require the implementation of administrative, physical and technological safeguards to protect the privacy of such protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties.

In the EU, we are subject to the European Regulation 2016/679, known as the General Data Protection Regulation (GDPR), as well as EU Member State implementing legislations. GDPR and EU Member State implementing legislation apply to the collection and processing of personal data, including health-related information, by companies located in the EU and processing personal information of individuals located in the EU. These laws impose strict obligations on the ability to process personal data, including health-related information, in particular in relation to their collection, use, disclosure and transfer. These include several requirements relating to (i) obtaining, in some situations, the consent of the individuals to whom the personal data relates, (ii) the information provided to the individuals about how their personal information is used, (iii) ensuring the security and confidentiality of the personal data, (iv) the obligation to notify personal data breaches to regulatory authorities and, as applicable, to communicate such breaches to affected individuals, (v) extensive internal privacy governance obligations, and (vi) obligations to honor rights of individuals in relation to their personal data (for example, the right to access, correct and delete their data). The

GDPR also imposes restrictions on the transfer of personal data to countries outside of the European Economic Area (EEA). The GDPR has increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional potential mechanisms to ensure compliance with the new EU data protection rules. Also, some uncertainty remains around the legal and regulatory environment for these evolving privacy and data protection laws and regulations.

We may become the subject of investigations and/or claims in respect of privacy matters and unfavorable outcomes in any of such matters could preclude the commercialization of products, harm our reputation, negatively affect the profitability of our products and subject us to substantial fines. In addition, our ongoing efforts to comply with evolving laws and regulations in the US, EU and elsewhere may be costly and require ongoing modifications to our policies, procedures and systems.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

Our current strategy does not involve acquisition plans. However, if acquisitions were to become necessary or attractive in order to access new products, technologies, research projects or geographical areas, or to express synergies with existing operations, we may not be able to identify appropriate targets or negotiate satisfactory conditions, including price conditions. In addition, we may be unable to obtain the financing for any such acquisitions under favorable conditions, and could be led to finance these acquisitions using cash that could be allocated to existing operations. We may not be able to realize anticipated benefits of acquiring any such businesses and may encounter numerous difficulties in connection therewith.

Risks Related to Ownership of Our Ordinary Shares and ADSs

Although not free from doubt, we do not believe we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for the 2019 taxable year. However, we cannot assure you that we will not be classified as a PFIC for 2020 or any future taxable year, which may result in adverse U.S. federal income tax consequences to U.S. holders (as defined in the section titled "Taxation—Material U.S. Federal Income Tax Considerations" in this Annual Report).

A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. Although the matter is not free from doubt, we do not believe that we were a PFIC for U.S. federal income tax purposes for the 2019 taxable year. Because certain aspects of the PFIC rules are not entirely certain and because this determination is dependent upon a number of factors, there can be no assurance that we were not a PFIC for the 2019 taxable year or that the IRS will agree with our conclusion regarding our PFIC statutes.

Further, no assurances may be given at this time as to our PFIC status for the current or future taxable years. The determination of PFIC status is fact-specific, and a separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). It is possible that we could be classified as a PFIC for 2020 or future taxable years due to changes in the composition of our assets or income, as well as changes to the market value of our assets. The market value of our assets may be determined in large part by reference to our market capitalization (and, therefore, the market price of our stock, which has fluctuated and is likely to continue to fluctuate, substantially).

If we are a PFIC for any taxable year during which a U.S. holder holds ADSs, the U.S. holder may be subject to adverse tax consequences, including (1) the treatment of all or a portion of any gain on disposition of the ADSs as ordinary income, (2) the application of an interest charge with respect to such gain and certain dividends and (3) compliance with certain reporting requirements. Each U.S. holder is strongly urged to consult its tax advisor regarding these issues and any available elections to mitigate such tax consequences. See the section titled "Taxation—Material U.S. Federal Income Tax Considerations" in this Annual Report.

The market price for our ADSs may be volatile or may decline regardless of our operating performance.

The trading price of the ADSs has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of our ADSs depends on a number of factors, including those described in this "Risk Factors" section, many of which are beyond our control and may not be related to our operating performance.

Since the ADSs were sold in our initial public offering in March 2015 at a price of $41.50 per share, the price per ADS has ranged as low as $9.50 and as high as $50.00 through March 4, 2020. The market price of the ADSs may fluctuate significant in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- our failure to develop and commercialize our product candidates or to do so in a timely manner;

- adverse results of delays in our or any of our competitors' pre-clinical studies or clinical trials;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, strategic alliances, or capital commitments;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the termination of a strategic alliance or the inability to establish additional strategic alliances;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our ADSs;
- price and volume fluctuations in trading of our ordinary shares on the Euronext Growth market of the Euronext in Paris;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- our inability to obtain reimbursement by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent holders from readily selling their ADSs and may otherwise negatively affect the liquidity of our capital shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Share ownership is concentrated in the hands of our principal shareholders and management, who will continue to be able to exercise substantial influence on us.

Our executive officers, directors, current 5% or greater shareholders and affiliated entities beneficially own approximately 33.28% of our ordinary shares outstanding (including those underlying our ADSs, but excluding shares that may be acquired upon exercise of stock options or warrants) as of December 31, 2019. As a result, these shareholders have significant influence over all matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate action might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other shareholders may view as beneficial.

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

The trading market for our ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. If few or no securities or industry analysts cover us, the trading price for our ADSs would be negatively impacted. If one or more of the analysts who covers us downgrades our securities or publishes incorrect or unfavorable research about our business, the price of our ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly this could also cause the price of our ADSs or trading volume to decline.

We do not currently intend to pay dividends on our securities. In addition, French law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our share capital and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, holders of our ordinary shares and ADSs are not likely to receive any dividends for the foreseeable future and any increase in value will depend solely upon any future appreciation. Consequently, holders of our equity securities may need to sell all or part of their holdings after price appreciation, which may never occur, as the only way to realize any future gains.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with standard applicable in France. Please see the section of this Annual Report titled "Memorandum and Articles of Association" for further details on the limitations on our ability to declare and pay dividends. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

Future sales of ordinary shares or ADSs in the public market could depress the market price of the ADSs.

We believe that additional capital may be needed to continue our planned operations, including conducting our planned clinical trials, manufacturing and commercialization efforts, expanded research and development activities and costs associated with operating as a public company. Sales of additional ordinary shares or ADSs by us, or the perception that these sales could occur, could cause the market price of our ADSs to decline.

In addition, if our existing shareholders sell, or indicate an intent to sell, substantial amounts of ordinary shares or ADSs, the market price of our ADSs could decline. In addition, such secondary sales may impair our ability to raise capital through the sale of additional equity securities.

As of December 31, 2019, we had 42,275,882 ordinary shares outstanding. All ADSs representing our ordinary shares are expected to be freely transferable by persons other than our "affiliates" without restriction. As of February 28, 2020, our directors and executive officers beneficially owned approximately 9,507,626 of our ordinary shares. Outstanding shares held by our affiliates, including our officers and directors, may be publicly sold in accordance with the requirements of Rule 144 under the Securities Act, including the volume and manner of sale requirements of that rule.

Risks Relating to Investing in a Foreign Private Issuer or French Company

Our By-laws and French corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our By-laws and the corporate laws of France, the country in which we are incorporated, could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of French law and our By-laws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- a merger (i.e., in a French law context, stock-for-stock exchange after which our company would be dissolved without being liquidated into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes cast of by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require the unanimous approval of our shareholders;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may in the future grant to our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights proportional to their shareholding in our company on the issuance by us of any additional shares or securities giving the right, immediately or in the future, to new shares for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;

- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the ratification by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can only be convened by its chairman (and our managing director, if different from the chairman, may request the chairman to convene the board) or, when no board meeting has been held for more than two consecutive months, by directors representing at least one-third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board of directors' decisions;
- our shares take the form of bearer securities or registered securities, if applicable legislation so permits, according to the shareholder's choice. Issued shares are registered in individual accounts opened by us or any authorized intermediary (depending on the form of such shares), in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions;
- under French law, a non-French resident as well as any French entity controlled by non-French residents may have to file a declaration for statistical purposes with the Bank of France (*Banque de France*) following the date of certain direct or indirect investments in us; see the section of this Annual Report titled "Ownership of Shares and ADSs by Non-French Persons";
- approval of at least a majority of the votes cast of the shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- transfers of shares shall comply with applicable insider trading rules;
- in the event where certain ownership thresholds would be crossed, a number of disclosures should be made by the relevant shareholder in addition to other certain obligations; see the section of this Annual Report titled "Declaration of Crossing of Ownership Thresholds"; and
- pursuant to French law, the sections of the By-laws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by a two-thirds majority of the votes cast of our shareholders present, represented by a proxy or voting by mail at the meeting.

Holders of our ADSs do not directly hold our ordinary shares.

Holders of ADSs are not treated as one of our shareholders and do not have ordinary shareholder rights. French law governs shareholder rights. The depositary, Citibank, N.A., is the holder of the ordinary shares underlying all ADSs. Holders of ADSs have only ADS holder rights. The deposit agreement among us, the depositary and each ADS holder, sets out ADS holder rights, as well as the rights and obligations of the depositary.

Holders of our ADSs may not be able to exercise their right to vote the ordinary shares underlying such ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement and not as a direct shareholder. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

Holders of ADSs may instruct the depositary of the ADSs to vote the ordinary shares underlying such ADSs. Otherwise, holders of our ADSs will not be able to exercise their right to vote, unless they withdraw the ordinary shares underlying such ADSs. However, holders of our ADSs may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for instructions, the depositary, upon timely notice from us, will notify holders of our ADSs of the upcoming vote and arrange to deliver our voting materials to such holders. We cannot guarantee that holders of our ADSs will receive the voting materials in time to ensure that they can instruct the depositary to vote such ordinary shares or to withdraw such ordinary shares so as to vote them directly. If the depositary does not receive timely voting instructions from holders of our ADSs, it may give a proxy to a person designated by us to vote the ordinary shares underlying such ADSs in accordance with the recommendation of

our board of directors. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that holders of our ADSs may not be able to exercise their right to vote, and there may be nothing such holders can do if the ordinary shares underlying such ADSs are not voted as requested.

The right of holders of our ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to holders of ADSs.

According to French law, if we issue additional shares or securities for cash, current shareholders will have preferential subscription rights for these securities proportionally to their shareholding unless they waive those rights at an extraordinary meeting of our shareholders (by a two-thirds majority vote) or individually by each shareholder. However, our ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement for our ADSs provides that the depositary will not make rights available to holders of our ADSs unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings and may receive no value for these rights.

Holders of our ADSs may be subject to limitations on the transfer of such ADSs and the withdrawal of the underlying ordinary shares.

ADSs, which may be evidenced by American Depositary Receipts, or ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to an ADS holders' right to cancel such ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of such ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, holders of our ADSs may not be able to cancel such ADSs and withdraw the underlying ordinary shares when such holders owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company. This may limit the information available to holders of ADSs.

We are a "foreign private issuer," as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and quarterly filings with the SEC, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. domestic public companies and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there may be less publicly available information concerning our company than there would be if we were a U.S. domestic issuer.

As a foreign private issuer, we follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq's corporate governance standards.

As a foreign private issuer listed on the Nasdaq Global Market, we are subject to corporate governance standards. However, Nasdaq's rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in France, which is our home country, may differ significantly from corporate governance standards of the Nasdaq. For example, neither the corporate laws of France nor our By-laws require a majority of our directors to be independent and our independent directors are not required to hold regularly scheduled meetings at which only independent directors are present. In addition, home country practice in France does not require us to maintain a nominating and corporate governance committee or to maintain a compensation committee composed entirely of independent directors. Currently, we follow

home country practice in certain key respects. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers. A discussion of our corporate governance practices is set forth in the section titled "Management—Corporate Governance Practices."

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of our most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2020.

In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and (i) more than 50% of our executive officers or more than 50% of the members of our board of directors are residents or citizens of the United States, (ii) more than 50% of our assets are located in the United States, or (iii) our business is principally administered within the United States we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic public company would be significantly more than costs we currently incur as a foreign private issuer.

It may be difficult to enforce civil liabilities against our company and directors and senior management and the experts named in this Annual Report.

Certain members of our board of directors and senior management and those of our subsidiaries, are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action are borne by the relevant shareholder or the group of shareholders.

The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

Provisions in our collaboration agreement with Servier may prevent or delay a change in control.

Our collaboration agreement with Servier provides that if a third party acquires control of us, directly or indirectly, by any means, or in the event that we sell or otherwise convey to a third party all or substantially all of our assets (or all or substantially all of our assets that are material to the performance of our obligations under the collaboration agreement), and such third party successor conducts research, development, manufacturing or commercialization activities on CD19 or any other CAR-T products within the indications developed by Servier, then Servier has the right to acquire for one lump sum payment an exclusive fully paid-up worldwide license over substantially all of the Cellectis intellectual property relating to the UCART19 products covered by the collaboration agreement (the "Servier buy out"). If we and Servier fail to agree on the amount of payment for the Servier buy out within ten days following Servier's provision of a buy-out notice, then the amount of the buy-out payment would be determined based a valuation process involving third-party valuators selected by us and Servier, respectively.

The Servier buy-out mechanism may have the effect of delaying or preventing a change in control transaction involving us, or may reduce the number of companies interested in acquiring us. If Servier were to exercise the Servier buy-out, it would gain exclusive development and marketing rights to UCART19 products covered by the collaboration agreement. Were this to happen, our successor would not receive milestone payments or royalty payments on net sales of any of the UCART19 products exclusively licensed to Servier in connection with the Servier buy-out.