could cause us to spend substantial resources and distract our personnel from their normal responsibilities and negative outcomes could result in adverse effects on our business.

- We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

PART I

Item 1. Identity of Directors, Senior Management and Advisers.
Not applicable.

Item 2. Offer Statistics and Expected Timetable.
Not applicable.

Item 3. Key Information.

A. [Reserved]

B. Capitalization and Indebtedness
Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Investing in the ADSs involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this Annual Report on Form 20-F before making an investment decision. Our business, financial condition or results of operations could be adversely affected if any of these risks occurs, and as a result, the market price of the ADSs could decline and you could lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception, we expect to incur losses in future periods and may not achieve or maintain profitability in the upcoming years. Even if we achieve profitability, we may need substantial additional funding in order to complete the development and commercialization

of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development or research operations.

Since our inception, we have incurred significant operating losses, including negative net results, attributable to shareholders. For the years ended December 31, 2021 and 2020, we incurred negative net results, attributable to shareholders of CHF 63.8 million and CHF 62.8 million, respectively. As of December 31, 2021, we had cumulative losses of CHF 251.0 million. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product candidates as well as costs incurred for research programs and from selling, general and administrative costs associated with our operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities that, together with anticipated selling, general and administrative expenses, may result in incurring losses in future periods. Our losses, among other things, will continue to cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase substantially if and as we:

- complete the Phase 1a clinical trial of MP0310 in fibroblast activation protein, or FAP, positive cancer patients;
- complete the Phase 1 clinical trial of MP0317, our second product candidate in our oncology program;
- continue to prepare for the Phase 1 clinical trial of MP0533, our new CD3 T cell engaging candidate against acute myeloid leukemia (AML);
- continue our research activities for developing suitable candidates that could neutralize viruses such as the Respiratory Syncytial Virus (RSV) or the BK Polyomavirus (BKV);
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs;
- continue the research and development of our other product candidates;
- seek to enhance our DARPin technology and build on our proprietary product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- obtain, maintain, expand, protect and enforce our intellectual property and other proprietary rights and obtain licenses to third-party intellectual property;
- add clinical, regulatory, scientific, operational, financial, legal, intellectual property, compliance and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- experience any delays or encounter any issues relating to any of the above, including failed studies, ambiguous trial results, safety issues, other regulatory challenges or third party supply or manufacturing issues.

Since our inception in 2004, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us or our licensees to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other comparable foreign authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of the ADSs and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of the ADSs also could cause you to lose all or a part of your investment.

We may need substantial additional funding in order to complete the development and commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development or research operations.

To date, we have funded our operations through public and private placements of equity securities, upfront, milestone, option exercise, reservation fee, expense reimbursement, FTE and sponsored research payments received from our collaborators, recharging of third party costs and interest income from the investment of our cash, cash equivalents and financial assets. We expect to require additional funding in the future to sufficiently finance our operations and advance development of our product candidates.

We expect that our existing cash, cash equivalents, together with anticipated funding through collaborations, will enable us to fund our operating expenses and capital expenditure requirements into 2025. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements for MP0310 licensed to Amgen, MP0317 or our preclinical programs will depend on many factors, including:

- the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;

- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement, misappropriation or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- selling and marketing activities undertaken in connection with the potential commercialization of our current or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of milestone and royalty payments from future sales of our product candidates, if approved.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Further, as a Swiss corporation, we have less flexibility to raise capital than U.S. companies, particularly in a quick and efficient manner. As a result, we may not be able to access the capital markets as frequently as comparable U.S. companies. See the Risk Factor entitled “Our status as a Swiss corporation means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs” for additional information related to our ability to timely raise capital. If adequate funds are not available on commercially acceptable terms or at all when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

The effects of health epidemics, including the ongoing COVID-19 coronavirus pandemic, in regions where we, or the third parties on which we rely, have business operations could adversely impact our business, including our preclinical studies and clinical trials, as well as the business or operations of third parties with whom we conduct business.

In December 2019, a novel strain of coronavirus disease that causes COVID-19 was identified in Wuhan, China. The SARS-CoV-2 coronavirus has spread to a number of countries globally, and the disease outbreak was declared a pandemic by the World Health Organization in March 2020. More recently, other, potentially more infectious, variants of the SARS-CoV-2 coronavirus have been identified. The outbreak and government measures and regulations taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we requested most of our employees that are not required to work in the laboratory to work remotely. As the result of the pandemic, we may experience disruptions that could impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in commencing enrollment of patients or healthy volunteers in our clinical trials;
- delays or difficulties in securing clinical trial site locations, and delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delay of submissions to, and approvals of, regulatory authorities;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures that are deemed non-essential, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of regulatory authorities, which may impact review and approval timelines, including delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- interruption of, or delays in receiving, supplies of our product candidates or target material from our contract manufacturing organizations and other suppliers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our facilities; limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

For example, our Phase 1 trial of ensovibep, our COVID-19 antiviral product candidate licensed to Novartis, experienced a temporary delay from December 2020 through April 2021 due to an inability to dose healthy volunteers in the UK resulting from government restrictions that were imposed at the end of 2020 in connection with the COVID-19 pandemic. Dosing for the Phase 1 trial of ensovibep recommenced, and was subsequently completed, in April 2021.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak ultimately impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, the emergence of variants, the transition to endemic status, travel restrictions and social distancing in Switzerland, the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in countries around the world to contain and treat the disease.

Raising additional capital may cause dilution to holders of our common shares or ADSs, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations with our existing cash, cash equivalents and current financial assets, proceeds from debt or equity offerings, revenue from our collaborations and interest income from the investment of our cash, cash equivalents and financial assets. In order to further advance the development of our product candidates, discover additional product candidates and pursue our other business objectives, however, we will need to seek additional funds.

We cannot guarantee that future financing will be available in sufficient amounts or on commercially reasonable terms, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our common shares or ADSs and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs and our common shares to decline. The sale of additional equity or convertible securities would dilute all of our

existing shareholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

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 development programs or the commercialization of any of our product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Risks Related to the Development and Clinical Testing of Our Product Candidates

We are heavily dependent on the success of our DARPin platform to identify and develop product candidates. If we or our collaborators are unable to successfully develop and commercialize product candidates based on our platforms or experience significant delays in doing so, our business may be harmed.

We are heavily dependent on the success our DARPin platform technology and the product candidates currently in our core programs. Our commercial prospects will be heavily dependent on product candidates identified and developed using our DARPin platform. To date, we have invested substantially all of our efforts and financial resources to identify, acquire intellectual property for, and develop our DARPin platform technology and our programs, including conducting preclinical studies and early-stage clinical trials, and providing general and administrative support for these operations.

We may not be successful in our efforts to further develop our DARPin platform technology and current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, European Commission (granted on the basis of a positive opinion from the Committee for Medicinal Products for Human Use of the EMA and commonly referred to as EMA approval) or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all.

All of our product candidates are in preclinical or various stages of clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates, particularly MP0317, abicipar and product candidates that we have licensed to our partners, including ensovibep and MP0310, are prolonged, delayed or not commercially viable, we or our collaborators may be unable to obtain required regulatory approvals, and therefore may be unable to commercialize our product candidates on a timely basis or at all, which will adversely affect our business.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we or our collaborators for such candidates must demonstrate through extensive preclinical studies and clinical trials

that our products are safe, pure and potent or effective in humans. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Prior to obtaining approval to commercialize a product candidate in the United States or in other countries, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Additionally, clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. For example, our Phase 1 trial of ensovibep, our COVID-19 antiviral product candidate licensed to Novartis, experienced a temporary delay from December 2020 through April 2021 due to an inability to dose healthy volunteers in the UK resulting from government restrictions that were imposed at the end of 2020 in connection with the COVID-19 pandemic. Dosing for the Phase 1 trial of ensovibep recommenced, and was subsequently completed, in April 2021.

Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory approval to commence a trial;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, or ethics committee approval at each site;
- delays in or failure to recruit suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials;
- third-party actions claiming infringement by our product candidates in clinical trials and obtaining injunctions interfering with our progress;
- safety or tolerability concerns could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;

- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results; and
- the quality or stability of the product candidate falling below acceptable standards; and
- the impact of the ongoing COVID-19 pandemic, which may slow potential enrollment, reduce the number of eligible patients for potential clinical trials, cause delays in clinical trials, or delays or difficulties in shipping and delivering in a timely manner supplies, samples or products required for our operations.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee, or DRC, or Data Safety Monitoring Board, or DSMB, for such trial or by the EMA, the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination 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 site by the EMA, the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our product candidates belong, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, we have faced and may face in the future bioburden during drug substance production campaigns or particles in drug product preparations at our CMOs which led or may lead to regulatory actions, including from the FDA. While we and our partners endeavor to maintain appropriate backup supply with respect to our product candidates, and not all such bioburden or particles result in regulatory action or delays, we cannot assure that any such issues would not result in delays in our clinical trials or product development or other adverse impacts on our business.

Changes in local regulations as part of a response to the COVID-19 pandemic may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or delays, or cause us to discontinue the clinical trials altogether. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early.

Clinical trials must be conducted in accordance with the FDA, the EMA and other applicable regulatory authorities' legal requirements and regulations, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted or ethics committees. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our

collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

Further, conducting clinical trials in multiple countries, such as the Phase 2/3 global registration study for ensovibep, our COVID-19 antiviral product candidate licensed to Novartis, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with adhering to GCP, regulations and other foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

In addition, future clinical trials that could be conducted in countries outside Switzerland, the European Union and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-European Union and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

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

A key element of our strategy is to use and expand our platform to build a pipeline of product candidates and progress these product candidates through clinical development. So far none of the products candidates originating from our platform has received marketing approval from the FDA or other regulatory authorities. The scientific discoveries that form the basis for our efforts to discover and develop targeted oncology therapeutic candidates for cancer patients are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. There can be no assurance that any development problems we may experience in the future related to our platform will not cause significant delays or unanticipated costs or that such development problems can be solved. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance.

Our COVID-19 antiviral product candidates may face significant competition from vaccines and other treatments for COVID-19 that are approved, available for emergency use, or in development. In addition, the addressable market for our COVID-19 antiviral product may be smaller than we or third parties currently project.

Many biotechnology and pharmaceutical companies are developing treatments for COVID-19 or vaccines against severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the virus that causes COVID-19, and any treatment we may develop will face significant competition. Many of these companies, which include large pharmaceutical companies, have greater resources for development, manufacturing and established commercialization capabilities. These companies may develop treatments more rapidly or effectively than our partner, Novartis, does, may develop a treatment that becomes the standard of care, may develop a treatment at a lower cost, superior formulation or more convenient way of administration, or may be more successful at commercializing an approved treatment, all of which could adversely impact our business. In addition, a decline, or a widespread perception of a decline, in the spread or severity of the ongoing COVID-19 pandemic, or an increase in available alternative treatments for or widespread immunity to SARS-CoV-2, could reduce the total addressable market for our

COVID-19 antiviral product candidates. As a result, our partner Novartis may not be able to successfully commercialize our COVID-19 antiviral product candidates for the treatment of COVID-19, even if approved, or compete with other treatments or vaccines, which could potentially reduce payments to us under our collaboration agreement and adversely impact our business and operations. Moreover, if and as the pandemic transitions to an endemic phase, the public health emergency declarations underlying emergency use authorization may cease and require that sponsors seek full approval of COVID-19 treatments, which could adversely impact the development timeline for our partner Novartis.

Preclinical drug development is uncertain. Some or all of our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA or EMA approval to market a new pharmaceutical or biological product we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug application, or IND, in the United States, or a Clinical Trial Authorization Application, or CTA, in Europe. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or EMA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. Thus, we cannot be sure that we will be able to submit INDs or CTAs for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or CTAs will result in the FDA or EMA allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per product candidate. Delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. We may encounter similar or different safety issues in this trial or our other clinical trials in the future. Moreover, we may continue to be affected by delays associated with the preclinical testing and studies of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of preclinical studies and studies for a product candidate may be delayed by many factors, including, for example:

- the inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA or EMA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, even if clinical trials do begin for our preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety, purity and potency or efficacy to obtain the requisite regulatory approvals for any of our product candidates or product candidates employing our technology.

Positive results from early preclinical studies of our product candidates would not necessarily be predictive of the results of later preclinical studies and any ongoing or future clinical trials of our product candidates. If we were to achieve positive results from preclinical studies, but were unable to then replicate those positive results in our later preclinical studies and ongoing future clinical trials, we

might be unable to successfully develop, obtain regulatory or marketing approval for and commercialize our product candidates.

Any positive results from our preclinical studies of our product candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials, and there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates.. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. For example, while we have observed biological activity in patient samples following administration of an initial dose in our ongoing MP0310 Phase I clinical trial, there can be no assurance that such biological activity will be similarly observed and maintained following administration of additional doses or any drop in biological activity could be overcome with additional development regarding more frequent dosing regimens, in each case with respect to our ongoing MP0310 Phase 1 trial or in future clinical trials with respect to our MP0310 program or in any of our other current or future product candidates, including MP0317, the second candidate in our oncology program. In addition, positive results in later stage clinical trials of one of our product candidates in an indication may not be predictive of the safety or efficacy of our other product candidates in other indications, even if they employ a similar mechanism of action.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. For example, our therapeutics in oncology, ophthalmology and virology can result in the creation of anti-drug antibodies that can neutralize the effects of the therapeutic, require that higher doses be used to obtain a therapeutic effect or cause adverse events. Whether anti-drug antibodies will be created and how they react can often not be predicted from nonclinical or even clinical studies, and their detection or appearance can be delayed. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

Some of our product candidates utilize a novel mechanism of action which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Some of our product candidates, such as AMG 506 (MP0310), which is licensed to Amgen, and MP0317, the lead product candidates from our oncology program, utilize novel mechanisms of action which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies’ lack of experience with them. The novelty of our mechanism of action may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, 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. The novel mechanisms of action also means that fewer people are trained in or experienced with product candidates of such type, which may make it more difficult to find, hire and retain personnel

for research, development and manufacturing positions. Any such events could adversely impact our business prospects, financial condition and results of operations.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our product development strategy.

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we may develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. The FDA generally expects contemporaneous regulatory approvals of the companion diagnostic and the therapeutic product. We do not develop companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining regulatory approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates.

In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate.

We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary and interim data should be viewed with caution until the final data are available. Adverse changes in the final data compared to the interim data could significantly harm our business prospects.

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

Because the number of patients in certain of our clinical trials is small, the results from such trials may be less reliable than results achieved in larger clinical trials.

A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power to allow a meaningful interpretation of the results. The preliminary results of studies with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects.

Our product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us 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, the EMA or other comparable foreign authorities. While our preclinical and clinical studies for our product candidates to date have generally been well tolerated from a risk-benefit perspective, the results from ongoing and future trials may not support this conclusion.

The results of future clinical studies may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA, the EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our prospects significantly. Further, because all of our product candidates and preclinical programs are based on our DARPin technology, any adverse safety or efficacy findings related to any product candidate or preclinical program may adversely impact the viability of our other product candidates or preclinical programs.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take our approved product off the market;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

If any of our product candidates has negative side effects, public perception of our DARPin platform and commercial opportunities for all of our current and future product candidates could be adversely affected.

Adverse side effects that may be caused by any of our product candidates could negatively impact the public perception of and commercial opportunities for all of our product candidates. The clinical and commercial success of our product candidates will depend in part on the absence of negative side effects caused by our product candidates. Even if an adverse side effect that results from one of our product candidates is unlikely to occur in our other product candidates, all of our product candidates could be adversely affected because the negative side effect may be perceived to be a likely side effect of all of our product candidates. In the clinical trials performed by AbbVie for abicipar in wet AMD, for example, ocular inflammation has been reported as an undesirable side effect. In June 2020, the FDA sent a CRL to AbbVie stating that ocular inflammation results in an unfavorable benefit-risk ratio in the treatment of nAMD. However unlikely it is that ocular inflammation will be a side effect of our other product candidates in indications outside of ophthalmology, the public may perceive our DARPin technology or our product candidates to pose a heightened risk of inflammation, thus negatively affecting the commercial opportunities of our current and future product candidates. Additionally, in our ongoing Phase 1 clinical trial of MP0310 in FAP positive cancer patients, we observed protocol defined infusion-related reactions, or IRRs, in 12 of 23 patients. These adverse events may negatively affect the perception of the DARPin technology platform, the commercial opportunity for our product candidates or cause us to suspend clinical trials.

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

The market for pharmaceutical products is highly competitive. Our competitors include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than us. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and

retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products. The fields in which we operate are characterized by rapid technological change and innovation. There can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and products that are equally or more effective or are more economically attractive as any of our current or future technology or product. Competing products or technology platforms may gain faster or greater market acceptance than our products or technology platform and medical advances or rapid technological development by competitors may result in our product candidates or technology platforms becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. Additionally, certain of our product candidates may be administered in combination with approved pharmaceutical products. Our ability to develop and ultimately commercialize our product candidates used in combination with other therapies will depend on our ability to access these drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a sufficient supply of these drugs on commercially reasonable terms or at all. If we, our product candidates or our technology platforms do not compete effectively, it may have an adverse effect on our business and results of operation.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business could be adversely affected.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. For example, the dynamic evolution of the COVID-19 pandemic makes it difficult to anticipate the availability of patients in countries where our partner has planned to open clinical sites for clinical trials with ensovibep and may delay such clinical trials. Since some of our product candidates could be focused on addressing sub-groups of cancer patients, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Furthermore, if the actual number of patients with these pathologies is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our drug candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of one of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Changes in government regulations in response to the ongoing COVID-19 pandemic may require us to change the ways in which our clinical trials are conducted, which could result in delays. For example, our Phase 1 trial of ensovibep, our COVID-19 antiviral product candidate licensed to Novartis, experienced a temporary delay from December 2020 through April 2021 due to an inability to dose

healthy volunteers in the UK resulting from government restrictions that were imposed at the end of 2020 in connection with the COVID-19 pandemic. Dosing for the Phase 1 trial of ensovibep recommenced, and was subsequently completed, in April 2021. Furthermore, change in government regulations considering the availability of standard drug of care against COVID may also require us to change the ways in which our clinical trials were planned to be conducted. For example, certain regulatory authorities no longer allow the performance of placebo-controlled studies in the COVID space which will require changes to the study design and study protocol of clinical trials with ensovibep and may delay such study.

Additionally, our ability to successfully initiate, enroll and complete clinical trials in foreign countries is subject to numerous risks unique to conducting business in foreign countries, including:

- different standards for the conduct of clinical trials;
- difficulty in identifying and partnering with qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology research and products.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us and our corporate collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our corporate collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception and injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales;
- our reputation may suffer; and

- the inability to commercialize any of our product candidates, if approved.

Although we maintain adequate clinical trial insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of the events described above occur, this could have an adverse effect on our business and results of operations.

We conduct clinical trials for our product candidates outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials.

We also conduct clinical trials outside the United States, including in Europe and are likely to continue to do so in these or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

The regulatory approval processes of the FDA, the EMA 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, the EMA and comparable foreign authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial 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 any product candidate or product candidates licensed to our partners and it is possible that none of such existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including the size of our clinical trials or the doses tested;

- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or may require us to test additional dose regimens of our product candidates;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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 any of our product candidates, which would significantly harm our business. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

We or our partners may seek fast-track designation for some or all of our product candidates, but we may not receive such designation, and even if we do, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.

We or our partners may seek fast-track designation and review for some or all of our product candidates. For example, in June 2021 ensovibep received FDA fast track designation for the treatment of COVID-19 in hospitalized and ambulatory settings, and in February 2022, Novartis requested emergency use authorization from the FDA for ensovibep to treat COVID-19. If a drug is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for FDA fast track designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. Thus, even if we or our collaborators believe a particular product candidate is eligible for this designation, such as we received for ensovibep in June 2021, the FDA may decide not to grant it. Moreover, even if we do receive fast track designation, we or our collaborators may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from the clinical development program.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA, the EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, recordkeeping, exporting and importing for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our 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 candidate.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA, the EMA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates;
- our reputation may suffer; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product’s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label based on the physician’s independent medical judgement. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the

promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Our product candidates are classified as biologics in the United States and, therefore, can only be sold if we obtain a BLA from the FDA. The holder of a BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of a BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Failure to comply with a BLA or any other ongoing regulatory obligation may result in suspension of approval to manufacture or distribute the relevant product, as well as fines or imprisonment for violations.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we or one of our distributors, licensees or co-marketers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or in other countries. For example, the policies and executive actions of the Biden administration may impact our business and industry. It is difficult to predict how these policies and executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these policies or executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidates, our business, financial condition and results of operations could be adversely affected.

Risks Related to Commercialization of Our Product Candidates

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care

and Education Reconciliation Act of 2010, or collectively the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expanding the types of entities eligible for the 340B drug discount program;
- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to now provide 70% point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. On June 17, 2021 the U.S. Supreme Court

dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by U.S. Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA and the Infrastructure Investment and Jobs Act, will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 unless additional U.S. Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration’s proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health & Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers

and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. In addition, Congress is considering additional health reform measures. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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 in other countries. 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, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We may be subject to healthcare laws, regulation and enforcement. Our failure to comply with these laws could harm our results of operations and financial conditions.

Although we do not currently have any products on the market, our current and future operations may be directly, or indirectly through our relationships with healthcare providers, healthcare institutions, patients, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and healthcare institutions who participate in our clinical research programs, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including, without limitation, the civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent or for knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by certain health plans, healthcare clearinghouses and healthcare providers, known as covered entities, as well as their business

associates that perform certain services involving the use, disclosure or transmission of individually identifiable health information for or on behalf of a covered entity, and their covered subcontractors;

- the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal physician payment transparency legislation, commonly referred to as Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the above laws, including reporting requirements detailing interactions with and payments to healthcare providers.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these 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, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations.

The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. For example, the definition of the “remuneration” under the U.S. federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if “one purpose” of remuneration is to induce referrals, the U.S. federal Anti-Kickback Statute is violated.

Additionally, recent healthcare reform legislation has strengthened federal and state healthcare fraud and abuse laws. For example, the ACA amends the intent requirement of the U.S. federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them in order to

have committed a violation. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequate reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, private health insurers and managed care organizations, is essential for most patients to be able to afford products such as our product candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidate, pricing of existing drugs may limit the amount we will be able to charge for our product candidate. Third-party payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If coverage and reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health

care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

Moreover, increasing efforts by governmental and third-party payors in the European Union, the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The future commercial success of our product candidates will depend on the degree of market acceptance of our potential products among physicians, patients, healthcare payors and the medical community.

Our product candidates are at varying stages of development and we may never have a product that is commercially successful. To date, we have no product authorized for marketing. Our lead product candidates are in the relatively early stages of clinical development. Our lead product candidates will require further clinical investigation, regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenues. Furthermore, when available on the market, our products may not achieve an adequate level of acceptance by physicians, patients and the medical community, and we may not become profitable. If our products are not accepted, we may need to increase our efforts to educate the medical community and third-party payors on the benefits of our products, which may require significant resources and may never be successful. Market acceptance of our future products by physicians, patients and healthcare payors will depend on a number of factors, many of which are beyond our control, including:

- the wording of the product label;
- changes in the standard of care as well as recommendations from relevant national and/or international associations for the targeted indications for any product candidate;
- sales, marketing and distribution support;
- potential product liability claims;
- acceptance by physicians, patients and healthcare payors of each product as safe and effective;
- relative convenience, ease of use, ease of administration and other perceived advantages over alternative products;
- availability of coverage and adequate reimbursement from third-party payors and the willingness of patients to pay out-of-pocket in the absence of adequate reimbursement;
- prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with our products in relation to alternative treatments;
- the extent to which products are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether our products are designated in the label, under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line therapy.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched. Furthermore, even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues. In addition, we are entitled to royalties on future commercial sales of ensovibep made by or on behalf of Novartis in certain territories but have agreed to forgo royalties in other territories, including lower income countries; if our product candidates are commercialized more largely

in territories for which we have agreed to forgo royalties, this could have a material adverse impact on our revenues and financial results.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable collaboration partners.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of pharmaceutical products. To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into collaboration or license arrangements with third parties.

To the extent possible, we may establish our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the major European Union countries and the United States for certain of our product candidates. There are risks involved should we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch or market our products effectively since we have no experience in the sales and marketing of pharmaceutical products. In addition, recruiting and training a sales force is expensive and time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or profitability could be lower than if we were to market and sell any products that we develop ourselves. Such collaborative arrangements may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements, may be adversely affected by business combinations or significant changes in our collaborator's business strategy. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our products, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations.

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

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. 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 our product candidates approved 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 U.S. Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates or any future product candidates may be delayed, and our business will be harmed.

For planning purposes, we estimate the timing of achieving various scientific, clinical, regulatory, and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, regulatory submissions or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of clinical trials, receipt of regulatory approval, or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achieving the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs, and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, EMA and comparable foreign regulatory authorities, and the timing thereof;
- other actions, decisions, or rules issued by regulators;
- our ability to access sufficient, reliable, and affordable supplies of materials used in the manufacture of our product candidates;

- our ability to manufacture and supply clinical trial materials to our clinical sites on a timely basis;
- the efforts of our collaborators with respect to the commercialization of our approved products, if any; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing, as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our current or any future product candidates may be delayed, and our business, results of operations, financial condition, and prospects may be adversely affected.

Risks Related to Our Business and Industry

Nearly all aspects of our activities are subject to substantial regulation. No assurance can be given that any of our product candidates will fulfill regulatory compliance. Failure to comply with such regulations could result in delays, suspension, refusals and withdrawal of approvals, as well as fines.

The international biopharmaceutical and medical technology industry is highly regulated by the FDA, the EMA and other comparable foreign authorities and by other national or supra-national regulatory authorities that impose substantial requirements covering nearly all aspects of our activities notably on research and development, manufacturing, preclinical tests, clinical trials, labeling, marketing, sales, storage, record keeping, promotion and pricing of our product candidates. Such regulation is further subject to regular review by the FDA, the EMA and other comparable foreign authorities which may result in changes in applicable regulation. If we do not comply with one or more of these requirements in a timely manner, or at all, our product development could experience significant delays as a result of the FDA, the EMA or other comparable regulatory authorities recommending non-approval or restrictions on approval of a product candidate, leading to an inability to successfully commercialize any of our product candidates, which would materially harm our business. Any failure of any of our product candidates in clinical studies or to receive regulatory approval could have a material adverse effect on our business, results of operations and financial condition. If any of our product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process, this will prevent such product candidate from obtaining approval in a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

Compliance with requirements laid down by local regulatory authorities is necessary in each country where we, or any of our partners or licensees, conduct said activities in whole or in part. Local regulatory authorities notably include the EMA and the FDA. In order to market our future products in regions such as the European Economic Area, United States of America, Asia Pacific and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedures vary among countries and can require additional clinical testing, and the time required to obtain approval may differ from that required to obtain for example FDA or EMA approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA or EMA does not ensure approval by the comparable foreign authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA or EMA.

There can be no assurance that our product candidates will fulfil the criteria required to obtain necessary regulatory approval to access the market. Also, at this time, we cannot guarantee or know the exact nature, precise timing and detailed costs of the efforts that will be necessary to complete the remainder of the development of our research programs and products candidates. Each of the FDA, the EMA and other comparable foreign authorities may impose its own requirements, may discontinue an approval or revoke

a license, may refuse to grant approval, or may require additional data before granting approval, notwithstanding that approval may have been granted by the FDA, the EMA or one or more other comparable foreign authority. The FDA, the EMA or other comparable foreign authorities may also approve a product candidate for fewer or more limited indications or patient sub-segments than requested or may grant approval subject to the performance of post-marketing studies. The EMA's, the FDA's or other regulatory authority's approval may be delayed, limited or denied for a number of reasons, most of which are beyond our control. Such reasons could include, among others, the production process or site not meeting the applicable requirements for the manufacture of regulated products, or the products not meeting applicable requirements for safety, purity or potency, or efficacy, during the clinical development stage or after marketing. No assurance can be given that clinical trials will be approved the FDA, the EMA or other comparable foreign authorities or that products will be approved for marketing by such regulatory authorities in any pre-determined indication or intended use. Any of the FDA, the EMA and other comparable foreign authorities may disagree with our interpretation of data submitted for their review.

We and our collaborative partners are, or may become subject to, numerous ongoing other regulatory obligations, such as data protection, environmental, health and safety laws and restrictions on the experimental use of animals. The costs of compliance with such applicable regulations, requirements or guidelines could be substantial, and failure to comply could result in sanctions, including fines, injunctions, civil penalties, denial of applications for marketing authorization of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase our or our collaborative partners' costs or delay the development and commercialization of our product candidates.

Changes in funding for the FDA, the SEC, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC, and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Our professional liability insurance and our accident insurance, which cover for costs and expenses we may incur due to environmental liability that may be asserted against us or due to injuries to our employees resulting from the use of hazardous materials, may not provide adequate coverage against potential liabilities.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be adversely affected.

Further with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our product candidates or products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct or unauthorized activities that violate: the regulations of the FDA, the EMA and other comparable foreign

authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

Our high dependency on public perception of our products may negatively influence the success of these products.

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

Future adverse events in research into the oncology and virology fields that we focus our research efforts on, or the biopharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

Failure to successfully identify, develop and commercialize additional products or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, a key element of our long-term growth strategy is to develop and market additional products and product candidates. Because we have limited managerial resources, research programs to identify product candidates will require substantial additional technical, financial and human resources, whether or not any product candidates are ultimately identified. The success of this strategy depends partly upon our ability to identify, select and develop promising product candidates and products. Our technology platforms may fail to discover and to

generate additional product candidates that are suitable for further development. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics that indicate that it is unlikely to be a product that will receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our DARPin technology approach, we may not be able to obtain product or collaboration revenues in future periods, which would adversely affect our business and results of operations.

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

Because we have limited financial and managerial resources, we focus on research programs and DARPin product candidates for specific indications, mode of actions or targets. As a result, we may forego or delay pursuit of opportunities with other DARPin product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and DARPin product candidates for specific indications may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential or target market for a particular DARPin product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

Service or supply failures, or other failures, business interruptions or other disasters affecting the manufacturing facilities of any party participating in the supply chain would adversely affect our ability to supply our products.

Our product candidates are biologics and require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims and insufficient inventory.

Also, certain raw materials or other products necessary for the manufacture and formulation of our product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. The COVID-19 pandemic has caused delays and difficulties in the timely shipping and delivery of supplies, samples and products required for our clinical trials. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing and other services related to the manufacture of our product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to supply product candidates, which could materially and adversely affect our business and future prospects.

We may develop our DARPin platform and other current or future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop our DARPin platform and other current or future product candidates in combination with one or more currently approved therapies. Even if any product candidates we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our DARPin platform or any other current or future product candidates or that safety, efficacy, manufacturing, or supply issues could arise with these existing therapies. This could result in our own product candidates being removed from the market or being less successful commercially.

We may also evaluate our DARPin platform or any other current or future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. For example, we entered into a collaboration agreement with Amgen in December 2018 to evaluate AMG 506 (MP0310) in combination with Amgen`s oncology pipeline products, including its investigational bispecific TCE, or BiTE®, molecules. We will not be able to market and sell our DARPin product candidates or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. These unapproved therapies may face the same risks described with respect to our product candidates, including the emergence of adverse events and delays in their clinical trials. If the FDA or comparable foreign regulatory authorities do not approve these other therapies or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the therapies we choose to evaluate in combination with our DARPin product candidates or any other product candidate we develop, we may be unable to obtain approval of or market our DARPin product candidates or any other product candidate we develop.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (commonly known as processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. In the United States, numerous federal and state laws, rules and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws that govern the collection, processing of personal information, including health-related personal information, could apply to our operations or the operations of our collaborators. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we may be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

Additionally, the California Consumer Privacy Act, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) and includes a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. It will also create a new California Privacy Protection Agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Other states have enacted data privacy laws as well. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. Data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data. Additionally, EU member states are also able to legislate separately on health and genetic data, and we must comply with these local laws where we operate. The Swiss Federal Act on Data Protection, or DPA, also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The DPA has been revised, and the revised version and its revised ordinances are expected to enter into force in mid/end of 2022 or beginning of 2023.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. The European Commission released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data

transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity, additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data, imprisonment of company officials. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to interruptions or stoppages in our business operations (including, as relevant, clinical trials), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or revision or restructuring of our operations.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs mandated by us or by our partners, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the EMA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to

perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

We also face the risk of potential infringement, unauthorized disclosure, misappropriation or other violation of our intellectual property by our third party contractors or CROs, which may reduce our trade secret protection and allow our potential competitors or other third parties to access and exploit our proprietary technology. Our third party contractors or CROs also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. For more information regarding our intellectual property, see “Risk Factors—Risks Related to Intellectual Property”.

There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms. Switching or adding additional CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely and will continue to rely on collaborative partners regarding the development of our research programs and product candidates. If we are not able to maintain our current relationships or enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be adversely affected.

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of our existing and future research programs and product candidates.

We currently have a collaborative research relationship with the pharmaceutical companies Novartis Pharma AG, or Novartis, Amgen Inc., or Amgen, and Allergan, an AbbVie, Inc. company, or AbbVie, for the development of product candidates resulting from such collaborations. We had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to

develop our existing or future research programs and product candidates could be delayed, the commercial potential of our products could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights and other proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these intellectual property and other proprietary rights.

Our dependence on collaborative partners subjects us to a number of risks, including, but not limited to, the following:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to our research programs and product candidates;
- for collaboration agreements where we are solely or partially responsible for funding development expenses through a defined milestone event, the payments we receive from the collaboration partner may not be sufficient to cover the expenses we have or would need to incur in order to achieve that milestone event;
- we may be required to relinquish significant rights, including intellectual property or other proprietary rights, marketing and distribution rights;
- our anticipated payments under any partnership agreement (e.g., royalty payments for licensed products) may not materialize;
- we rely on the information and data received from third parties regarding their research programs and product candidates and will not have control of the process conducted by the third party in gathering and composing such data and information.
- if rights to develop and commercialize our product candidates subject to collaborations revert to us for any reason, we may not have sufficient financial resources to develop such product candidates, which may result in us failing to recognize any value from our investments in developing such product candidates;
- a collaborative partner may decide not to pursue, or discontinue the collaborative development of, our product candidates;
- a collaborative partner may develop a competing product either by itself or in collaboration with others, including one or more of our competitors;
- our collaborative partners' willingness or ability to complete their obligations under our partnership arrangements may be adversely affected by business combinations or significant changes in a collaborative partner's business strategy;
- we may experience delays in, or increases in the costs of, the development of our research programs and product candidates due to the termination or expiration of collaborative research and development arrangements;
- we may have disagreements with collaborative partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, that might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborative partners may not properly maintain, enforce or defend our intellectual property rights or other proprietary information or may such use proprietary information in such a way as to invite

litigation or other intellectual property-related proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; or

- collaborative partners may infringe, misappropriate or otherwise violate the intellectual property or other proprietary rights of third parties, which may expose us to litigation and potential liability, and collaborators may also allege that we are liable for potential infringement, misappropriation or other violations of third-party intellectual property or proprietary rights during the research and development work for the collaboration.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership regardless of the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to provide us with required target material for developing and selecting product candidates as well as to produce commercial supplies of any approved product candidate.

We do not currently have the infrastructure or capability internally to manufacture our product candidates for use in the conduct of our clinical studies or for commercial supply, if our products are approved. Instead, we rely on, and expect to continue to rely on contract manufacturing organizations, or CMOs. We currently rely mainly on a few CMOs for the manufacturing of our product candidate materials. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the production of our product candidates in accordance with relevant regulations (such as cGMP), which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

If we were to experience an unexpected delay in receiving required target material or loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or planned clinical studies or commercialization. We could be unable to find

alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. Moreover, our suppliers are subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay our clinical studies and the commercialization of our products, if approved, which would adversely affect our business and results of operation.

In complying with the manufacturing regulations of the FDA, the EMA and other comparable foreign authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against our CMOs and subsequently against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA, the EMA or other comparable foreign authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. For example, we have faced and may face in the future bioburden during drug substance production campaigns or particles in drug product preparations at our CMOs which led or may lead to regulatory actions, including from the FDA. While we and our partners endeavor to maintain appropriate backup supply with respect to our product candidates, and not all such bioburden or particles result in regulatory action or delays, we cannot assure that any such issues would not result in delays in our clinical trials or product development or other adverse impacts on our business. We face risks inherent in relying on our CMOs, as any disruption, such as a fire, natural hazards or vandalism at any such CMO could significantly interrupt our manufacturing capability. Our CMOs currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

The manufacturing of all of our product candidates requires using cells which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Working cell banks have not yet been manufactured. Half of each master cell bank is stored at a separate site so that in case of a catastrophic event at one site we believe sufficient vials of the master cell banks are left at the alternative storage site to continue manufacturing. We believe sufficient working cell banks could be produced from the vials of the master cell bank stored at a given site to assure product supply for the future. However, it is possible that we could lose multiple cell banks and have our manufacturing significantly impacted by the need to replace these cell banks, which could materially adversely affect our business, prospects, financial condition and results of operations.

We do not and will not have access to all information regarding the product candidates we license to our collaboration partners. Consequently, our ability to inform our shareholders about the status of such product candidates, and to make informed operational and investment decisions about the product candidates to which we have retained development and commercialization rights, may be limited.

We do not and will not have access to all information regarding the product candidates being developed and potentially commercialized by Novartis or Amgen, including potentially material information about clinical trial design and execution, safety reports from clinical trials, spontaneous safety reports if the

product is later approved and marketed, regulatory affairs, process development, manufacturing, marketing and other areas known by Novartis or Amgen. In addition, we have confidentiality obligations under our agreement with Novartis or Amgen. Thus, our ability to keep our shareholders informed about the status of product candidates under our collaboration will be limited by the degree to which Novartis or Amgen keeps us informed and allows us to disclose such information to the public. If Novartis or Amgen fails to keep us informed about the clinical development and regulatory approval of our collaboration and product candidates licensed to it, we may make operational and investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

Our financial prospects are dependent upon the manufacture, development and marketing efforts of our licensees. Our licensees may act in their best interest rather than in our best interest, which could materially adversely affect our business, financial condition and results of operations.

We rely on our licensees to manufacture, fund and conduct the clinical development and commercialization of product candidates, and our licensees have complete control over such activities. Our ability to generate revenue in the near term will depend primarily on the successful development, regulatory approval, marketing and commercialization of product candidates by our licensees. Such success is subject to significant uncertainty, and we have limited control over the manufacturing processes of such product candidates as well as the resources, time and effort that licensees may devote to such product candidates. Any of several events or factors could have a material adverse effect on our ability to generate revenue from our licensee’s potential commercialization of product candidates.

In addition, our licensees have the right to make decisions regarding the development and commercialization of product candidates under the collaborations without consulting us and may make decisions with which we do not agree. For example, On August 5, 2021 AbbVie terminated the license and collaboration agreement for abicipar. Conflicts between our licensees and us may arise if there is a dispute about the progress of the clinical development of a product candidate, the achievement and payment of a milestone amount or the ownership of intellectual property developed during the course of our collaboration agreements. If any of our licenses terminate with our licensees, it may be necessary for us to assume responsibility at our own expense for the development of the applicable product candidates. In that event, we would likely be required to limit the size and scope of one or more of our programs or increase our expenditures and seek additional funding, which may not be available on acceptable terms or at all, which would materially adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our product candidates and the DARPin technology, the prosecution, grant, enforcement, defense and maintenance of which may be challenging and costly. Failure to obtain, maintain, enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our product candidates, methods used to manufacture those products and methods for treating patients using those products, or on licensing in such rights. Failure to obtain, maintain, enforce, protect or extend adequate patent and other intellectual property rights could adversely affect our ability to develop and market our products and product candidates or pursue collaborations with partners for our product candidates.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that issued or granted patents will not later be found to be invalid or unenforceable. The patent position of biopharmaceutical companies is generally uncertain because it involves complex legal

and factual considerations, and has been the subject of much litigation in recent years. The standards applied by the United States Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, and other foreign patent offices in granting patents are not always identical or applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from our pending patent applications or, if issued, patents may vary in scope depending on the jurisdiction. As such, we do not know the degree of future protection that we will have on our proprietary products and technology in the various jurisdictions. The scope of patent protection that the USPTO, the EPO and other foreign patent offices will grant with respect to the DARPin product candidates in our product pipeline is uncertain. It is possible that the USPTO, the EPO and other foreign patent offices will not allow broad claims that cover DARPin product candidates closely related to our product candidates or to the specific protein building blocks. As a result, upon receipt of EMA or FDA approval, competitors may be free to market other products almost identical to ours, thereby decreasing our market share.

The patent prosecution process is expensive, time-consuming and complex, and we and our current or future licensors, licensees or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors’, licensees' or collaboration partners’ patent rights are highly uncertain. Our and our licensors’ pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Moreover, in some circumstances, we may not have the right to control the preparation, filing, prosecution and maintenance of the licensed patent applications or other intellectual property, or to maintain the patents, or may not have the first right to enforce the intellectual property. We may need to enter into new license or royalty agreements, covering technology that we license from or license to third parties or have developed in collaboration with our collaboration partners and are reliant on patent procurement activities of our licensors, licensees or collaboration partners. Therefore, we may not be able to adequately influence the patent prosecution or enforcement of these patents and patent applications, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees and we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business and that does not compromise the patent rights. If our current or future licensors, licensees or collaboration partners fail to obtain, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or lost. If our licensors, licensees or collaboration partners are not fully cooperative or disagree with us as to the preparation, filing, prosecution, maintenance, defense or enforcement of any licensed patent rights, such patent rights could be compromised. The patent examination process may require us or our licensors, licensees or collaboration partners to narrow the scope of the claims of our or our licensors’, licensees’ or collaboration partners’ pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may invalidate patents in whole or in part or prevent patents from issuing from pending patent applications. Even if patents do successfully issue and even if such patents cover our product candidates,

third parties may initiate an opposition, interference, re-examination, post-grant review, inter partes review, nullification, revocation, derivation, or other actions in court or before patent offices challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable. Such proceedings have a higher impact in the biopharmaceutical industry than in other industries, given that biopharmaceutical products are often protected by only one or few patents. Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the practiced technology. An adverse determination in any such proceeding could reduce the scope of, invalidate, or render unenforceable our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Even if our patent applications or those of our licensors, licensees or collaboration partners issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our DARPin platform advances or product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications are confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that we or our licensors, licensees or collaborators were the first to make the inventions claimed in any patent application, or were the first to file any patent application related to a product candidate. Furthermore, as to the United States, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date, or if the other party is able to obtain a compulsory license.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, including generic versions of such products. Moreover, it is possible that some future patents and patent applications owned or in-licensed by us may be co-owned with third parties, including our collaboration partners and other third parties with whom we conduct research and development. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Furthermore, it is possible that some future patents and patent applications owned or in-licensed by us may be subject to a reservation of rights by one or more third parties. For example, this may happen if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. 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 for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. 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, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may fail in enforcing our intellectual property rights and issued patents covering one or more of our product candidates or DARPin technology or our intellectual property rights and issued patents could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we or our licensors or collaboration partners may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors’ or collaboration partners’ adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners’ efforts, we or our licensors or collaboration partners may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the European Union and the United States. We may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our DARPin technology, and then compete directly with us, without payment to us.

If we or one of our licensors or collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, including our DARPin technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Third parties could also raise challenges to the validity of patent claims before administrative bodies in the United States, Europe or other foreign jurisdictions, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patent claims in such a way that they no longer cover our technology or DARPin platform, or any product candidates that we may develop. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. A claim for unenforceability could involve an allegation that someone connected with

prosecution of the patent withheld relevant information from or made a misleading statement to the USPTO, the EPO or other patent offices during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our issued patents, for example, we cannot be certain that there is no invalidating prior art, of which we, our licensors or collaboration partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose part or all of the patent protection afforded by the affected patent. Such a loss of patent protection could have a material adverse impact on our business. Further, litigation could result in substantial costs and diversion of management resources, and reputational harm, regardless of the outcome, which could harm our business and financial results.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities and negative outcomes could result in adverse effects on our business.

Our success depends, in part, on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the “freedom to operate.” The biotechnology and pharmaceutical industries in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, companies producing therapeutics in the virology, oncology and immuno-oncology fields have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result, we may be required to defend against claims of intellectual property infringement, misappropriation or other violation that may be asserted by third parties against us and, if the outcome of any such litigation is adverse to us, it may affect our ability to compete effectively.

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or elements thereof, our manufacture or uses relevant to our products or development plans, the targets of our product candidates, or other attributes of our product candidates or our technology. In such cases, we may not be in a position to develop or commercialize the applicable products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, or at all. In the event that a relevant patent has not expired at the time of approval of such product candidate and the patent owner were to bring an infringement action against us, we may have to argue that our product, its manufacture, importation or use does not infringe, misappropriate or otherwise violate a valid claim of the patent in question. Alternatively, if we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would need to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity. In the event that a patent is successfully asserted against us such that the patent is found to be valid and enforceable and infringed by our product, unless we obtain a license to such a patent, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our product. Similarly, the targets for certain of our product candidates have also been the subject of research by other companies, which have filed patent applications or own issued patents on aspects related to the targets or their uses. There can be no assurance that any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

It is also possible that we failed to identify relevant patents or applications. For example, certain U.S. applications filed after November 29, 2000 that will not be filed outside the United States may remain confidential until patents issue. In general, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing from which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge, in particular with respect to our COVID-19 antiviral product candidates. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to gain broad coverage in the areas in which we are active. Additionally, claims in pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

Third-party intellectual property right holders, including our competitors, may actively bring infringement, misappropriation or other claims against us. We may not be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products.

If we fail in any such dispute, in addition to being forced to pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing, misappropriating or violating any third-party intellectual property rights. We might also be forced to redesign product candidates so that we no longer infringe, misappropriate or otherwise violate third-party intellectual property rights, which may result in significant cost or delay to us or be technically infeasible, or to seek a license to any such third-party intellectual property rights that we are found to infringe, misappropriate or otherwise violate, which license may not be available on commercially reasonable terms, or at all. Even if we or our licensors or collaboration partners obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners, and it could require us or our licensors or collaboration partners to make substantial royalty and other payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. Any of these events, even if we were to ultimately prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our involvement in litigation, and in any interference, derivation, reexamination, inter partes review, post grant review, opposition or other post-grant proceedings or other intellectual property proceedings inside and outside of the European Union or the United States, even if resolved in our favor, may cause us to incur significant expenses, distract our technical and management personnel from their normal responsibilities and cause substantial delays in marketing our products. In addition, there could be public announcements of the results of hearings, motions, other interim proceedings or developments, or of final verdicts and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on our share price. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

In addition, if the breadth or strength of protection provided by our or our licensors' or collaboration partners' patents and patent applications is challenged or threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. 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. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, and we may not be successful in obtaining or maintaining additional necessary rights related to our product candidates through acquisitions and in-licenses.

We rely upon licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our product candidates. We may also need to obtain additional licenses to advance the development and commercialization of any product candidates we may develop. Additionally, we have in the past collaborated and may in the future collaborate with U.S. and/or European academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In some instances, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable product candidate or program. Our current license and collaborations agreements also impose, and we expect that future agreements will likely impose various reporting, prosecution, diligence, fee payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing or collaboration partners regarding our rights or obligations under the agreements, including any such conflict, dispute or disagreement arising from our alleged failure to satisfy payment obligations under any such agreement, we may owe damages, the counterparty may have a right to terminate the affected agreement, and our and our licensees' ability to utilize the affected intellectual property in drug discovery and development efforts, and our ability to enter into collaboration or marketing agreements for an affected product candidate, may be adversely affected. Our business could also suffer if a licensor or collaborator fails to abide by the terms of the agreement, if any licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms or at all. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. For more information regarding our license and collaboration agreements, see "Business—License and Collaboration Agreements."

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our current or future licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our current or future licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-

licensed. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. We may be unable to acquire or in-license, on reasonable terms or at all, any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

If in the future we do undertake any acquisitions, the process of integrating an acquired business, technology, service, products or product candidates into our business may result in unforeseen operating difficulties and expenditures, including diversions of resources and management’s attention from our core business, or any acquired intellectual property may be subject to claims of invalidity or unenforceability or held to be invalid. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing shareholders. Future acquisitions could also result in the incurrence of debt, actual or contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks or names. We may not be able to protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have rights senior to ours, it could interfere with our use of our current trademarks throughout the world.

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

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest effective U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has

expired, we may be open to competition from competitive medications, including biosimilar medications or generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, at least not long enough to recoup the costs incurred in developing our products.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act and similar legislation in the European Union and several other relevant countries around the world. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may be able to enter the market with competing products sooner than we expect, and our business, financial condition, results of operations, and prospects could be materially harmed.

The base patents relating to the DARPin base technology we use to generate our DARPin product candidates expired in September 2021 (except for one patent in the United States), after which our competitors may use the technology claimed in such patents, which may materially adversely affect our business and competitive position.

The base patents that we had licensed from the University of Zurich in 2004 expired in September 2021 (except for one patent in the United States) and we terminated the license agreement effective October 2021. Our competitors may be able to utilize the technology claimed in such patents to develop product candidates that compete with ours. In addition, we have been exploring entering into a non-exclusive license with the University of Zurich for the remaining U.S. patent that will expire in 2023 but there can be no assurance that we will enter into such license. If we do not enter into such non-exclusive license, a third party may obtain an exclusive license to the patent that will expire in 2023. Any of these events could harm our reputation as being the leader in the DARPin technology, and could have an adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of our intellectual property rights.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States and the European Union. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and the European Union, or from selling or importing products made using our inventions in and into all countries outside the United States and the European Union.

We often file our first patent application, or our priority filing, at the EPO or the USPTO. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our or our licensors’ or collaboration partners’ technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the United States and the European Union. These products may compete with our product candidates, and our and our licensors' or collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the European Union, and companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Proceedings to defend or enforce our and our licensors' or collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaboration partners' efforts and attention from other aspects of our business, could put our and our licensors' or collaboration partners' patents at risk of being invalidated or interpreted narrowly, could put our and our licensors' or collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaboration partners. We or our licensors or collaboration partners may not prevail in any lawsuits that we or our licensors or collaboration partners initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

If we fail to comply with our obligations under the agreements pursuant to which we license intellectual property rights from third parties, or otherwise experience disruptions to our business

relationships with our licensors, we could lose the rights to intellectual property that are important to our business.

We are a party to agreements under which we are granted rights to intellectual property that are important to our business and we expect that we may need to enter into additional license agreements in the future. Under certain license agreements, we may not control the preparation, filing, prosecution or maintenance of the licensed intellectual property, or may not have the first right to enforce or defend the intellectual property. In those cases, we may not be able to adequately influence patent prosecution, enforcement or defense, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees and we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business and that does not compromise the patent rights. Existing license agreements impose, and we expect that future license agreements will impose, various development obligations as well as other obligations, such as payment of royalties. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing product candidates covered by the licensed intellectual property. For more information regarding our license and collaboration agreements, see “Business—License and Collaboration Agreements.”

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any current or future collaboration relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations; and
- 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.

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

It is possible that we may be unable to obtain any necessary additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our

current technology, including our DARPin product candidates, manufacturing methods or future methods or products resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant.

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

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

- others may be able to make compounds that are similar or substantially equivalent to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- the patents of third parties, including patents related to repeat protein technology, may have an adverse effect on our business.
- we or our current or future licensors or strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have licensed.
- we or our current or future licensors or strategic partners might not have been the first to file patent applications covering certain of our or their inventions.
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our current or future patent applications will not lead to issued patents.
- issued patents that we own or license may not provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors.
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of third parties without obtaining a proper license, rendering us susceptible to claims of infringement, misappropriation or other violation of such third parties' intellectual property rights;
- we may not develop additional technologies that are patentable; and
- the patents of others may have an adverse effect on our business; in particular, our product candidates may in the future be tested for new indications, and if one proves to be effective against a specific new indication, we may be confronted with existing patents covering such indication.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Our success is heavily dependent on the extent of our intellectual property rights, particularly patents. Obtaining, defending and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the European Union, United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy-Smith America Invents Act, or the AIA, was enacted in the United States in September 2011, resulting in significant changes to the U.S. patent system.

For example, assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. As of March 16, 2013, under the AIA, the United States transitioned to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Therefore, a third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention even if we had made the invention before it was made by the third party. This will require us to be cognizant of the time from invention to filing of a patent application, and circumstances could prevent or dissuade us from promptly filing patent applications on our inventions.

The AIA also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include changes that limit where a patentee may file a patent infringement suit and that allow third party submissions of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and other applicable bodies in the European Union and other foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to defend and enforce our existing patents and patents that we might obtain in the future.

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

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business and competitive position. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to protect.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors, CROs and advisors to enter into confidentiality agreements with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes and, despite these efforts, any of these parties may unintentionally or willfully breach the agreements and use or disclose our confidential information to competitors, and such agreements may not provide an adequate remedy in the event of unauthorized disclosure or use of confidential information. Enforcing a claim that a third party illegally disclosed or misappropriated trade secrets or confidential know-how is expensive, time-consuming and unpredictable. In addition, the enforceability of confidentiality agreements and trade secrets may vary from jurisdiction to jurisdiction. Furthermore, if a third party lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such third party from using that technology or information to compete with us or from disclosing it to others, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

Failure to effectively maintain and protect trade secrets or confidential know-how could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors may be able to limit our use of our trade secrets or confidential know-how.

We may be subject to claims by third parties asserting that we or our employees have infringed, misappropriated or otherwise violated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our consultants and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these consultants and employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our consultants and employees 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 these consultants and employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such consultant's or employee's current or former employer, or have breached their non-competition agreement. Litigation may be necessary to defend against such claims.

In addition, we or our licensors may be subject to claims that former employees, consultants, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our consultants and employees who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against

third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

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

Periodic maintenance and annuity fees on any of our owned or licensed patents and patent applications are due to be paid to the USPTO, the EPO and other foreign patent agencies in several stages over the lifetime of the patents and patent applications. The USPTO, the EPO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market earlier with similar products or technology, which would have an adverse effect on our business.

Risks Related to Our Organization and Operations

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. These key management individuals include the members of our board of directors and executive management, including Dr. Patrick Amstutz, our Chief Executive Officer, Dr. Michael Tobias Stumpp, our Chief Operating Officer, Andreas Emmenegger, our Chief Financial Officer, and Dr. Nicolas Leupin, our Chief Medical Officer.

The loss of key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive biotechnology and pharmaceutical industries, and particularly, in the oncology and immuno-oncology fields, depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other biotechnology and pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable. Furthermore, we will need to recruit new managers and qualified scientific personnel to develop our business if we expand into fields that will require additional skills. Additionally, there is a larger pool of qualified scientific and medical personnel in the United States than in Switzerland, and we may need to increase our presence in the United States in order to attract and retain the necessary human resources. Our inability to attract and retain these key persons could prevent us

from achieving our objectives and implementing our business strategy, which could have an adverse effect on our business and prospects.

We expect to expand our development, regulatory and sales and marketing capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, sales and marketing and support functions such as finance, human resources, legal, intellectual property, information technology and administration. To manage our anticipated future growth, 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. Due to our limited resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may not be able to integrate efficiently or achieve the expected benefits of any acquisitions of complementary businesses, product candidates or technologies.

Since our inception in 2004, we have grown organically without any acquisitions. Should we in the future contemplate to acquire any complementary business, product candidates or technologies, our ability to integrate and manage acquired businesses, product candidates or technologies effectively will depend upon a number of factors including the size of the acquired business, the complexity of any product candidate or technology and the resulting difficulty of integrating the acquired business's operations, if any. Our relationship with current employees or employees of any acquired business may become impaired. We may also be subject to unexpected claims and liabilities arising from such acquisitions. These claims and liabilities could be costly to defend, could be material to our financial position and might exceed either the limitations of any applicable indemnification provisions or the financial resources of the indemnifying parties.

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

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, increase of interest rates, or political instability in particular economies and markets;
- differing regulatory requirements for drug approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced ability to obtain, maintain, protect and enforce intellectual property rights and other proprietary rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in regulations and customs, tariffs and trade barriers;

- changes in currency exchange rates of the euro, U.S. dollar and Swiss franc and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of stock options granted under our employee stock plan;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- litigation resulting from claims against us by third parties, including claims of breach of noncompete and confidentiality provisions of our employees' former employment agreements with such third parties;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from cyber-attacks, geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Additionally, in connection with the ongoing conflict between Russia and Ukraine, the U.S. government and other governments have imposed enhanced export controls on certain products and sanctions on certain industry sectors and parties in Russia, and have indicated they will consider imposing additional sanctions and other similar measures in the near future. Although we do not have any operations in Russia or Ukraine, further escalation of geopolitical tensions could have a broader impact that expands into other markets where we do business, which could adversely affect our business, our supply chain or our collaborators.

Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly regarding U.S. dollars, euros, British pounds and Swiss francs. Our functional currency is the Swiss franc and the majority of our operating expenses are paid in Swiss francs, but we also may receive payments from our business partners, including Novartis and Amgen, in U.S. dollars or euros and we regularly acquire services, consumables and materials in U.S. dollars, euros and Swiss francs. Further, potential future revenue may be derived from abroad, particularly from the United States and the European Union. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the Swiss franc, the euro, the U.S. dollar and these other currencies, which may also have a significant impact on our reported

results of operations and cash flows from period to period. Besides our natural hedging, currently, we do not have any exchange rate hedging arrangements in place.

In addition, the possible abandonment of the euro by one or more members of the European Union could materially affect our business in the future. Despite measures taken by the European Union to provide funding to certain European Union member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more European Union member states, or in more extreme circumstances, the abandonment of the euro or the dissolution of the European Union. The effects on our business of a potential dissolution of the European Union, the exit of one or more European Union member states from the European Union or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

Recent developments relating to the United Kingdom's referendum vote in favor of withdrawal from the European Union could adversely affect us.

The United Kingdom held a referendum on June 23, 2016, in which a majority voted for the United Kingdom's withdrawal from the European Union, or Brexit. As a result of this vote, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules continued to apply. The Trade and Cooperation Agreement, or the Trade and Cooperation Agreement, which outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020 and formally entered into force on May 1, 2021. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, Great Britain is no longer covered by the centralized procedures for obtaining European Union-wide marketing authorizations and a separate marketing authorization will be required to market our product candidates in Great Britain.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, could make it more difficult to commercialize, or prevent us from commercializing our product candidates in the United Kingdom, or Great Britain, and restrict our ability to generate revenue and achieve and sustain profitability. While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom and the European Union, there are additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business.

Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

As a result of the Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the European Union. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, we cannot be certain of the full extent to which Brexit could adversely affect our business, results of operations and financial condition.

We are exposed to unanticipated changes in tax laws and regulations, adjustments to our tax provisions, exposure to additional tax liabilities, or forfeiture of our tax assets.

The determination of our provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and our determination of whether we will be able to obtain a future tax benefit from our deferred tax assets. We cannot guarantee that our interpretations will not be challenged by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof, including through tax rulings, by the relevant tax authorities, will not be subject to change. Any adverse outcome of such a challenge may lead to adjustments in the amounts recorded in our financial statements, and could have a material adverse effect on our operating results and financial condition.

We are subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations applicable to the compensation of personnel and third parties. Transactions between current group companies, as well as additional companies that may form part of our group in the future, are subject to transfer pricing regulations, which may be subject to change or our existing transfer pricing system could be challenged by the relevant tax authority, and any such changes or challenges could adversely affect us.

Our effective tax rate could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, or the interpretation thereof by the relevant tax authorities, including changes to the U.K. research and development tax credit regime or the "patent box" regime, possible changes to the corporate income tax base, changes to the additional deduction for expenditure on research and development personnel in Switzerland and other tax incentives. An increase in our effective tax rate could have an adverse effect on our business, financial position, results of operations and cash flows.

In addition, we may not be able to use, or changes in tax regulations may affect the use of, certain tax loss carryforwards that we have generated in prior years. For instance, as of December 31, 2021, we had substantial tax loss carry forwards. In general, some of these tax loss carry forwards may be forfeited in whole, or in part, as a result of various transactions, or their utilization may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganization by us or any transaction relating to our shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. If not used, tax loss carryforwards for Swiss corporate income tax purposes expire seven years after the tax year in which they were incurred. Due to our limited income, there is a high risk that our tax loss carryforwards will expire in part or in their entirety and therefore will not be able to be used to offset future taxable income for Swiss corporate income tax purposes. Furthermore, any tax loss carry forwards that we report on our Swiss tax returns are subject to review and confirmation by the competent Swiss tax authorities in their tax assessment of the tax year for which the tax loss carryforwards are used to offset taxable income. Consequently, we are exposed to the risk that the competent Swiss tax authorities may not accept the reported tax loss carryforwards in part or in their entirety.

Changes in our effective tax rate or tax liability may have an adverse effect on our results of operations.

Our effective tax rate could increase due to several factors, including:

- changes in the relative amounts of income before taxes in the jurisdictions in which we operate that have differing statutory tax rates;
- changes in tax laws, tax treaties, and regulations or the interpretation of them;
- changes to our assessment about our ability to realize any deferred tax assets that are based on estimates of our future results, the prudence and feasibility of possible tax planning strategies, and the economic and political environments in which we do business;
- the outcome of any current or future tax audits, examinations, or administrative appeals; and
- any limitations or adverse findings regarding our ability to do business in some jurisdictions.

Any of these developments could adversely affect our business, results of operations and financial condition.

As a result of changes in, or in the interpretation of, tax laws, treaties, rulings, regulations or agreements of Switzerland or any other country in which we currently operate or may in the future operate, the loss of a major tax dispute or a challenge to our operating structure, intercompany pricing policies or the taxable presence of our existing or any future subsidiaries in certain countries, or other factors, our effective income tax rates may increase in the future, which could adversely affect our net income and cash flows.

We operate in multiple jurisdictions and our profits are taxed pursuant to the tax laws of these jurisdictions. The tax laws applicable to our business activities, however, are subject to changes in interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we currently do or may in the future elect to do business. Our effective income tax rate may be affected by changes in or interpretations of tax laws, treaties, rulings, regulations or agreements in any such jurisdiction, the resolution of issues arising from any future tax audits with various tax authorities, utilization of net operating loss and tax credit carryforwards, changes in geographical allocation of income and expense, and changes in management’s assessment of matters such as the realizability of deferred tax assets. In the past, we have experienced fluctuations in our effective income tax rate. Our actual tax rate may vary from our expectation and that variance may be material. Our effective income tax rate in a given fiscal year reflects a variety of factors that may not be present in the succeeding fiscal year or years. There is no assurance that our effective income tax rate will not change in future periods.

Due to the Swiss corporate tax law reform that took effect on January 1, 2020, all Swiss cantons, including the Canton of Zurich, have abolished previously existing cantonal tax privileges. Therefore, since January 1, 2020, we are subject to standard cantonal taxation. The standard effective corporate tax rate in Schlieren, Canton of Zurich, can change from time to time. The standard combined (federal, cantonal, municipal) effective corporate income tax rate, except for dividend income for which we could claim a participation exemption, for 2021 in Schlieren, Canton of Zurich, will be approximately 19.41%.

We urge our shareholders to consult with their legal and tax advisors with respect to the potential tax consequences of investing in or holding our ADSs and common shares.

Risks Related to the ADSs

The price of our ADSs may be volatile and may fluctuate due to factors beyond our control.

The market price of our ADSs and our common shares may fluctuate significantly due to a variety of factors, many of which are beyond our control, including:

- positive or negative results of testing and clinical trials reported or conducted by us, strategic partners or competitors;
- delays in entering into strategic relationships with respect to development or commercialization of our product candidates or entering into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- impact of the COVID-19 pandemic on the economy or financial markets; or
- price and volume fluctuations attributable to inconsistent trading volume levels of our ADSs and/or common shares.

These and other market and industry factors may cause the market price and demand for our ADSs and common shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs or common shares and may otherwise negatively affect the liquidity of our ADSs and common 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.

We have and will continue to incur increased costs as a result of operating as a U.S.-listed public company, and our board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company in the United States, and particularly after we no longer qualify as an emerging growth company, we have and will continue to incur significant legal, accounting and other expenses that we did not incur as a public company listed only on the SIX Swiss Exchange. We are a corporation (*Aktiengesellschaft*), organized under the laws of Switzerland in accordance with articles 620 et seqq. CO and subject to the listing rules and the applicable regulations for companies listed on the SIX Swiss Exchange, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market, or Nasdaq, and other applicable securities rules and regulations that impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and certain additional corporate governance practices. Our board of directors and other personnel are required to

devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report on our internal control over financial reporting beginning with our December 31, 2022 Form 20-F. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, continue to engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Certain significant shareholders will continue to own a substantial number of our securities and as a result, may be able to exercise significant influence over the outcome of shareholder votes. These shareholders may have different interests from us or your interests.

We have a number of significant shareholders. For an overview of our current significant shareholders, please see "Principal Shareholders."

Currently, we are not aware that any of our existing shareholders have entered or will enter into a shareholders' agreement with respect to the exercise of their voting rights. Nevertheless, depending on the level of attendance at our general meetings of shareholders, or the General Meeting, these significant shareholders could have the ability to significantly influence the outcome of decisions taken at any such General Meeting. Any such voting by these shareholders may not be in accordance with our interests or those of our other shareholders. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our ADSs.

Future sales, or the possibility of future sales, of a substantial number of our securities could adversely affect the price of the shares and dilute shareholders.

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our ADSs and our common shares could decline significantly. As of December 31, 2021, we had 32,292,648 common shares outstanding (including common shares represented by ADSs). In addition, common shares subject to outstanding options under our equity incentive plans and the common shares reserved for future issuance under our equity incentive plan will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations.

We intend to register all common shares that we may issue under our equity compensation plans. Once we register these common shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and any applicable lock-up agreements.

Provisions of our articles of association or Swiss corporate law might deter acquisition bids for us that might be considered favorable and prevent or frustrate any attempt to replace or remove the then board of directors.

Provisions of our articles of association may make it more difficult for a third party to acquire control of us. For example, our board of directors is authorized to deny the preemptive rights of shareholders and allocate them to third parties as a defense of an actual, threatened or potential takeover bid, in relation to which our board of directors, upon consultation with an independent financial adviser retained by it, has not recommended to the shareholders acceptance on the basis that the board of directors has not found the takeover bid to be financially fair to the shareholders.

In addition, several provisions of Swiss corporate law and certain other provisions of Swiss law, such as obligations to disclose significant shareholdings and merger control regulations, that apply to us may make an unsolicited tender offer, merger, change in management or other change in control of our company more difficult. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of our securities. These provisions may also have the effect of depriving ADS holders of the opportunity to sell their ADSs at a premium. In addition, the board of directors of Swiss companies may in certain instances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the authorized capital) or through share buy-backs.

Fluctuations in exchange rates may increase the risk of holding ADSs and common shares.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the euro, U.S. dollar and Swiss franc. Our functional currency is the Swiss franc, and the majority of our operating expenses are paid in Swiss franc, but we also receive or may receive payments from business partners in U.S. dollars, and we regularly acquire services, consumables and materials in U.S. dollars and euros. Further, potential future revenue may be derived from abroad, particularly from the United States or the European Union. As a result, our business and the price of our ADSs and common shares may be affected by fluctuations in foreign exchange rates between the Swiss franc and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Besides natural hedging, currently, we do not have any exchange rate hedging arrangements in place.

Moreover, because our common shares currently trade on the SIX Swiss Exchange in Swiss francs, and our ADSs trade on the Nasdaq Global Select Market in U.S. dollars, fluctuations in the exchange rate between the U.S. dollar and the Swiss franc may result in temporary differences between the value of our ADSs and the value of our common shares, which may result in heavy trading by investors seeking to exploit such differences.

Our common shares and ADSs are traded on more than one market and this may result in price variations and adversely affect the liquidity and value of the ADSs; in addition, investors may not be able to easily move common shares for trading between such markets. Furthermore, because of this dual listing, securities and stock exchange laws, regulations and rules apply to us that may be irreconcilable or otherwise difficult to comply with contemporaneously.

Our common shares have traded on the SIX Swiss Exchange since 2014 and our ADSs have traded on the Nasdaq Global Select Market since June 2021. Trading in our ADSs or common shares on these markets takes place in different currencies (U.S. dollars on the Nasdaq Global Select Market and Swiss Francs on the SIX Swiss Exchange), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Switzerland). The trading prices of our common shares and our ADSs on these two markets may differ due to these and other factors. Any

decrease in the price of our common shares on the SIX Swiss Exchange could cause a decrease in the trading price of our ADSs on the Nasdaq Global Select Market. Investors could seek to sell or buy our common shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our share prices on one exchange and the common shares available for trading on the other exchange. In addition, holders of ADSs cannot immediately surrender their ADSs and withdraw the underlying common shares for trading on the other market without effecting necessary procedures with the depositary. This could result in time delays and additional cost for holders of ADSs.

Because different types of our equity securities are admitted to trading and listed on two different stock exchanges in two different jurisdictions, two sets of securities laws and regulations and stock exchange rules apply to us contemporaneously. It cannot be excluded that the laws, regulations and/or rules of one jurisdiction or trading venue may require us to effect disclosures or filings or grant shareholders and/or holders of our ADSs certain rights that would be unlawful under the laws, regulations and/or rules of the respective other jurisdiction or trading venue. For this or other reasons, it may prove difficult or impossible for us to at all times comply with the laws, regulations and/or rules of both jurisdictions and trading venues at the same time.

Holders of ADSs are not treated as holders of our common shares.

Holders of our ADSs are not treated as holders of our common shares, unless they withdraw the common shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the common shares underlying our ADSs. Holders of our ADSs therefore do not have any rights as holders of our common shares, other than the rights that they have pursuant to the deposit agreement.

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying common shares.

ADSs 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 the right of ADS holders to cancel their ADSs and withdraw the underlying common shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of common shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our common shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying common shares when they 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 common shares or other deposited securities.

We are entitled to amend the deposit agreement and to change the rights of ADS holders under the terms of such agreement, or to terminate the deposit agreement, without the prior consent of the ADS holders.

We are entitled to amend the deposit agreement and to change the rights of the ADS holders under the terms of such agreement, without the prior consent of the ADS holders. We and the depositary may agree to amend the deposit agreement in any way we decide is necessary or advantageous to us or to the depositary. Amendments may reflect, among other things, operational changes in the ADS program, legal

developments affecting ADSs or changes in the terms of our business relationship with the depositary. In the event that the terms of an amendment are materially disadvantageous to ADS holders, ADS holders will only receive 30 days' advance notice of the amendment, and no prior consent of the ADS holders is required under the deposit agreement. Furthermore, we may decide to direct the depositary to terminate the ADS facility at any time for any reason. For example, terminations may occur if we become the subject of a takeover or a going-private transaction. If the ADS facility will terminate, ADS holders will receive at least 30 days' prior notice, but no prior consent is required from them. Under the circumstances that we decide to make an amendment to the deposit agreement that is disadvantageous to ADS holders or terminate the deposit agreement, the ADS holders may choose to sell their ADSs or surrender their ADSs and become direct holders of the underlying common shares, but will have no right to any compensation whatsoever.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our common shares provides that, to the fullest extent permitted by law, holders and beneficial owners of ADSs irrevocably waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to the ADSs or the deposit agreement.

If this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

Moreover, as the jury trial waiver relates to claims arising out of or relating to the ADSs or the deposit agreement, we believe that, as a matter of construction of the clause, the waiver would likely to continue

to apply to ADS holders who withdraw the common shares from the ADS facility with respect to claims arising before the cancellation of the ADSs and the withdrawal of the common shares, and the waiver would most likely not apply to ADS holders who subsequently withdraw the common shares represented by ADSs from the ADS facility with respect to claims arising after the withdrawal. However, to our knowledge, there has been no case law on the applicability of the jury trial waiver to ADS holders who withdraw the common shares represented by the ADSs from the ADS facility.

You will not have the same voting rights as the holders of our common shares and may not receive voting materials in time to be able to exercise your right to vote.

Except as described in this Annual Report on Form 20-F and the deposit agreement, holders of the ADSs are not able to exercise voting rights attaching to the common shares represented by the ADSs. Under the terms of the deposit agreement, holders of the ADSs may instruct the depositary to vote the common shares underlying their ADSs. Otherwise, holders of ADSs are not able to exercise their right to vote unless they withdraw the common shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations to vote them in person or by proxy in accordance with applicable Swiss laws and regulations and our articles of association. Even so, ADS holders may not know about a meeting far enough in advance to withdraw those common shares. If we ask for the instructions of holders of the ADSs, the depositary, upon timely notice from us, will notify ADS holders of the upcoming vote and arrange to deliver our voting materials to them. Upon our request, the depositary will mail to holders a shareholder meeting notice that contains, among other things, a statement as to the manner in which voting instructions may be given. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the common shares underlying their ADSs. In addition, regardless of whether timely voting instructions are provided to the depositary, at our request, the depositary will represent all common shares underlying the ADSs for the purpose of establishing a quorum at a meeting of our shareholders. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that its shares are recorded in its name at midnight (Central European Time) at the end of the 28th day preceding the date of the meeting of shareholders. In addition, the depositary's liability to ADS holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, holders of ADSs may not be able to exercise their right to give voting instructions or to vote in person or by proxy and they may not have any recourse against the depositary or us if their common shares are not voted as they have requested or if their shares cannot be voted.

A beneficial owner of our common shares that is not registered in our shareholders register may not be able to exercise certain rights attached to the common shares.

The financial rights attached to our common shares transfer to a holder of those shares upon purchasing such shares in a stock market transaction. Any voting rights or rights related to voting rights only transfer once the acquirer has been registered in the shareholders' register as shareholder of such common shares. A beneficial owner that is not directly registered in the shareholders' register can enjoy the financial rights, voting rights and rights related to voting rights only through the entity that acts as nominee or depositary for those common shares and is recorded in the shareholders' register as the shareholder of record of those shares. This is also the case if you hold ADSs. It is possible that a nominee or a depositary will be unwilling to exercise certain rights attached to the common shares, such as rights that require litigation. Therefore, failing to register in the shareholders' register may result in your inability to exercise certain rights as a shareholder.

We do not expect to pay dividends in the foreseeable future.

We have not paid any dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. In addition, payment of any future dividends to shareholders would be subject to shareholder approval at our General Meeting, upon proposal of the board of directors, which proposal would be subject to the approval of the majority of the non-executive directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, certain limitations apply to the payment of future dividends pursuant to Swiss law and our articles of association. In addition, payment of future cash dividends may be made only if our shareholders' equity exceeds the sum of our paid-in and called-up share capital plus the reserves required to be maintained by Swiss law or by our articles of association. Accordingly, investors cannot rely on cash dividend income from ADSs and any returns on an investment in the ADSs will likely depend entirely upon any future appreciation in the price of the ADSs.

You may not receive distributions on our common shares represented by our ADS or any value for them if it is illegal or impractical to make them available to holders of ADSs.

The depositary for our ADSs will pay to you or distribute the cash dividends or other distributions it or the custodian receives on our common shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our common shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of our ADSs, common shares, rights or anything else to holders of our ADSs. This means that you may not receive the distributions we make on our common shares or any value from them if it is unlawful or impracticable to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

Holders of our common shares outside Switzerland and ADS holders may not be able to exercise pre-emptive rights.

Under Swiss law, shareholders may receive certain pre-emptive rights to subscribe on a pro rata basis for issuance of equity or other securities that are convertible into equity. Due to laws and regulations in their respective jurisdictions, however, non-Swiss shareholders may not be able to exercise such rights unless we take action to register or otherwise qualify the rights offering under the laws of that jurisdiction. There can be no assurance that we would take any such action and we reserve the right to determine whether we should take such action in any jurisdiction. If shareholders in such jurisdictions were unable to exercise their subscription rights, their ownership interest in the Company would be diluted.

ADS holders have no pre-emptive rights to subscribe to newly issued shares unless we grant such rights to the foreign depositary. The right to exercise such pre-emptive rights is set out in the agreement between the ADS holder and the depositary.

We are a Swiss corporation. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are a Swiss corporation. Our corporate affairs are governed by our articles of association and organizational rules and by the laws governing companies, including listed companies, incorporated in Switzerland. The rights of our shareholders and the responsibilities of members of our board of directors

may be different from the rights and obligations of shareholders and directors of companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board of directors is required by Swiss law to consider the interests of our company, and may also have regard to the interests of our shareholders, our employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a holder of ADSs. Swiss corporate law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court. Our shareholders generally are not permitted to file a suit to reverse a decision or an action taken by our board of directors but are instead only permitted to seek damages for breaches of fiduciary duty. As a matter of Swiss law, shareholder claims against a member of our board of directors for breach of fiduciary duty would have to be brought to the competent courts in Schlieren, Canton of Zurich, Switzerland, or where the relevant member of our board of directors is domiciled. In addition, under Swiss law, any claims by our shareholders against us must be brought exclusively to the competent courts in Schlieren, Canton of Zurich, Switzerland.

On June 19, 2020, the Swiss Parliament approved legislation that will modernize certain aspects of Swiss corporate law. The new legislation, which will alter the rights of shareholders under Swiss law, and as a consequence the rights of holders of our ADSs, is due to come into effect on January 1, 2023, subject to certain transitional periods. See "Item 10. - Memorandum and Articles of Association - Swiss Corporate Law Reform" . There can be no assurance that Swiss law will not once again change in the future, which could adversely affect the rights of our shareholders or holders of our ADSs. Furthermore, there can be no guarantee that Swiss law does or will protect our shareholders or the holders of our ADSs in a similar fashion as the laws of U.S. jurisdictions would, in particular as regards corporate law principles, if we were a U.S.-incorporated company.

Our common shares are issued under the laws of Switzerland, which may not provide investors with the same protections provided by incorporation in Delaware.

We are organized under the laws of Switzerland. A further summary of applicable Swiss law is contained in this Annual Report on Form 20-F. There can be no assurance that Swiss law will not change in the future or that it will provide investors with the same protections afforded to investors of a Delaware corporation, which could adversely affect the rights of investors.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Switzerland and our registered office and domicile is located in Schlieren, Switzerland. Substantially all of our assets are located outside the United States. A number of our directors and executive officers are not residents of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws. We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent solely predicated upon the federal and state securities laws of the United States. Original actions against persons in Switzerland based solely upon the U.S. federal or state securities laws are governed, among other things, by the principles set forth in the Swiss Federal Act on Private International Law.

The United States currently does not have a treaty with Switzerland providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in

Switzerland. In order to obtain a judgment which is enforceable in Switzerland, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in Switzerland. Such party may submit to the Swiss court the final judgment rendered by the U.S. court. If and to the extent that the Swiss court finds that the jurisdiction of the U.S. court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the court of Switzerland will, in principle, give binding effect to the judgment of the U.S. court, unless such judgment contravenes principles of public policy of Switzerland. Also, mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply. Swiss courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Swiss court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in Switzerland are solely governed by the provisions of the Swiss Federal Private International Law Act. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if:

- the non-Swiss court had jurisdiction pursuant to the Swiss Federal Act on Private International Law;
- the judgment of such non-Swiss court has become final and non-appealable;
- the judgment does not contravene Swiss public policy;
- the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and
- no proceeding involving the same position and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state and this decision is recognizable in Switzerland.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors or certain experts named herein who are residents of Switzerland or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

Our status as a Swiss corporation means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve to, or authorize our board of directors to, increase our share capital. While our shareholders may authorize share capital that can be issued by our board of directors without additional shareholder approval, Swiss law limits this authorization to 50% of the share capital registered in the commercial register at the time of the authorization. The authorization, furthermore, has a limited duration of up to two (for authorizations taking effect on or after January 1, 2023: five) years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. For an overview of the changes in Swiss corporate law due to come into effect on January 1, 2023, see "Item 10. - Memorandum and Articles of Association - Swiss Corporate Law Reform". Additionally, subject to specified exceptions, including exceptions explicitly described in our articles of association, Swiss law grants preemptive rights to existing shareholders to subscribe for new issuances of shares, which may be limited or withdrawn only under certain limited conditions. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different categories of shares as do the laws of some other jurisdictions. These Swiss law requirements relating to our capital management may

limit our flexibility, and situations may arise where greater flexibility would have provided benefits to our shareholders. For changes to Swiss corporate law potentially affecting the rights of the holders of our ADSs, see also "Item 10. - Memorandum and Articles of Association - Swiss Corporate Law Reform"

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. As a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of Nasdaq.

Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors regularly have scheduled meetings at which only independent directors are present.

Although Swiss law also requires that we adopt a compensation committee, we follow home country requirements with respect to such committee. As a result, our practice varies from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees. In addition, in accordance with Swiss law, we have opted not to implement a nominating committee. We have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the independent director oversight of director nominations requirements of Nasdaq Listing Rule 5605(e).

Furthermore, in accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to

provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. To this extent, our practice varies from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30 for a given fiscal year (the end of our second fiscal quarter for a given fiscal year), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1 of such year. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we lost foreign private issuer status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We would be required to change our accounting from reporting under IFRS to reporting under U.S. generally accepted accounting principles. We would also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results compared to three years for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to the last day of the

fiscal year ending after the fifth anniversary of our initial U.S. public offering, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year-end). We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of ADSs representing our shares or our shares.

Management will be required to assess the effectiveness of our internal controls annually beginning with our second annual report to be filed with the SEC. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we are or become classified as a passive foreign investment company, U.S. holders of ADSs may suffer adverse tax consequences as a result.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we will be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares or ADSs) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, U.S. holders of our ADSs may suffer adverse tax consequences, including having gains realized on the sale of our ADSs treated as ordinary income rather than capital gain, the loss of the preferential rate applicable to dividends received on ADSs by individuals who are U.S. holders, and having interest charges apply to certain distributions by us and gains from the sales of our ADSs.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets. Our status may also depend, in part, on how quickly we utilize the cash proceeds from this or any future offering of our common shares or ADSs in our business. Based upon the value of our assets and the nature and composition of our income and assets, we expect that we will not be classified as a PFIC for the taxable year ended December 31, 2021, although no assurances can be made in this regard. Because the determination of whether we are a PFIC for any taxable year is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in the taxable year ended December 31, 2022 or any future taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ended December 31, 2021, and also expresses no opinion with regard to our expectations regarding our PFIC status in the future.

The tax consequences that would apply if we are classified as a PFIC would be different from those described above if a U.S. holder of ADSs were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. holders of ADSs with the information necessary for a U.S. shareholder to make a QEF election. Accordingly, prospective investors should assume that a QEF election will not be available.

General Risks

We depend on our information technology systems, and any failure of these systems could harm our business. Security incidents, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we may process large amounts of confidential and sensitive data, including personal data (such as health-related data), intellectual property, and proprietary business information (collectively, sensitive information). We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may have access to sensitive information. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and have generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products.

We and the third parties upon which we rely may also be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), ransomware attacks, supply-chain attacks, software

bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our business operations.

In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices and security incidents, which could lead to the loss of sensitive information. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We experience such security incidents of varying degrees from time to time, and we incur costs in protecting against or remediating such security incidents. For example, around June 2019, one of our former employee's email account was likely compromised via a phishing attack. Upon learning of this incident, we engaged in a number of mitigation actions, including the disablement of the employee's email inbox to prevent further unauthorized access. We have found no evidence that personal data was exposed; accordingly, we were not required under U.S. laws and other applicable laws to notify authorities.

We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may

experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include governmental enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and/or oversight, restrictions on processing sensitive information (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

If securities or industry analysts cease coverage of us, or publish inaccurate or unfavorable research about our business, the price of the ADSs and our trading volume could decline.

The trading market for the ADSs and our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts cover us, the trading price for the ADSs and our common shares would likely be negatively affected. If one or more of the analysts who cover us downgrade the ADSs or our common shares or publish inaccurate or unfavorable research about our business, the price of the ADSs and our common shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for the ADSs and our common shares could decrease, which might cause the price of the ADSs and our common shares and trading volume to decline.

We may be at risk of securities class action litigation.

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