PART I

Item 1. Identity of Directors, Senior Management and Advisors

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

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the U.S. Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry, any of which could materially adversely affect our business, financial condition, results of operations, or market price of our securities. The risks and uncertainties summarized and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Condition

We cannot assure you of the adequacy of our capital resources to successfully complete the development and commercialization of our product candidates, and a failure to obtain additional capital, if needed, could force us to delay, limit, reduce or terminate one or more of our product development programs or commercialization efforts.

As of December 31, 2022, we had cash and cash equivalents and current and non-current other financial assets of € 907.2 million. We believe that we will continue to spend substantial resources for the foreseeable future developing our proprietary product candidates, including pelabresib and tafasitamab in additional indications. These expenditures will include costs associated with development, conducting clinical trials, seeking regulatory approvals, as well as commercializing Monjuvi and launching and commercializing other products approved for sale and potentially acquiring new products. In addition, other unanticipated costs may arise. Because the outcome of our anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our proprietary product candidates.

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

- the success of our commercialization efforts and market acceptance for Monjuvi or any of our current or future product candidates for which we receive marketing approval;
- the costs of maintaining, expanding or contracting for sales, marketing and distribution capabilities in connection with commercialization of Monjuvi and any of our current or future product candidates for which we receive marketing approval;
- the numerous risks and uncertainties associated with developing therapeutic product candidates;
- the number and characteristics of product candidates that we pursue;

- the rate of enrollment, the need to expand, the progress, the costs and the outcomes of our clinical trials, which may or may not meet their intended endpoints;
- the timing of, and cost involved in, conducting non-clinical studies that are regulatory prerequisites to conducting clinical trials of sufficient duration for successful product registration;
- the cost of manufacturing clinical supply and establishing a commercial supply of our product candidates and the cost of continued manufacturing of commercial supply of Monjuvi;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful, including for obtaining regulatory approvals for tafasitamab (for additional indications or in additional geographies) and for pelabresib;
- the timing of, and costs involved in, conducting post-approval studies that may be required by regulatory authorities, including those required for Monjuvi;
- the terms and timing of any collaborative, licensing, or other arrangements that we may establish, including any required milestone and royalty payments thereunder and any non-dilutive funding that we may receive;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs, if any, and the outcome of any such litigation;
- the timing, receipt, and amount of sales of, or royalties or milestones on, our existing products and future products, if any; and
- the costs to maintain the commercial organization including key executives.

In addition, our operating plan may change as a result of many factors currently unknown to us. As a result of these factors, we may need additional funds sooner than planned. We expect to finance future cash needs primarily through a combination of public or private equity offerings, strategic collaborations, debt financings, and non-dilutive funding. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, limit, reduce or terminate one or more of our product development programs or commercialization efforts.

We have sufficient liquid funds to ensure business operations for the forecast period (next 12 months) without requiring additional proceeds from external refinancing. However, in the current capital market environment, opportunities for external financing are limited compared to the prior year. In order to determine the medium and long-term liquidity requirements, We maintain a comprehensive liquidity plan based on our corporate planning that includes the simulated effects of various scenarios. To further reduce our financial risk, we take the outcome of the liquidity plan into account when prioritizing research and development projects and determining the financing requirements. Whilst the opportunity for equity financing is limited if the share price remains at a low level, we also have access to other non-dilutive financing options, such as opportunistic out-licensing of (pre)clinical assets or the sale of potential future royalties.

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

We are a commercial-stage biopharmaceutical company. We have incurred significant losses since our inception and our consolidated net loss for the year ended December 31, 2022 was € 151.1 million. As of December 31, 2022, our accumulated deficit was approximately € 823.4 million. The probability of being profitable strongly depends on the successful development of our other product candidates and the commercial success of Monjuvi, and we may continue to incur losses in the coming years as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States. These activities will continue and will therefore impact significantly our profit or loss and our working capital in the foreseeable future.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the U.S. FDA or the EMA to perform trials in addition to those that we currently expect to perform, such as post-approval trials or if there are any delays in completing our currently planned clinical trials, the partnering process for our proprietary product candidates or in the development of any of our proprietary product candidates.

Our ability to generate revenue and achieve profitability in the future depends in large part on our ability, alone or with our collaborators and partners, and our current and any future approved products, and successfully complete the development of and obtain the necessary regulatory approvals for our current and any future product candidates. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. In addition, our revenues depend in part on the activities of our partners, over which we have no control, in respect of pursuing translational research and clinical trial activities and, where marketing approval has been granted and we have not retained commercialization rights, commercialization of our product candidates. Even if we achieve profitability in the future, we may

not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause our investors to lose all or part of their investment.

Our operating results may fluctuate significantly in the future.

Our results of operations may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control. The revenues we generate and our operating results will be affected by numerous factors, including, but not limited to:

- the development status of our product candidates and, particularly, the timing of any milestone payments to be paid or received by us under our collaboration agreements;
- the incurrence of clinical expenses that could fluctuate significantly from period to period;
- the commercial success of the products marketed by our partners and the amount of royalties to us associated therewith;
- our ability to continue to successfully commercialize Monjuvi and any other future products marketed by ourselves;
- foreign exchange fluctuations;
- the unpredictable effects of collaborations during these periods;
- the timing of our satisfaction of applicable regulatory requirements;
- the rate of expansion of our clinical development and other development efforts;
- the effect of competing technologies and products and market developments; and
- general and industry-specific economic conditions.

If our operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares could decline substantially and any fluctuations in our operating results and cash flows may, in turn, cause the price of our shares to fluctuate substantially.

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

Identifying and acquiring rights to develop potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that may take years to complete. We may never generate the necessary data or results required to obtain regulatory approval and achieve product sales, and even if one or more of our product candidates is approved, they may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may seek additional funding through a combination of equity offerings, debt financings, including convertible bond offerings, collaborations, licensing arrangements, strategic alliances and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our shares. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our shares to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we have projected, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of any 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.

We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plan.

MorphoSys AG has implemented a business continuity plan to prevent the collapse of critical business processes to a large extent or to enable the resumption of critical business processes in case a natural disaster, public health emergency, such as the COVID-19 pandemic, or other serious event occurs. However, depending on the severity of the situation, it may be difficult or in certain cases impossible for us to continue our business for a significant period of time. Our contingency plans for disaster recovery and business continuity may prove inadequate in the event of a serious disaster or similar event and we may incur substantial costs that could have a material adverse effect on our business.

Risks Related to the COVID-19 Pandemic

Our business may be materially and adversely affected by the COVID-19 pandemic or similar pandemic, epidemic, outbreak of an infectious disease or public health crisis. The extent to which the COVID-19 pandemic or similar pandemic, epidemic, outbreak of an infectious disease or public health crisis may impact our business will depend in part on future developments, which are uncertain and unpredictable in nature.

Our business could be adversely affected by health crises in regions where we operate or otherwise do business. For example, the COVID-19 pandemic and the related adverse public health developments, including orders to shelter-in-place, travel restrictions, and the burden of additional requirements on businesses, may adversely affect workforces, organizations, healthcare communities, economies, and financial markets globally, leading to increased market volatility. The COVID-19 pandemic and its aftermath may also disrupt the normal operations of businesses across industries, including ours. We cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic, or a future public health crisis, may have on our business, financial condition, results of operations and cash flows. These impacts of which may materially and adversely affect our business, include the following:

- The COVID-19 pandemic may likely continue to have, an impact on various aspects of our clinical studies, especially with emergence of new COVID-19 variants. Policies at various clinical sites and federal, state, local and foreign laws, rules and regulations are continuing to evolve, including through the implementation of quarantines and travel restrictions, and direction of healthcare resources toward pandemic response efforts. The ebb and flow in COVID-19 infections since the start of the pandemic have impacted patient access to treatment facilities in the U.S. Therapies planned in “hot spot” regions, for example, may be postponed due to a lack of capacity. Furthermore, safety protocols implemented at various sites of care may restrict the ability of our sales force to engage in-person with medical personnel. As a result, there is a risk that we will not achieve the revenue planned from the sale of Monjuvi in the U.S. We assess any potential impact of this risk, however, as moderate.
- We currently rely on third parties to manufacture, perform quality testing, and ship our drug products for our clinical studies and commercial supplies. The third parties in our supply chain are subject to restrictions in operations arising from the COVID-19 pandemic, and in addition, a number of these third parties have experienced operational disruptions, which have affected activities necessary for our development and commercialization efforts. These restrictions and disruptions in operations have also given rise to staffing shortages from time to time, which may result in production slowdowns and/or disruptions in delivery systems, potentially interrupting our supply chain and limiting our ability to manufacture drug product for our clinical studies and for commercial use. Further, during a public health emergency, certain manufacturing facilities and materials may be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials and/or commercial products, which could lead to delays in these trials and/or issues with our commercial supply.
- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic or a future public health crisis. The U.S. FDA, EMA and comparable regulatory agencies may have slower response times or lack resources to continue to monitor our clinical studies or to engage in other activities related to review of regulatory submissions in drug development. As a result, review, inspection, and other timelines may be materially delayed for an unknown period of time. Any de-prioritization of our clinical studies or delay in regulatory review resulting from such disruptions could materially affect the development of our product candidates.
- We have implemented policies at our locations to mitigate the risk of exposure to COVID-19 by our personnel, including restrictions on the number of staff in any given research and development laboratory, a work-from-home policy applicable to the majority of our personnel, and a phased approach to bringing personnel back to our locations over time. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical study sites and other important agencies and contractors.

The ultimate impact of the COVID-19 pandemic or a future public health crisis on our business operations is highly uncertain and subject to change and will depend on future developments which are difficult to predict, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and other actions taken to contain or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our commercialization efforts, our clinical studies, healthcare systems or the global economy, and if the ultimate impact of the COVID-19 pandemic or a future public health crisis and the resulting uncertain economic and healthcare environment is more severe than we anticipated, we may not be able to execute on our current operating plan or on our strategy. If the duration of the COVID-19 pandemic or a future public health crisis and the associated period of business and social restrictions and economic uncertainty is longer than we anticipated, our cash, cash equivalents, and marketable securities may not be sufficient to fund the activities under our operating plan for the time period that we anticipated, and we may be required to revise our operating plan further. To the extent the COVID-19 pandemic or a future public health crisis adversely affect our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Risks Related to Commercialization

We have limited experience as a commercial company, and we may not be successful in, or have limited success in, our continued commercialization of Monjuvi, in which case our financial results and future prospects may be substantially harmed. In July 2020, the U.S. FDA granted accelerated approval to Monjuvi, a CD-19 directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). We are still evaluating tafasitamab in other clinical trials for the treatment of B-cell malignancies. Our ability to generate, and the degree to which we generate, product revenue from Monjuvi will depend heavily on our successful commercialization of the product and ability to gain approval for Monjuvi in expanded indications.

The development and commercialization of Monjuvi could be unsuccessful if:

- we fail to maintain the necessary financial resources and expertise to manufacture, market and sell Monjuvi;
- we (or our partners) fail to continue to develop and implement effective marketing, sales and distribution strategies and operations for the development and commercialization of Monjuvi;
- we fail to maintain a commercially viable manufacturing process for Monjuvi that is compliant with current good manufacturing practices;
- we fail to continue to obtain adequate pricing and third party reimbursement for Monjuvi;
- patients are not able to afford Monjuvi based on the cost-sharing required by third-party payors;
- we encounter any third party patent interference, derivation, inter partes review, post-grant review, reexamination or patent infringement claims with respect to tafasitamab;
- we fail to comply with regulatory and legal requirements applicable to the sale of Monjuvi, including the timely conduct and successful completion of the required post-marketing clinical trial;
- competing drug products are approved for the same indication as Monjuvi;
- new significant safety risks are identified; and
- tafasitamab does not demonstrate acceptable safety and efficacy in current or future clinical trials, or otherwise does not meet applicable regulatory standards for approval in indications other than for the treatment of adult patients with r/r DLBCL.

If we experience significant delays or an inability to successfully develop and commercialize Monjuvi, our business would be materially harmed.

The commercial success of Monjuvi in the U.S. and Minjuvi in Canada and the EU, and of any additional products, will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of Monjuvi, Minjuvi and of any additional products will depend in part on the medical community, patients, and third-party or governmental payers accepting such product(s) as medically useful, cost-effective, and safe.

Monjuvi, Minjuvi and any other products that we may bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue. See the section of this annual report titled "Item 4.B. Business Overview Coverage, Reimbursement and Pricing" below. The degree of market acceptance of Monjuvi, Minjuvi and of any future products will depend on a number of factors, including:

- the breadth of the approved clinical indications for our product candidates;
- the potential efficacy and potential advantages over alternative treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the pricing of our product and of any future products;
- publicity concerning our product, any future products, or competing products and treatments;
- sufficient third-party insurance coverage or reimbursement; and
- potential product liability claims.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and payers on the benefits of our products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors. Any of these factors may cause Monjuvi, Minjuvi or any future products, to be unsuccessful or less successful than anticipated.

We are reliant on Incyte for the successful commercialization of tafasitamab outside of the United States. If Incyte does not successfully commercialize tafasitamab outside of the United States, our future prospects may be substantially harmed.

Tafasitamab is co-marketed by Incyte and MorphoSys in the United States under the trade name Monjuvi and by Incyte in Europe, Canada and other jurisdictions under the trade name Minjuvi. Under our agreement with Incyte, Incyte maintains commercial rights to tafasitamab outside of the United States and we will receive tiered royalties on ex-U.S. net sales of tafasitamab in a mid-teens to mid-twenties percentage range of net sales. Thus, our ability to generate revenue from Minjuvi outside the United States will depend heavily on Incyte's ability to successfully obtain the requisite marketing approvals outside the United States and commercialize the product.

If we are unable to establish and maintain sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. Although we have established sales and marketing capabilities to support our sales of Monjuvi in the U.S., we will need to further build our sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, our other product candidates if and when they are approved, including, for example, to support the potential approval of one or more product candidates in the European Union.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our medicines on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

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

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of product revenue to us are likely to be lower than if we were to market and sell any medicines that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our medicines effectively. If we do not maintain sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

If we are unable to advance our proprietary product candidates to clinical development, obtain regulatory approval for our product candidates, including for tafasitamab (for additional indications or in additional geographies) and for pelabresib, and ultimately successfully commercialize them or experience significant delays in doing so, our business will be materially harmed.

We have several product candidates in clinical development, and other product candidates and development candidates are currently in preclinical or earlier stages of development. Although we may receive certain payments from our collaboration partners, including upfront payments, payments for achieving certain development, regulatory or commercial milestones and royalties, our ability to generate revenue from our product candidates' sales is dependent on receipt of regulatory approval for, and successful commercialization of, such product candidates, which may never occur. Our business and future success is particularly dependent on our ability to develop, either alone or in partnership, successfully, receive regulatory approval for, and then successfully commercialize our proprietary product candidates. Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales or royalties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies (including safety studies) required to obtain regulatory approval in the United States, the European Union and other jurisdictions for our product candidates;
- successful enrollment of patients in, and completion of, clinical studies (including safety studies) required to obtain regulatory approval in the United States, the European Union and other jurisdictions for our product candidates;
- successful demonstration of reproducibility in the production process and ability for market supply;
- strategic commitment to particular product candidates and indications by us and our collaborators;
- receipt of product approvals, including marketing approvals, from applicable regulatory authorities;
- successful local and regional pricing and reimbursement negotiations with third-party payors to enable patients' access to our products;
- successful validation of biomarkers and development of biomarker assays in those studies or programs where biomarkers are part of the development plan;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates and brands;
- securing market supply and distribution network;
- securing quality raw material supplies;
- the successful launch and marketing of approved products and/or brands, whether alone or in collaboration with others;
- acceptance of our approved products and/or brands by patients, the medical community and third-party payors;
- effectively competing with other therapies and ability to demonstrate clinically meaningful benefits;
- enforcing and defending intellectual property rights and claims;
- maintaining a continued acceptable safety and efficacy profile of the products following approval;

- fulfillment of post-marketing commitments and requirements from applicable regulatory authorities; and
- maintaining a continued, sufficient supply of drug product in acceptable quality.

If we do not achieve one or more of these factors in a complete and timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially adversely affect our business, financial condition, results of operations and prospects and, in case of product candidates, technologies and licenses we have acquired, may result in a significant impairment of assets.

Further, our product candidates may not receive regulatory approval even if we are successful in conducting clinical trials, non-clinical studies and assembling required CMC (chemistry, manufacturing and controls) information. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations and partnership. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the commercialization potential, our ability to supply sufficient amounts of product candidates, the uptake of our product candidates and the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the market potential that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize future product candidates both in the United States and potentially in the European Union, and additional foreign jurisdictions. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Clinical trials are very expensive, resource intensive and complex to design and implement and involve uncertain outcomes. If clinical trials or production of our product candidates are prolonged, delayed or terminated, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all, which may materially adversely affect our business, financial condition, results of operations and prospects.

We are currently conducting clinical trials for pelabresib, tafasitamab and tulmimetostat in various indications. Each of our clinical trials requires the investment of substantial resources and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays or termination relating to various causes, including, among other things:

- difficulties in identifying and enrolling patients who meet trial eligibility criteria;
- failure of patients to complete the clinical trials or return for post-treatment follow-up;
- delays in accumulating the required number of clinical events for data analyses;
- clinical investigators or sites deviating from trial protocol or failing to comply with regulatory requirements or meet their contractual obligations;
- delay or failure to obtain required regulatory approvals to start the clinical trial in the participating countries;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, clinical trial sites and contract manufacturing organizations, or CMOs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and CMOs;
- delays in or failure to obtain institutional review board, or IRB, approval at participating trial sites;
- failure of third-party contractors used in our clinical trials or contract manufacturing organizations, or CMOs, to comply with regulatory requirements or meet their contractual obligations in a timely manner, or not at all;
- changes in regulatory requirements;
- the development and approval of competitive products;
- results from clinical trials of competing compounds, which may give rise to concerns about the target, the envisioned mode of action, the compound class or the commercial potential of the product candidate we are evaluating;
- higher-than-expected costs of clinical trials of our product candidates;
- insufficient or inadequate supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidate;
- scheduling conflicts with participating investigators/trial sites due to competing trials;

- outbreak of pandemic and natural disaster;
- urgent safety measures;
- pre-defined interim analysis of clinical trial data (futility analysis) or unfavorable and unforeseen non-clinical or clinical information that reveals that the product candidate has an unfavorable risk-benefit ratio;
- suspension/termination of approval of clinical trial conduct by Ethics Committees, or ECs, IRBs, the U.S. FDA, or Competent Authorities, or CA;
- strategic decision to stop the clinical trial or the clinical development program; and
- recommendations of the data safety monitoring board/data monitoring committee, or DSMB/DMC, based on provided clinical safety data.

It is uncertain whether any of our clinical trials will begin as planned, will need to be redesigned or amended or will be completed on schedule. 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 conduct. 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, by a DSMB/DMC for such trial or by the U.S. 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 or trial site by the U.S. FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, 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. 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, and our ability to generate product revenues from any of these product candidates will be delayed. 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. 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.

Clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practice, or cGMP, and supplied accordingly under good distribution practice, or GDP, requirements and other regulations. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Even though we have agreements governing their committed activities, we depend on our collaborators and on clinical trial sites and CROs to conduct and monitor our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or CROs fail to enroll participants for our clinical trials, fail to conduct and monitor the study to GCP standards or are delayed for a significant time or fail 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.

If we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are unfavorable or are only modestly favorable, if there are safety concerns associated with our product candidates, or if we are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we contemplate, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with product labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- face higher pricing and reimbursement hurdles;
- be subject to additional post-marketing testing or other requirements; or
- remove the product from the market after obtaining marketing approval.

The occurrence of any such events may materially adversely affect our business, financial condition, results of operations and prospects.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our products or any future products are smaller than we estimate or if any approval that we obtain for a product is for a smaller patient population than anticipated, our business, financial condition, results of operations and prospects may be materially adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our product development strategy, including determining indications on which to focus in preclinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, any limitations on populations and indications in approved product labeling, patient access, product pricing and reimbursement as well as the approval of new or competing medicines. The number of patients in the addressable markets may turn out to be lower than expected or new patients may become increasingly difficult to identify or gain access to. Additionally, even if we obtain significant market share for a product within an approved indication, if the potential target populations for the product is small, it may be difficult to achieve profitability without obtaining marketing approval for additional indications. Any of these factors could materially adversely affect our business, financial condition, results of operations and prospects.

The speed at which we complete our clinical trials depends on many factors, including, but not limited to, patient enrollment. If we are unable to enroll patients in our clinical trials, our development efforts and business, financial condition, results of operations and prospects could be materially adversely affected.

Patient enrollment and pandemic outbreak are significant factors in the timing and successful completion of clinical trials. Patient enrollment is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating. Because there is a relatively limited number of patients worldwide, patient enrollment may be challenging. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and delay or potentially jeopardize our ability to receive regulatory approval, commence product sales and generate revenue. Any of these occurrences may harm our clinical trials, which could materially adversely affect our business, financial condition, results of operations and prospects.

Results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the U.S. FDA, the EMA or comparable foreign regulatory authorities.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in late-stage clinical trials or product approval by the U.S. FDA, the EMA, or comparable foreign regulatory authorities. We will generally be required to demonstrate with substantial evidence through well-conducted, possibly controlled clinical trials that our product candidates are safe and effective for use in a well-defined patient population before we can seek regulatory approvals for their commercial sale. Our ongoing and planned clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. Success in preclinical studies or early-stage clinical trials does not mean that future clinical trials or registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy to the satisfaction of the U.S. FDA, the EMA and comparable foreign regulatory authorities, despite having progressed through preclinical studies and initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. Similarly, interim results of a clinical trial do not necessarily predict final results.

Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect on patients in open-label clinical trials receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

The regulatory approval processes of the U.S. FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable and if we fail to obtain regulatory approval in any jurisdiction, we will not be able to commercialize our products in that jurisdiction, and our business, results of operations, financial condition and prospects may be materially adversely affected.

The time required to obtain approval by the U.S. FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including clinical trial designs, their outcome and the substantial discretion of the regulatory authorities. In addition, approval laws, regulations, policies or the type and amount of clinical data or other information necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Our existing product candidates or any product candidates we may seek to develop in the future may never obtain regulatory approval.

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

- the U.S. FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or the results of our clinical trials may not meet the level of statistical significance required by the U.S. FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate to the satisfaction of the U.S. FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication(s) in the proposed population;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the U.S. FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected may not be sufficient to support the submission of a BLA, NDA or other submission, or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the U.S. FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the laws, regulations or policies of the U.S. FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data or other regulatory submissions insufficient for approval; and
- MorphoSys' critical business operations, including but not limited to the Company's supply chain, clinical trial conduct, as well as timelines for regulatory and commercial execution may be influenced negatively in case the implemented disaster recovery and business continuity plan may prove inadequate.

The approval process may result in failing to obtain regulatory approval to market any of our future product candidates, which would significantly harm our business, results of operations and prospects. The U.S. FDA, the EMA and other regulatory 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 U.S. FDA, the EMA or any other regulatory authority. These authorities could require additional clinical data, including clinical trials designed with internal controls, in order to support regulatory approvals.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our future product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a future product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Commercialization of our products in more than one jurisdiction requires separate regulatory approval in each jurisdiction and compliance with the numerous and varying regulatory requirements of each jurisdiction. The approval procedures vary from country to country and may require additional testing or other steps. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain, and subject to unanticipated delays. In addition, in many countries outside the United States and in particular in many of the Member States of the European Union, a product must undergo health economic assessments to agree on pricing and/or be approved for reimbursement before it can be approved for sale in that country, or before it becomes commercially viable. The U.S. FDA and the EMA may come to different conclusions regarding approval of a marketing application. Approval by the U.S. FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the U.S. FDA or the EMA. In addition, failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, including as a result of population and other demographic difference

across countries. We may not obtain regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize a product in any market. We may be required to conduct additional preclinical studies or clinical trials, which would be costly and time-consuming. If we or any future partner are unable to obtain regulatory approval for our product candidates in one or more significant jurisdictions, then the commercial opportunity for our product candidates, and our business, results of operations, financial condition and prospects, may be materially adversely affected.

Disruptions at the U.S. FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the U.S. FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the U.S. FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the U.S. FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the U.S. FDA and other agencies may also slow the time necessary for drugs or biologics or modifications to approved drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the U.S. FDA, have had to furlough critical U.S. FDA employees and stop critical activities.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the U.S. FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval. Should the U.S. FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the U.S. FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the U.S. FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If the U.S. FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates and for any approvals we may seek which could adversely affect our business.

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

Undesirable side effects that may be caused by our product or product candidates could cause us, our collaboration partners or the 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 U.S. FDA, the EMA or comparable foreign regulatory authorities. The results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the U.S. 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 product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive regulatory approval and we or others identify undesirable side effects caused by such approved products (or any other similar products), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products and require us or our collaborators to take such products off the market;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication, or correspondence to alert physicians and other healthcare providers about new or updated information regarding the approved product, such as Dear Health Care Provider letters;

- we or our collaborators may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we or our collaborators may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we or our collaborators may be subject to regulatory investigations and government enforcement actions;
- we or our collaborators may decide or be required to remove such product candidates from the marketplace;
- we or our collaborators could be sued and potentially held liable for injury caused to individuals exposed to or taking our product candidates;
- sales of the product(s) may decrease substantially; and
- our reputation and the reputation of our collaborators may suffer.

Any of these events could prevent us or our collaborators from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and therefore could have a material adverse effect on our business, financial condition, results of operations and prospects.

We and our collaboration partners have conducted and intend to conduct additional clinical trials for selected product candidates at sites outside the United States, and the U.S. FDA may not accept data from trials conducted in such locations or may require additional U.S.-based trials.

We and our collaboration partners have conducted, are currently conducting and intend in the future to conduct, clinical trials outside the United States, particularly in, but not limited to, the European Union, where we are headquartered.

Although the U.S. FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the U.S. FDA. For example, the clinical trial must be well-designed and conducted by qualified investigators in accordance with GCP, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the U.S. FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside of the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to applicable local laws, U.S. FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the U.S. FDA will accept data from trials conducted outside of the United States. If the U.S. FDA does not accept the data from any clinical trials that we or our collaboration partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these or other product candidates in the United States. In other jurisdictions, for instance, in Japan, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

We are required to comply with comprehensive and ongoing regulatory requirements for our approved drug, Monjuvi/Minjuvi, and if we receive regulatory approval, for our product candidates, including conducting confirmatory clinical trials of any drug that receives accelerated approval. In addition, our approved product and 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 drugs, which may materially adversely affect our business, prospects, financial condition and results of operations.

Any current or future product candidate for which we receive accelerated approval from the U.S. FDA, including Monjuvi, or similar conditional approval from the EMA or comparable regulatory authorities in other jurisdictions may be required to undergo one or more confirmatory clinical trials. If such drug fails to meet its safety and efficacy endpoints in such confirmatory clinical trials, the regulatory authority may withdraw its approval. There is no assurance that any such drug will successfully advance through its confirmatory clinical trial(s). Therefore, even if a drug receives accelerated approval from the U.S. FDA or similar conditional approval from the EMA or comparable regulatory authorities, such approval may be withdrawn at a later date, and under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

If the U.S. 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, marketing, promotion and recordkeeping 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, continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, as well as applicable product tracking and tracing requirements, all of which may result in significant expense and limit our ability to commercialize such products. 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 and surveillance to monitor the safety and efficacy of the product.

Further, on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act became law in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances U.S. FDA’s existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to U.S. FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

In addition, regulatory policies may change or additional government regulations or legislation may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we fail to comply with existing requirements, 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 regulatory approval that we may have obtained or face regulatory or enforcement actions, which may materially adversely affect our business, prospects, financial condition and results of operations.

We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any of our products that receive regulatory approval, which may materially adversely affect our business, prospects, financial condition and results of operations.

Once a product is approved by the U.S. FDA, the EMA or a comparable foreign regulatory authority for marketing, it is possible that previously unknown problems may occur with the product, including problems with third-party manufacturers or manufacturing processes, packaging or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our products, it may result in, among other things:

- restrictions on the marketing or manufacturing or packaging of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the U.S. FDA, the EMA or comparable foreign regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- requirements to conduct additional clinical trials, change our product labeling or submit additional applications or application supplements;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any of these events, or any government investigation of alleged violations of law could require us to expend significant time and resources, could generate negative publicity, and may impair our ability to sell such product. If we or our

collaborators are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which may materially adversely affect our business, prospects, financial condition and results of operations.

We may allocate our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success, which may materially adversely affect our business, prospects, financial condition and results of operations.

Because we have limited financial and managerial resources, we must limit our licensing, research and development programs to specific product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities, and our decisions concerning the allocation of research, collaboration, management and financial resources towards particular product candidates may not lead to the development of viable commercial products.

A breakthrough therapy designation or fast track designation by the U.S. FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and either designation does not increase the likelihood that our product candidates will receive marketing approval.

We may seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the U.S. FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

We may also seek fast track designation for some of our product candidates. If a product candidate is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for U.S. FDA fast track designation for a particular indication. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the U.S. FDA.

The U.S. FDA has broad discretion whether or not to grant breakthrough therapy designation or fast track designation. Accordingly, even if we believe one of our product candidates meets the criteria for breakthrough therapy designation or fast track designation, the U.S. FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation or fast track designation for a product candidate may not result in a faster development process, review or approval compared to other drugs and does not assure ultimate approval by the U.S. FDA. In addition, even if one or more of our product candidates qualify for breakthrough designation or fast track designation, the U.S. FDA may later decide that the drugs no longer meet the conditions for qualification.

We may seek orphan drug designation for some of our product candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for some of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the U.S. FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the European Union, the European Commission grants orphan medicinal product designation after receiving the opinion of the European Medicines Agency's, or EMA's, Committee for Orphan Medicinal Products on an orphan medicinal product designation application. Orphan medicinal product designation may be granted in respect of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized for marketing in the European Union (or, if such a method exists, the product would be of a significant benefit to those affected by the condition). In addition, designation is granted for products intended for the diagnosis, prevention, or

treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would generate sufficient return to justify the necessary investment in developing the product. In the European Union, orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the U.S. FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the U.S. and ten years in the European Union. The European Union exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the U.S. FDA can subsequently approve another drug for the same condition if the U.S. FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the U.S. may be lost if the U.S. FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to continue seek orphan drug designation for our product candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our product candidates, there is no guarantee that we will enjoy the benefits of those designations.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current products and product candidates, and we and our collaborators will face competition with respect to any product candidates that we or they may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates in the hematology/oncology area. Some competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. For additional information regarding our competition, see the section of this annual report titled “Item 4.B. Business Overview.”

We are developing our product candidates for the treatment of cancer. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy, and cancer drugs are frequently prescribed off-label by healthcare professionals. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that our product candidates, if approved, will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. In addition, our competitors may discover biomarkers that more efficiently measure metabolic pathways than our methods, which may give them a competitive advantage in developing potential products. Our competitors may also obtain marketing approval from the U.S. FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Additionally, even if we are successful in achieving marketing approval to commercialize a product candidate faster than our competitors, we may face competition due to the changing regulatory environment. In the United States, for small molecule drugs, the FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example for new indications, dosages, or strengths of an existing drug. This

three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving abbreviated new drug applications, or ANDAs, for drugs containing the active agent for the original indication or condition of use. The FDCA also provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Three-year and five-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Further, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar,” or biosimilar, to or “interchangeable” with an U.S. FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In the European Union, a competitor may reference data from biological products already approved after the expiry of an eight year data exclusivity period, but will not be able to get on the market until 10 years after the time of approval of the reference product. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products.

If competitors are able to obtain marketing approval for drugs or biosimilars referencing our products, our products may become subject to competition from such drugs or biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other clinical 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, our programs.

Risks Related to Our Reliance on Partnerships and Other Third-Parties

Collaborations on products and product candidates are important to our business, and future collaboration and license agreements may also be important to us. If we are unable to maintain any of these partnerships or if these partnerships are not successful, our business could be materially adversely affected.

We have in the past entered into, and intend to continue to enter into on a case-by-case basis, collaborations with other companies that we believe provide us with valuable funding and other benefits. However, we cannot ensure that any such collaboration will continue or be successful. For example, in March 2015, we and Celgene Corporation (now part of Bristol-Myers Squibb) agreed to end the existing co-development and co-promotion agreement for felzartamab, following which we regained the rights to felzartamab. We have subsequently partnered Chinese regional rights to felzartamab, and our partner I-Mab will further develop felzartamab in multiple myeloma, or MM, and potentially also for additional indications, for China, Hong Kong, Macao and Taiwan. We cannot ensure that such collaboration will be successful. Our inability to find a partner for any of our product candidates may result in our termination of that specific product candidate program or evaluation of a product candidate in a particular indication. In June 2022, Human Immunology Biosciences, Inc. (HI-Bio) obtained exclusive rights to develop and commercialize felzartamab across all indications worldwide, with the exception of Greater China. In November 2018, we entered into a collaboration and licensing agreement with I-Mab for an additional proprietary program, MOR210. Our partner I-Mab will perform certain preclinical and clinical development activities(China, Hong Kong, Macao, Taiwan and South Korea). In June 2022 HI-Bio obtained exclusive worldwide rights to develop and commercialize MOR210

across all indications worldwide, with the exception of Greater China and South Korea. In January 2020, we entered into a collaboration and license agreement with Incyte Corporation, or Incyte, to further develop and commercialize our proprietary antibody tafasitamab globally. This agreement received clearance by the U.S. antitrust authorities under the Hart-Scott-Rodino Act as well as by the German and Austrian antitrust authorities on or before March 2, 2020, and became effective on March 3, 2020. Under the terms of the agreement, we and Incyte are co-commercializing tafasitamab in the U.S., while Incyte has exclusive commercialization rights outside of the U.S. In addition, we and Incyte have agreed to co-develop tafasitamab broadly in r/r DLBCL, frontline DLBCL, as well as additional indications beyond DLBCL, such as follicular lymphoma (FL) and marginal zone lymphoma (MZL). We cannot ensure that any such collaboration or license agreement or further clinical development or the commercialization will be successful. In June 2022, we announced with Pfizer and Incyte a clinical trial collaboration and supply agreement to investigate the immunotherapeutic combination of Pfizer's TTI-622, a novel SIRPα-Fc fusion protein, and Monjuvi (tafasitamab-cxix) plus lenalidomide in patients with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant (ASCT).

In the future, we may enter into additional collaborations and license agreements to fund our development programs or to gain access to sales, marketing or distribution capabilities and we may also enter into collaborations and licensing or purchasing agreements under which we provide funding and gain access to targets, technologies or compounds.

Under the collaboration agreements where we grant our partners an exclusive license to certain therapeutic antibodies for specific targets we receive license fees, research and development funding, milestone payments and/or, if a product is approved for marketing, royalties in return. Following the discovery and preclinical testing phase, these partners are typically solely responsible for the further development of the product candidate and therefore exercise full control over its further development and potential commercialization. In other collaborations, for example with Incyte, we also rely on both parties' and capabilities to co-develop and co-commercialize. In clinical trial collaborations, for example the one signed with Pfizer, we rely on the partners' capabilities and diligence for performance of the agreed trial. Our existing collaborations, and any future collaborations and licensing or purchasing agreements we enter into, therefore may pose a number of risks, including the following:

- collaborators, licensees or licensors may have significant discretion in determining the efforts and resources that they will apply to these collaborations or license agreements;
- collaborators, licensees or licensors may not perform their obligations as expected by us or by health authorities, such as the U.S. FDA, the EMA or comparable foreign regulatory authorities;
- collaborators, licensees or licensors may dissolve, merge, be bought, or may otherwise become unwilling to fulfill the initial terms of the collaboration or license agreement with us;
- collaborators, licensees or licensors may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities or the actual or perceived competitive situation in a specific indication;
- collaborators, licensees or licensors may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or may require a new formulation of a product candidate for clinical testing;
- collaborators, licensees or licensors may not put sufficient resources or may delay or underperform in their activities to seek regulatory approval, pricing approval and perform commercial and medical affairs activities to market and sell the product;
- collaborators, licensees or licensors may not be compliant with applicable laws and regulations;
- collaborators, licensees or licensors could independently develop, or develop with third-parties, products that compete directly or indirectly with our products or product candidates if the partner believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator or licensee with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- a target, technology or compound we in-license, collaborate/co-develop or acquire could be determined to not perform in any pre-clinical, clinical, supply or commercialization activities as expected, including but not limited to showing deficiencies in pharmacology, pharmacokinetics, toxicology, safety, efficacy or manufacturing data, or such data may not

be competitive with other projects from third parties, which may cause us to devote additional resources to the research, development, manufacturing and commercialization, may cause a delay or failure of regulatory approval or may cause us to stop the project and write off the investment already taken;

- We are co-commercializing Monjuvi together with Incyte in the United States, and to the extent we are reliant on marketing and distribution activities provided by Incyte we may not be able to meet commercial demand, as applicable, in a timely manner or at all;
- disagreements with collaborators, licensees or licensors, including disagreements over proprietary rights, contract interpretation and breach of contract claims, payment obligations or the preferred course of development, supply and commercialization, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities, including financial obligations for us with respect to products or product candidates, or delays or withholding of any payments due or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators, licensees or licensors may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators, licensees or licensors may infringe the intellectual property rights of third-parties, which may expose us to litigation and potential liability; and
- collaborations, or license agreements may be terminated for the convenience of the collaborator or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our research, development and commercial partnerships do not result in the successful development and commercialization, as applicable, of products or if one of our partners terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the agreement. If any commercial partner underperforms or terminates the agreement with us, we may generate less revenues or less profits / more losses. If we do not receive the funding, or do not generate the revenues or profits, we expect under these agreements, the development and commercialization of our product candidates and products could be delayed, and we may need additional resources to develop and commercialize our proprietary product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our program collaborators and licensees. If our in-licensing or acquisition activities do not result in the successful development and commercialization, we may generate less revenues or less profits / more losses.

Additionally, subject to its contractual obligations to us, if one of our partners is involved in a business combination, the partners might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new partners in a timely manner.

We face significant competition in seeking new partnerships.

For all our proprietary product candidates, we face significant competition. This may negatively impact our ability to enter into potential partnerships or licensing agreements for our compounds. In June 2022 we signed a collaboration and license agreement and equity participation agreement with HI-Bio for the development of felzartamab outside of China in autoimmune indications. Also for any in-licensing and acquisition activities, we face significant competition. Our ability to reach definitive agreements for partnerships will depend, among other things, upon our assessment of the partner’s resources and expertise, the terms and conditions of the proposed partnership and the proposed partner’s evaluation of a number of factors. The factors, depending on the type of partnership we or the partner would consider, may include the design or results of clinical trials, the likelihood of approval by the U.S. FDA, the EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, market access and pricing considerations in the respective territory, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, incidence and prevalence of the respective disease, and industry and market conditions generally. The partner may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. In the case of in-licensing or acquisition partnerships, the partner may also consider alternative offers or partners other than MorphoSys to be more attractive, or keeping all rights to themselves.

Collaborations and commercialization partnerships are complex and time-consuming to negotiate and document. If we are unable to reach agreements with suitable partners on a timely basis, on acceptable terms, or at all, we may have to curtail or even stop the development of a product candidate in one or all indications, in one or all territories in the world, reduce or delay one or more of our development programs, delay its potential commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or

commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and other partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates in any or all indications or bring them to market in any or all territories in the world and our business may be materially and adversely affected. If we fail to identify additional targets, technologies or compounds for in-licensing, collaboration, co-development or commercialization, we may not be able to further expand our pipeline. If we succeed to identify further targets, technologies or compounds for in-licensing, collaboration, co-development or commercialization, we may need to increase our expenditures.

Our reliance on third-party suppliers could harm our ability to commercialize our drugs or any other drug candidates that may be approved in the future.

We do not currently own or operate manufacturing facilities for the production of our drugs or any other drug candidates that may be approved in the future. Our third-party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our drugs. As a result, there can be no assurances that we will be able to obtain sufficient quantities of our drugs or any other drug candidates that may be approved in the future, which could have a material adverse effect on our business as a whole. We are not certain, however, that our suppliers will be able to meet our demand, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers. In addition, the COVID-19 pandemic considered to be overcome with regard to travel and meeting restrictions could still adversely impact our suppliers and result in delays as disruptions in global supply chains might still take some time to be resolved.

Establishing additional or replacement suppliers for the drug substance or drug product used in our drug candidates or approved drugs, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory, any interruption or delay in the supply of components or materials, or our inability to obtain such drug substance and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We rely and expect to continue to rely on third-parties, including research/medical institutions, clinical investigators, CROs and/or other service providers, to conduct our development activities (preclinical studies, quality testing and clinical trials) and perform data collection, analysis and reporting, which may result in costs and delays in the development of our product candidates. 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 materially adversely affected.

We rely and expect to continue to rely on public and private medical/research institutions, clinical investigators, CROs, service providers and collaboration partners to conduct our early phase and late phase product development activities including the conduct of preclinical studies and clinical trials. Our development activities conducted in reliance on third-parties may be delayed, suspended or terminated, including for the following reasons:

- the third-parties do not devote a sufficient amount of resources, time or effort to our activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines;
- we replace a third-party; or
- the quality or accuracy of the data obtained by third-parties is compromised due to their failure to adhere to the study plans/protocols, GxP, regulatory requirements or for other reasons.

Although we perform sponsor oversight and audits using risk-based approaches, we do not have the ability to control every action of third-parties in their conduct of development activities. Nevertheless, we are responsible for ensuring that each of our development activities is conducted in accordance with the applicable study plan/protocol, GxP, legal, regulatory, intellectual property and scientific standards, and our reliance on these third-parties does not relieve us of our sponsor responsibilities. We and our third-parties are required to comply with GxP standards, which are regulations and guidelines enforced by the U.S. FDA, the competent authorities of the member states of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GxPs through periodic inspections of trial sponsors, principal investigators and trial sites, CROs and/or other involved service providers. If we or any of our third-parties fail to comply with applicable GxP standards, the study data generated in our preclinical studies and/or clinical trials may be deemed unreliable and the U.S. FDA, the EMA or comparable foreign regulatory authorities may

require us to perform additional studies before potentially approving our marketing authorization applications. We cannot ensure that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our development activities comply with GxP regulations. If third-parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our study plans/protocols, GxP and other regulatory requirements or for other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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

We currently rely on third-party suppliers and CMOs for the manufacturing and distribution of our product candidates, and our dependence on these third-parties may impair the development of our product candidates. Moreover, we rely on third-parties to produce commercial supplies of approved product candidate and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third-parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or in compliance with applicable laws. 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 product candidates and products.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical (with the exclusion of non-GLP testing), clinical product supplies, our commercial product, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale under GMP. We therefore rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, for the supply of cGMP-grade, clinical trial materials and commercial quantities of our product candidates and our approved products. The facilities used by our CMOs or other third-party manufacturers to manufacture our product candidates might be subject to the U.S. FDA's, the EMA's and other comparable regulatory authorities' preapproval inspections and routine inspections that will be conducted after we submit our BLA or NDA to the U.S. FDA or the required approval documents to any other relevant regulatory authority or after approval. Although we perform oversight of the manufacturing and testing activities by involvement in e.g. the Change Control and Deviation management of the CMO and qualification audits prior to contracting a CMO and subsequent regular audits of such facilities and GMP procedures, we are completely dependent on our contract manufacturers or other third-party manufacturers for compliance with cGMPs for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture sufficient amounts of material that conforms to applicable specifications and the strict regulatory requirements of the U.S. FDA, the EMA or another comparable regulatory authority, we may not be able to secure and/or maintain regulatory approvals for our products manufactured at these facilities. In addition (except for our oversight obligations described above), we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control and quality assurance procedures and qualified personnel. If the U.S. FDA, the EMA or another comparable regulatory authority finds deficiencies at these facilities for the manufacture of our product candidates or products for commercial sale, or if it withdraws any approval because of deficiencies at these facilities in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, once approved. If, for any reason, we were to experience an unexpected loss of supply of our product candidates, combination drug, or placebo or comparator product used in certain of our clinical trials, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. If market demand increases, our current planning assumptions the CMO might not be willing or able to supply this additional material, leading to supply shortage on the market.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and our approved product for commercial sale. For certain items, there are a limited number of suppliers for raw materials that we use to manufacture our products and appropriate lead times for ordering such materials are factored into the manufacturing plans. However, there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, for commercial sale. Moreover, we currently do not have any agreements in place for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have access to a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, could considerably delay the completion of our clinical trials, product testing and potential regulatory approval of our product candidates. Such delays could for example be caused by the implementation of corrective actions at the supplier, or even replacement of a contract manufacturer or other involved third-parties. If we or our manufacturers are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates. Additionally, we may experience unforeseen difficulties or challenges in the manufacture of our product candidates on a commercial scale compared to the manufacture for clinical purposes. We currently rely on CMOs for the manufacturing of each of our proprietary product candidates. Thus any regulatory action, service failure, business interruptions, or other disasters affecting BI's facilities or the facilities of our other CMOs for our other proprietary product candidates could result in a significant delay in the production and supply of tafasitamab and could, as a result, have a material adverse effect on our business, results of operations, financial condition and prospects. In order to mitigate this risk, we have initiated the establishment of second and third suppliers for tafasitamab.

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

The manufacture of our product candidates is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The processes for manufacturing our approved product and our product candidates is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process or product loss during fill and finishing. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions.

If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for our approved product or other product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

Risks Related To Our Intellectual Property Rights

If we are unable to obtain and maintain sufficient intellectual property protection for our products or product candidates, or if the scope of our intellectual property protection is not sufficiently broad, our ability to commercialize our products or product candidates successfully and to compete effectively may be materially adversely affected.

Our success depends in large part on our ability to obtain and maintain protection with respect to our intellectual property and proprietary technology. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The patent position of pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably and can change. The patent applications that we own or in-license may fail to result in issued patents, and if they do, such patents may not cover our products or product candidates in the United States or in other countries. Accordingly, we cannot predict whether additional patents protecting our technology or our product candidates will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide us with a competitive advantage. Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our licensed and owned patents, the reproduction of our manufacturing or other know-how or marketing of competing products in violation of our proprietary rights generally. Any of these outcomes could impair our ability to prevent competition from third-parties, which may have a material adverse effect on our business.

Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, we or our licensors may only pursue, obtain or maintain patent protection in a limited number of countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art or other documents or experiments that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our products or product candidates, third-

parties (including our licensees) may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third-parties may have or obtain rights to patents which they may use to prevent or attempt to prevent us from commercializing any of our patented product candidates, or which might require us to take license to such patents in order to be able to commercialize the respective product candidates. If these other parties are successful in obtaining valid and enforceable patents, and establishing our infringement of those patents, we could be prevented from selling our products unless we were able to obtain a license under such third-party patents. In addition, third-parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency of competent jurisdiction may find our patents invalid and/or unenforceable.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or otherwise provide us with a competitive advantage. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. We may not have adequate remedies in the case of a breach of any such agreements, and our trade secrets and other proprietary information could be disclosed to our competitors or others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies. In addition, the research resulting in certain of our licensed patent rights and technology has been, and may in the future be, funded by the government or other institutional organizations that may have certain rights, including march-in rights, to such patent rights and technology.

If the patent applications we own or have in-licensed with respect to our product candidates fail to issue as patents, if their breadth or strength of protection is narrowed or threatened, or if they fail to provide meaningful exclusivity, it could dissuade companies from collaborating with us and adversely affect our competitive position. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third-parties. Any successful challenge to any patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product or product candidate that we may develop and could impair or eliminate our ability to collect future revenues and royalties with respect to such products or product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product or product candidate. In addition, patents have a limited lifespan. In the United States and most foreign jurisdictions, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application to which the patent claims priority. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. Even if patents covering our product candidates are obtained, once such patents expire, we may be vulnerable to competition from generic, similar or biosimilar products. The launch of a generic version or biosimilar version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations or prospects.

We do not know if, when, or how the U.S. FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business.

On August 3, 2017, the Congress passed the U.S. FDA Reauthorization Act of 2017 (“FDARA”). FDARA, among other things, codified the U.S. FDA’s preexisting regulatory interpretation, to require that a drug Sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The law reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the U.S. FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where U.S. FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The U.S. FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the U.S. FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the U.S. FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Obtaining and maintaining our patent protection, including patents licensed from third-parties, 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.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial loss, complete loss or unenforceability of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we or our licensors fail to maintain the patents and patent applications covering or otherwise protecting our product candidates, it could materially harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent applications in-licensed from a third-party, any failure on our part to maintain the in-licensed intellectual property could jeopardize our rights under the relevant license and may expose us to liability.

Third-parties might claim that we have not complied with the provisions of the respective governmental patent agencies. For example, third-parties might claim that not all prior art documents, or not all other documents or experiments, were submitted to the respective agencies under appropriate law. Such claims could lead to proceedings that are time-consuming and expensive. Such proceedings can result in abandonment or lapse of a patent or patent application, resulting in partial loss, complete loss or unenforceability of patent rights in the relevant jurisdiction. If such third-party claims are raised in the context of a pending litigation, then such proceedings can also result in a judgment that would require us to pay the other parties' litigation expenses.

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

Even if the patent applications we own or license are issued, competitors may infringe these patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming.

In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put our patents or our licensors' patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings, or other similar enforcement and revocation proceedings, provoked by third-parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares.

Even if resolved in our favor, litigation or other legal proceedings relating to our, our licensor's or other third-parties' intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares. If not resolved in our favor, litigation may require us to pay any portion of our opponents' legal fees. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

By letter dated June 10, 2021, MorphoSys was notified by a licensor of the initiation of arbitration proceedings in the United States. The licensor alleges breach of contract and claims damages for the licensor's argued loss of revenues. Despite the patent expiry in 2018 confirmed by the licensor at the time, this is now disputed and a significantly longer patent term is assumed. Taking into account the associated legal and consulting costs, the potential amount in dispute in the proceedings, based on our current estimates, is in the mid-double-digit million of euros range. A decision by the arbitration court is expected in the first quarter 2023. Based on the current assessment of the facts, MorphoSys believes that the arguments presented are unfounded and that the arbitration will likely be decided in MorphoSys' favor.

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

From time to time, authorities in the United States, the European Union and other government authorities may change the standards of patentability, and any such changes could have a negative impact on our business.

For example, in the United States, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. As a result of these changes, patent law in the United States may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them.

Also, case law may have a substantial impact on the way patents are prosecuted, examined and litigated. This also affects the scope of protection that is available in a specific jurisdiction. In the United States, Amgen Inc. v. Sanofi 872 F.3d 1367 (2017) had an impact on the way antibody claims are examined and litigated.

Developments of patent law in other jurisdictions may impact our business. For example, it is currently not clear what impact the planned introduction of the Unified Patent Court in the European Union will have. Patents that are valid and enforceable under the current system may be considered invalid and/or unenforceable under the new system. Also patents may be invalidated not just in one single jurisdiction, but across all countries of the European Union in one single trial.

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

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

Patents could be issued to third-parties that we may ultimately be found to infringe. Third-parties may have or may obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to identify or correctly interpret third-party patents, or to obtain or maintain a license to any technology that we require may materially harm our business, financial condition, results of operations or prospects. Furthermore, we could be exposed to a threat of litigation.

In the pharmaceutical and biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third-parties seeking to invalidate the patents held by those third-parties or to obtain a judgment that our products or processes do not infringe those third-parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation, inter partes review or opposition proceedings to determine the priority of invention, inventorship or validity of the applicable patent rights which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third-parties initiate litigation claiming that our processes or the processes of our CMOs or CROs, products or uses thereof infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

Any such lawsuit would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third-party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court may order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third-parties and require us to cease using the technology that is at issue or to license the technology from third-parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business, financial condition, results of operations or prospects.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products, methods or uses thereof either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on our business. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity or enforceability of the patents in court. We may not have sufficient resources to bring these actions to a successful conclusion and there is no assurance that such a license would be available or that a court would find in our favor. In addition, if we do not obtain a license, do not develop or obtain non-infringing technology, or fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations or prospects.

We are dependent on third-parties for the prosecution, protection, and enforcement of intellectual property rights relating to some of our products and product candidates.

While we normally seek to obtain the right to control the prosecution, maintenance, enforcement and defense of intellectual property rights related to our products and product candidates, there may be times when our licensors or collaborators control, or have a first right to control, the filing, prosecution, enforcement and defense of such rights. For instance, pursuant to the 2nd amended and restated collaboration and license agreement with Novartis Pharma AG, or Novartis, Novartis has a first right to file, prosecute and enforce all patent rights related to products generated under this agreement. Pursuant to the development and license agreement with GlaxoSmithKline, GSK has a first right to file, prosecute and enforce all patent rights related to otilimab. Pursuant to the development and license agreement with Xencor Inc., Xencor has a first right to file, prosecute and enforce certain patent rights which are in-licensed by us and relate to tafasitamab. Pursuant to the collaboration and license agreement with Incyte Corp., Incyte has a first right to file, prosecute and enforce certain patent rights related to tafasitamab. We cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or the payment of all applicable prosecution and maintenance fees related to our technologies or any of our product candidates. We also cannot be certain that the drafting or prosecution of the licensed patents by our licensors have been conducted accurately and in compliance with applicable laws and regulations, and will result in valid and enforceable patents and other intellectual property rights. If they fail to do so, we could lose our rights to the intellectual property, our ability to develop and commercialize those products or product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

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

Our registered or unregistered trademarks or trade names, as well as the registered or unregistered trademarks or trade names used by our licensees or distributors in relation with our products or product candidates, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other trademarks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers. Over the

long term, 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 materially adversely affected.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators, CMOs, CROs and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third-parties. Our agreements with employees as well as our personnel policies also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property or that we may obtain full rights to such inventions at our election. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. We also face the risk that present or former employees could continue to hold rights to intellectual property used by us, may demand the registration of intellectual property rights in their name and demand damages pursuant to the German Employee Invention Act. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third-parties in their work for us, disputes may arise between us and those third-parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third-party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may not be successful in obtaining necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in-licenses.

We may seek to acquire or in-license product candidates to expand our product candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidates from third-parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify product candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such product candidates.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment.

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the U.S. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, furthermore, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

Our intellectual property agreements with third-parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our 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.

Risks Related to Employee Matters

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

As an innovation-driven and patient-centric company, we are highly dependent on the expertise of the members of our research and development team, as well as the other key functions such as commercial and supply to ensure that we can bring our medicines to our patients with the highest quality and compliance with required standards. In addition, the members of our Management Board are key in developing our long-term strategy and steering all areas of the company. They currently include Jean-Paul Kress, M.D., our Chief Executive Officer, Sung Lee, our Chief Financial Officer and Charlotte Lohmann, our Chief Legal Officer. Effective March 17, 2023, Sung Lee will step down from his position as the Company’s Chief Financial Officer and as a member of the Management Board. Lucinda Crabtree will join the Management Board as Chief Financial Officer presumably in Q2 2023 or Q3 2023 at the latest. Leadership transitions can be inherently difficult to manage, and an inadequate transition of our Chief Financial Officer may cause disruption to our business, including to our relationships with our employees and third-parties. Our Management Board members have fixed-term contracts typically of three years.

Recruiting and retaining qualified management, scientific, clinical, manufacturing, sales and marketing personnel is also critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

Risks Related to Tax Matters

We may be subject to tax audits or disputes or changes in tax laws.

Pending and future tax audits within our group, disputes with tax authorities and changes in tax law or fiscal regulations could lead to additional tax liabilities. We are subject to routine tax audits by the respective local tax authorities. Any additional tax liability could have an adverse effect on our business, financial condition, results of operations or prospects.

The accounting treatment of the payment that MorphoSys AG received from Royalty Pharma in the third quarter of 2021 could be examined by the tax authorities under German tax law in the context of a future tax audit. This examination is considered standard given the amount of the payment. Based on the Company's knowledge of German tax law and supported by tax experts, the Company has concluded that the tax risk assessment is medium in accordance with the Company's internal risk valuation system. Consequently, due to the remaining uncertainty and the significance, a contingent income tax liability in the amount of € 223.8 million is reported (refer to Note 6.2).

Risks Related to our Business and Industry

If we are unable to comply, or have not fully complied, with healthcare fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, transparency and health-information privacy and security laws in our relationships with healthcare professionals, institutional providers, principal investigators, consultants, customers (actual and potential), patients and third-party payors, we could face penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Our relationships with healthcare professionals, institutional providers, principal investigators, consultants, customers (actual and potential), patients and third-party payors are, and will continue to be, subject, directly and indirectly, to healthcare fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, transparency and information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. See the section of this annual report titled "Item 4.B. Business Overview Healthcare Law and Regulation."

Our business operations and activities may be directly or indirectly subject to various fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. As we obtained U.S. FDA approval for one of our proprietary product candidates in 2020 and commercialize this product in the United States, our exposure under such laws increased significantly, and our costs associated with compliance with such laws have increased. If we obtain U.S. FDA approval for additional proprietary product candidates in the future, our potential exposure and the costs associated with compliance will continue to grow. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business.

In the U.S. third party patient assistance programs that receive financial support from companies have also become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs and it is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses and reduce the availability of foundation support for our patients who need assistance.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the information privacy laws mentioned above, among other foreign laws.

The collection, processing, storing, sharing, use, disclosure and protection of personally identifiable information are subject to federal, state, local and foreign laws. The scope of these laws is changing, they are subject to differing interpretations and they may be costly to comply with and may be inconsistent between countries and jurisdictions or conflict with other rules. Numerous jurisdictions are currently considering, or have recently enacted, data protection legislation. In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personally identifiable information ("personal information"). In the United States, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

Globally, we are also subject to stringent privacy and data protection requirements, such as the General Data Protection Regulation ("GDPR"). The GDPR, effective since May 2018, imposes strict regulations regarding the collection, storage and all other processing of personal data including special protections for "sensitive information" which includes health and genetic information of data processes in the EU. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European activities. We could be adversely affected if we fail to comply fully with all of these requirements. Non-compliance with the GDPR can trigger significant fines of up to € 20 million or 4% of total worldwide annual turnover, whichever is higher.

In addition, further to the United Kingdom's (UK) exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £ 17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission ("EC") has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

Significantly, to enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with EEA and UK data protection laws. On June 4, 2021, the European Commission issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission's new standard contractual clauses but has issued a new version of a UK-specific transfer mechanism (i.e. the UK International Data Transfer Agreement or the UK International Transfer Addendum to accompany the European Commission's standard contractual clauses), to enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost.

There may be further divergence between the EEA and the UK. The United Kingdom has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EEA and the UK, and we will need to amend our processes and procedures to align with the new framework.

In the United States, there has been considerable legislative activity at the state level. California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. While there is currently an exception for protected health information that is subject to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and clinical trial regulations, as currently written, the CCPA may impact our business activities. There continues to be uncertainty surrounding the enforcement and implementation of the CCPA exemplifying the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Additionally, a California ballot initiative, the California Privacy Rights Act, or "CPRA," was passed in November 2020 and became effective on January 1, 2023. The CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA, as modified by the CPRA.

While we are currently not subject to the CCPA and will likely not fall under the purview of the CPRA, certain other state laws impose similar privacy obligations. Colorado, Connecticut, Utah and Virginia all passed laws that are similar to the CCPA and we also expect anticipate that more states may enact legislation similar to the CCPA. The CCPA has prompted a number of proposals for new federal and state-level privacy legislation which, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

Furthermore, the use and disclosure of personal health and other private information are subject to regulation in other jurisdictions in which we do business or expect to do business in the future.

Efforts to ensure that our business arrangements will comply with applicable information privacy laws may involve substantial costs. Various jurisdictions around the world continue to propose new laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Additionally, if our collaborators' operations or relationships with healthcare providers, customers, patients and third-party payors are found to be non-compliant with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which could also have a negative impact on us. Even if successful, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. 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.

The use of our investigational medicinal products in clinical trials and the sale of Monjuvi and any other 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 or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially 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 product, 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.

To cover such liability claims, we purchase clinical trial insurances in the conduct of each of our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We expanded our insurance coverage to include the sale of commercial products once we receive marketing approval for any of our proprietary products. 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 a material adverse effect on our business, prospects, financial condition and results of operations, including, but not limited to:

- decreased demand for our future product candidates;
- adverse publicity and injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- compensation in response to a liability claim;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize our products or product candidates.

We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. 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, financial condition, results of operations or prospects.

Price controls may be imposed in certain markets, which may adversely affect our future profitability.

In some countries, particularly Member States of the European Union, the pricing of prescription medicinal products is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, in particular, in many Member States of the European Union, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our

product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially adversely affected.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. See the section of this annual report titled "Item 4.B. Business Overview Healthcare Reform."

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. There have been several U.S. congressional inquiries, Administrative actions, and proposed bills 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 support programs, and reform government program reimbursement methodologies for drugs. Further, various regulatory proposals and policies have been issued to address the reimportation of drugs. For example, in October 2020, the U.S. FDA issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an U.S. FDA-approved drug or biological product that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. Individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs. To the extent that products that MorphoSys commercializes are subject to the legislative, regulatory, or other measures that promote or allow the reimportation of drugs the prices we receive for our products could decreases, which would adversely affect our future revenues and prospects for profitability.

In addition, individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing.

The policies of the U.S. FDA or similar regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 cannot predict whether future healthcare legislative or policy changes will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us.

Additionally, in the case of any United States federal government shutdown, now or in the future, that continued for a prolonged period of time, processes related to coverage and reimbursement determinations could be delayed. Resolving such delays could force us or our collaborators to incur significant costs, could limit our allowed activities or the allowed activities of our collaborators, could diminish any competitive advantages that we or our collaborators may attain or could adversely affect our business, financial condition, results of operations and prospects, the value of our common stock and our ability to bring new products to market as forecasted. Even without such delay, there is no guarantee we will receive approval or reimbursement for our product candidates on a timely basis, or at all.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program, and the Tricare Retail Pharmacy program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. For calendar quarters beginning January 1, 2022, manufacturers will need to start reporting the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program. Currently, only manufacturers participating in the Medicaid Drug Rebate Program are obligated to do so.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. The Centers for Medicare & Medicaid Services, or CMS, could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective in April 2016, to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. In December 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); and provided definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022). Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate Program and related policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation.

The HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective in January 2019. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated this regulation or other requirements of the program could negatively impact our financial results. Moreover, HRSA newly established an administrative dispute resolution, or ADR, process under a final regulation effective January 2021, for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer’s drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. This ADR regulation has been challenged in separate litigation instituted by PhRMA and by pharmaceutical manufacturers in multiple federal courts. Under the ADR final rule which became effective in January 2021, an ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. HRSA could also decide to terminate a manufacturer’s agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer’s covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program. In November 2022, HRSA issued a proposed rule to revise the ADR procedures contained in its January 2021 final regulation for disputes arising under the 340B drug pricing program between covered entities and manufacturers.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B Program. The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the U.S. Department of Veterans Affairs, FSS or Tricare Retail Pharmacy, or Tricare, programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We and our contract manufacturers and our suppliers could be subject to liabilities, fines, penalties or other sanctions under environmental, health and safety laws and regulations if we or they fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on our business.

We currently rely on and expect to continue to rely on third-parties for the manufacturing and supply of active pharmaceutical ingredients, or API, and drug products of our product and product candidates. These third-parties are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, transportation, use, storage, treatment and disposal of hazardous materials and wastes. Although we have auditing rights and obligations (according to cGMP regulations for sponsors of clinical trials) with all our CMOs for production of API and drug products and finished drug product, we do not have control over a manufacturer’s or supplier’s compliance with environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or in certain circumstances, an interruption in operations, any of which could adversely affect our business and financial condition if delayed manufacturing activities impact our clinical development activities and/or our commercial supply chain.

With respect to any hazardous materials or waste which we are currently, or in the future will be, handling, using, storing or disposing of, we cannot eliminate the risk of contamination or injury from these materials or waste, including at third-party disposal sites. In the event of such contamination or injury, we could be held liable for any resulting damages and liability. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with applicable environmental, health and safety laws. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

Our internal computer systems and physical premises, or those of our strategic collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs and our manufacturing operations.

Our internal computer systems and those of our current and any future strategic collaborators, vendors, and other contractors or consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, cybersecurity threats, terrorism, war and telecommunication and electrical failures. Cyber incidents have been increasing in sophistication and frequency and can include third parties gaining access to our data using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, ransomware, card skimming code, and other deliberate attacks and attempts to gain unauthorized access. Because the techniques used by computer programmers who may attempt to penetrate and sabotage our network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques.

While we have not experienced any material computer system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other disruptions. These cyber-attacks could be carried out by threat actors of all types (including but not limited to nation states, organized crime, other

criminal enterprises, individual actors and/or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by any of these threat actors. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any breach, loss, or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, or claims for damages either under the GDPR and relevant member state law in the EU, other foreign laws, and the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and other relevant state and federal privacy laws in the United States.

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

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an U.S. FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the U.S. FDA until four years following the date that the referenced product was first licensed by the U.S. FDA. In addition, the approval of a biosimilar product may not be made effective by the U.S. 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 U.S. 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 U.S. FDA. On July 9, 2021, President Biden issued an executive order directing the U.S. FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition. As a result, the ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty and evolving interpretation. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the U.S. FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

One or more of our product candidates approved as a biological product under a BLA may qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the U.S. 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.

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

On July 15, 2021, MorphoSys completed its acquisition of Constellation, adding two clinical stage assets pelabresib and tulmimetostat (CPI-0209) to its pipeline. We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition, including the Constellation acquisition, that delays or prevents us from realizing their expected benefits or enhancing our business. When acquiring businesses with promising products or technologies, we may not be able to realize the benefit of acquiring such businesses if, for instance, we are unable to successfully integrate them with our existing operations and company culture. We cannot assure you that, following any such acquisition, including the Constellation acquisition, we will achieve the expected synergies to justify the transaction. If we are unsuccessful in realizing any of the benefits following an acquisition, we may incur impairment charges in respect of the assets acquired, which could adversely affect our results of operations.

A “risk run” in the fall of 2021 identified a short-term, moderate organizational risk related to the operational integration of Constellation into the MorphoSys Group. Should MorphoSys be unable to integrate the acquired company into the Group’s structures and processes within a reasonable period of time, there is a risk that potential synergies may fail to be realized as planned. This risk also includes the potential departure of employees in key positions with specific background knowledge. To mitigate this risk, a project team has been formed consisting of experienced Constellation and MorphoSys employees from various departments that is focused on key aspects of the integration. By the end of the 2022 financial year, significant progress

had already been made in integrating the companies' operations. A global operating model was rolled out to manage major functions across locations and facilitate the business and decision-making processes. While the measures taken have greatly reduced integration risk, a financial risk exists that potential synergies will not be leveraged as planned.

We are subject to currency exchange rate fluctuations.

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 U.S. dollar and the euro. Our functional currency is the euro and a substantial proportion of our revenues and operating expenses is paid in U.S. Dollars. We also receive payments from our collaboration partners in U.S. dollars and we regularly acquire services, consumables and materials in U.S. dollars. As a result, our business may be affected by fluctuations in foreign exchange rates between the euro and the U.S. dollar, which may also have a significant impact on our reported results of operations and cash flows from period to period.

Risks Related to Ownership of Our Securities

We do not currently intend to pay dividends on our securities, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our shares.

We have never declared or paid any dividends on our ordinary shares and do not intend to do so in the foreseeable future. You are not likely to receive any dividends on our shares, and the success of an investment in our shares will depend upon any future appreciation in its value. Investors may need to sell all or part of their holdings of our shares after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that our shares will appreciate in value or even maintain the price at which our shareholders have purchased our shares.

Holders of our ADSs may not be able to participate in any future preemptive subscription rights issues or to elect to receive dividends in shares, which may cause dilution to their holdings.

Under German law, the existing shareholders have a preemptive right to subscribe for shares offered in proportion to the number of shares they hold in connection with any offering of shares. However, a shareholders' meeting may vote, by a majority, which represents at least three quarters of the share capital represented at the meeting, to waive this preemptive right provided that, from the company's perspective, there exists good and objective cause for such waiver.

Certain non-German shareholders may not be able to exercise their preemptive subscription rights in our future offerings due to the legislation and regulations of their home country. For example, ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

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

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

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

The Nasdaq Listing Rules include certain accommodations in the corporate governance requirements that allow foreign private issuers to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of Nasdaq. The application of such exceptions requires that we disclose the Nasdaq Listing Rules that we do not follow and describe the German corporate governance practices we do follow in lieu of the relevant Nasdaq corporate governance standard. We continue to follow German corporate governance practices in lieu of the corporate governance requirements of Nasdaq in certain respects. In particular, we follow German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of our code of conduct to our Supervisory Board, proxy solicitation in connection with shareholders' meetings, and obtaining shareholder approval in connection with the issuance of shares in connection with an acquisition, change of control transactions, the establishment of or material amendment to any equity-based compensation plans and the issuance of shares in a private placement in excess of 20% of the outstanding share capital at less than the greater of book or market value. To this extent, our practice varies from the requirements of Nasdaq. See the sections of this annual report titled "Item 6 —Directors, Senior Management and Employees" and "Item 16G —Corporate Governance."

U.S. holders of ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

A non-U.S. corporation will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, more than 25% (by value) of the stock.

Based on the current composition of our income and valuation of our assets, we believe it is possible that we could be treated as a PFIC for the 2022 taxable year, and we may also be treated as a PFIC in any future taxable year. However, a separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change. In particular, the total value of our assets for purposes of the asset test generally will be calculated taking into account the market price of our ADSs or ordinary shares, which may fluctuate considerably. Fluctuations in the market price of the ADSs and ordinary shares may result in our being a PFIC for any taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position.

If we were to be or become a PFIC for any taxable year during which a U.S. holder (defined below in "Taxation—U.S. Taxation") holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. holder. See the section of this annual report titled "Item 10 E. Taxation—U.S. Taxation—PFIC Rules."

The interpretation of the treatment of ADSs by the German tax authorities is subject to change.

The specific treatment of ADSs under German tax law is based on administrative provisions by the fiscal authorities, which are not codified law and are subject to change. Tax authorities may modify their interpretation and the current treatment of ADSs may change, as the circular issued by the German Federal Ministry of Finance (BMF-Schreiben), dated May 21, 2019, reference number IV C 1 – S 1980-1/16/10010 :001, shows. According to this circular, ADSs are not treated as capital participation (Kapitalbeteiligung) within the meaning of Section 2 Para. 8 of the Investment Tax Code (Investmentsteuergesetz). Such changes in the interpretation by the fiscal authorities may have adverse effects on the taxation of investors.

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

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2023.

In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares are 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 cannot 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.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher than the costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP rather than IFRS. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost, and we would still be required to prepare financial statements in accordance with IFRS under the rules of the Frankfurt Stock Exchange. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on United States stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

We will continue to incur increased costs as result of being a public company.

As a public company with ADSs listed on the Nasdaq Global Market, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, impose various requirements on the corporate governance practices of public companies. These and other rules and requirements may increase or change, resulting in an increase of our legal and financial compliance costs. Operating as a public company also makes it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. It may also be more difficult for us to attract qualified persons to serve on our board of directors or as executive officers.

U.S. investors may have difficulty enforcing civil liabilities against our company and members of our Supervisory Board and Management Board and the experts named in this report.

We are incorporated under the laws of Germany. The majority of our assets are located outside the United States and currently two of the three members of our Management Board and three out of six Supervisory Board members reside outside of the United States. As a result, effecting service of process upon such persons may require compliance with international treaty procedures that could cause delay and in some case interfere with establishing personal jurisdiction in front of U.S. courts. The United States and Germany do not currently have a treaty providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment rendered by a U.S. court based on civil liability would not automatically be recognized or enforceable in Germany. Therefore enforcing against members of our Management Board or Supervisory Board or against us, judgments obtained in U.S. courts' that are predicated upon the civil liability provisions of the U.S. federal securities laws may be impossible under German law as a result of public policy or jurisprudence providing defenses for German nationals. Foreign courts may refuse to consider claims brought under U.S. securities laws on either procedural grounds or substantive grounds. Even if a foreign court is willing to decide the merits of such a claim, it may decide to apply the law of the jurisdiction in which the foreign court is located, rather than U.S. law.

Further, if a foreign court applies U.S. law, the burden of proving applicable U.S. law will fall on the party making the claims, a process that may be time-consuming and costly. Procedural matters are typically governed by the law of the jurisdiction in which the foreign court is located.

The rights of shareholders in a stock corporation subject to German law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a German stock corporation with our registered office in Germany. Our corporate affairs are governed by the laws governing stock corporations incorporated in Germany and our articles of association. The rights of shareholders and the responsibilities of members of our Management Board (Vorstand) and Supervisory Board (Aufsichtsrat) may be different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our Management Board and Supervisory Board may take into account a broad range of considerations, including our interests, the interests of our shareholders, employees, creditors and, to a limited extent, the general public. 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. See the section of this annual report titled "Item 16G—Corporate Governance".

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.

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 conducted by us in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing conducted 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our shares.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition, or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets, including by the recent global political and military events, the COVID-19 pandemic, or any other health epidemic. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The ongoing Russian war against Ukraine adds uncertainty, continuing to take a strong human and economic toll in the two countries at war and beyond, particularly in Europe.

Item 4. Information on the Company.

A. History and Development of the company

MorphoSys AG was founded in 1992 in Martinsried, Germany, and was converted to a stock corporation on March 3, 1998 under the laws of Germany with an indefinite duration. Our legal and commercial name is MorphoSys AG. We were registered in the commercial register of the local court of Munich under number HRB 121023 on June 30, 1998. In 1999, MorphoSys was listed on the Frankfurt Stock Exchange, trading under the ticker symbol “MOR”. In 2014, MorphoSys joined the TecDAX index, and since September 2021, MorphoSys is part of the SDAX Index. In April 2018, following a U.S. initial public offering, American Depositary Shares of MorphoSys began trading on the Nasdaq, also under the symbol “MOR”. In July 2018, we established a wholly owned subsidiary, MorphoSys US Inc., to build our commercial infrastructure in the United States. MorphoSys US Inc. is the company’s agent in the United States and is located at 470 Atlantic Avenue, 14th Floor, Boston, Massachusetts 02210.

Our registered office is located at Semmelweisstrasse 7, 82152 Planegg, Germany, and our telephone number is +49 89-89927-0. Our website is *www.morphosys.com*. Information contained on our website is not incorporated by reference into this annual report, and you should not consider information contained on our website to be part of this annual report or in any other filings we make with the SEC, or in deciding whether to purchase or sell our ADSs. Material non-financial aspects are taken into account in a separate "Non-Financial Group Report," which is available on our website.

The SEC maintains an internet site at http://www.sec.gov that contains reports, information statements, and other information regarding issuers that file electronically with the SEC.

Principal Capital Expenditures:

In the years ended December 31, 2022, 2021 and 2020, our expenditures for property, plant and equipment were € 1.9 million, € 3.7 million, and € 4.3 million, respectively. In the years ended December 31, 2022, 2021 and 2020, our expenditures for intangible assets were € 13.3 million, € 22.5 million, and € 44.9 million, respectively.

In the course of the acquisition of Constellation in 2021, MorphoSys acquired € 719.4 million in intangible assets and € 1.6 million in property, plant and equipment.

For our commitments for capital expenditures, we refer to Item 5.B.