Risk Factors Comparison 2025-02-21 to 2024-02-23 Form: 10-K

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You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10- K. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations and the market price of our common stock. Risks related to commercialization and our products **Uncertainty and** ~~Evolving~~ **evolving** dynamics **our products,which** may adversely impact our accounting estimates. ~~Furthermore~~ **Additionally** ,we may seek to enter into agreements with others to utilize their marketing and distribution capabilities,but may be unable to enter into agreements on favorable terms,if at all.If we rely on others to commercialize our products,our revenues may be lower than if we commercialized these products ourselves.In addition,we may have little or no control over such third parties' sales efforts.If our partners commit insufficient resources to commercialize our products,and we cannot independently develop necessary marketing capabilities,we may be unable to generate sufficient product revenue to sustain our business.The ~~vaccine market,and~~ pharmaceutical market ~~more generally,~~ is intensely competitive,and we may **not compete effectively** in the market for **existing or new products, treatment methods or technologies. We compete with well- established, larger pharmaceutical companies for sales of our products, including against Pfizer and Sanofi for sales of our** COVID **vaccine and Pfizer and GSK for our RSV vaccine. These competitors (and others against whom we may compete now or in the future) have greater resources and experience than us across all stages of drug development and commercialization. For example, in 2024, our share of the COVID vaccine market declined due in part to increased commercial competition. Additionally, we faced continued exclusion from many European markets by a pandemic -** ~~19~~ **era competitor contract with the European Commission. For RSV** vaccines ~~are likely~~ **, we entered a market already occupied by** ~~to~~ **two** ~~impact our financial results, which~~ **larger competitors and may continue to face difficulties achieving market** ~~are~~ **share . These competitors** ~~likely to result in lower product revenues in 2024 than we~~ have **exploited and may in the future exploit their greater size, infrastructure, resources and** ~~experienced~~ **experience to gain advantages** in **contracting with customers by** ~~recent years. Through 2023~~ , ~~our only approved~~ **among other things, bundling their** ~~product~~ **products , leveraging larger supply chains** and **greater purchasing power and utilizing their** ~~sole source of product sales has been our COVID- 19 vaccine. The~~ global **networks** ~~market is transitioning to an endemic, commercial market for COVID- 19 vaccine sales, resulting in different market and production dynamics than during the pandemic, including a more fragmented customer base, less predictability in orders, greater seasonality of demand, increased distribution costs, and higher costs of goods sold. Furthermore, our assumptions regarding the product presentation that will be accepted or preferred by the market (e. g., single- dose presentation), which could vary by market, may prove incorrect~~ . In addition, certain U. S. private vaccine market practices, including regarding discounts, rebates and returns, may cause us to realize significantly lower revenues than list prices. We may also be adversely affected by similar market practices outside of the United States. **In some instances, our competitors have been able to offer more attractive terms than we can, and they may continue to do so in the future. More generally, the pharmaceutical market is intensely competitive and evolving. Other companies, academic institutions, governmental agencies and public and private research organizations are developing products that may compete with programs in our development pipeline. These competitors may have products that have already been approved and accepted by the medical community or are in later stages of development. For example, we are developing a seasonal flu vaccine, for which there is a well- developed market, and we may be unsuccessful in developing a product or achieving market share.** We ~~recognized $ 6~~ **may need to offer more favorable terms to gain market share (which we may be unable to do), which may negatively impact our profitability** . ~~7 billion~~ **Additionally, competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses** of **developing and commercializing our products. Additionally, any products that we develop may struggle to compete against those of our competitors for a variety of reasons, including relative safety and effectiveness, degree of any side effects, shelf- life, ease of administration and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals, the availability and cost of manufacturing, distribution, marketing and** sales **capabilities, price, reimbursement coverage and patent protection. Even if our products demonstrate superiority to those of competitors, consumers, retailers and the public may fail to appreciate that benefit, or existing purchase commitments** for ~~COVID~~ **a competitor' s product may discourage them from purchasing from us. These factors, or the perception of these factors, could lead to a competitor' s product being more successfully commercialized. Further, the mRNA medicines field is growing rapidly, with increased competitive pressure from large and more established pharmaceutical companies. The actual or perceived success or failure of others may adversely impact our ability to commercialize our products. We may be unsuccessful in executing our cost efficiency and portfolio prioritization efforts. Our broad clinical success and recent commercial challenges have necessitated a more selective and paced approach to our research and development investment. If we do not successfully implement our cost efficiency and prioritization programs, we may fail to meet our cash breakeven goals. Furthermore, as we pursue and fund the development of our prioritized programs, we may forego or delay pursuit of other opportunities that could later prove to have greater commercial potential. If our prioritized programs are unsuccessful, or not as successful as other programs could have been, we may be unable to realize a sustainable return on our investments and or achieve long - term growth** ~~19 vaccines delivered in 2023, compared to $ 18~~ . ~~4 billion~~ **We have** in **the past** ~~2022 and $ 17. 7 billion in 2021~~ , ~~as~~ **and may in the future, seek to resize our manufacturing infrastructure to reflect anticipated** demand for **our products** ~~COVID- 19 vaccines declined~~ . **This resizing may result** ~~We anticipate that sales of~~

COVID- 19 vaccines are likely to be lower in **our** 2024 than 2023. We expect the market for COVID- 19 vaccines to evolve based on a number of factors, including - **incurring** medical need, viral evolution, public health authority recommendations and consumer motivation to vaccinate. In the third quarter of 2023, we significantly resized our manufacturing infrastructure as we shifted to an endemic COVID- 19 vaccine market, and we may in the future incur additional costs associated with exiting commitments **, such as** with suppliers for raw materials and contract manufacturing organization **organizations** (CMOs). As **Additionally, as** a result of lower demand **for our products** , we have experienced, and may in the future experience, increased costs with respect to raw material suppliers as we seek to exit or modify our purchase commitments. Further, we have entered, and may in the future enter, into non- cancellable or take- or- pay purchase commitments for raw materials that require a long lead time to procure, increasing our commitment exposure. If we cannot effectively manage evolving demand dynamics, our business, financial condition, results of operations and prospects may suffer. Additionally, we may not see demand materialize for our products consistent with our projections. This may lead to lower than expected commercial sales or requests to defer, renegotiate or cancel existing contracts. Further, we may find that we need to dedicate greater resources to our commercial efforts than anticipated, and we may not realize a return on this investment. We may encounter difficulties producing or shipping our products consistent with our projections or future contractual commitments. We may encounter difficulties producing or shipping our products, including our COVID- 19 vaccine or other future products, consistent with our current expectations or on the terms set forth in our supply agreements or future sales contracts. Our ability to commercialize our products depends on our manufacturing capability, both at our own facilities and those of our partners, particularly for fill- finish capabilities. Further, adapting our COVID- 19 vaccine to new variants requires significant coordination with our partners, including for the sourcing of raw materials and production. Any capacity or production issues or delays experienced by our partners may cause us to fail to meet obligations under our supply agreements. We have limited sales, distribution and marketing experience and may be unable to effectively establish such capabilities or supplement our capabilities by entering into agreements with third parties. We have limited experience as a commercial organization and face risks and uncertainties as we shift to an endemic COVID- 19 vaccine market and prepare for the commercial launch of other medicines, including our anticipated RSV vaccine launch in 2024. As a result of this limited commercial experience, we may be unsuccessful in accurately anticipating future rates of return for - **or delayed** our products, which may adversely impact....., and we may not compete effectively in **updating** the market for existing products, new treatment methods and new technologies. The pharmaceutical market is intensely competitive and evolving. Many companies, academic institutions, governmental agencies and public and private research organizations are developing products for the same diseases that we are targeting or expect to target and such other parties may have: • greater resources and experience than us at every stage of drug discovery, development, testing, approval, manufacturing and commercialization; • multiple products that have been approved or are in late stages of development; and • arrangements in our target markets with purchasers, governments, leading companies and research institutions. We face intense competition with respect to our COVID - 19 vaccine, and it may not continue to compete favorably with existing or future vaccines and treatments. Other vaccines or treatments could prove to be safer, more effective, more convenient, have fewer side effects, be easier to ship or distribute or able to be developed at a lower cost than our vaccine. Even if our products demonstrate superiority to those of competitors, consumers and the public may fail to appreciate that benefit, or existing purchase commitments for a competitor' s product may discourage them from purchasing from us. These factors, or the perception of these factors, could lead to a competitor' s vaccine or treatment being more successfully commercialized. Further, the mRNA medicines field is growing rapidly, with increased competitive pressure from large and more established pharmaceutical companies. The actual or perceived success or failure of others may adversely impact our ability to commercialize our products. We also will face competition from products that have already been approved and accepted by the medical community to treat certain conditions we target. For example, we are developing a seasonal flu vaccine, for which there is a well- developed market, and we may be unsuccessful in developing a product or achieving market share. Our RSV vaccine, which we expect to launch beginning in 2024, will also face competition from existing RSV vaccines. In markets that we enter after competitors have already introduced a competing product, we may have difficulty achieving market share. Further, we may need to offer more favorable terms to gain market share in an existing market or to compete in a new market, which may negatively impact our profitability. If we successfully develop and obtain approval for other product candidates, we may compete with products under development by competitors based on many factors, including the relative safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Our competitors may be more successful in commercializing their products, which would adversely affect our business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved. We may be unsuccessful or delayed in updating our COVID- 19 vaccine to protect against future variants of the SARS- CoV- 2 virus , and updated versions of our COVID- 19 vaccine may not protect against such variants . **New** As the SARS- CoV- 2 virus continues to evolve, new strains of the virus may prove **be** more transmissible or cause more severe **disease** forms of COVID- 19 than earlier strains. Our current COVID - 19 vaccines could be ineffective, or less effective than desired, in protecting against these new variants. Additionally, our decisions regarding vaccine development will be informed by guidance from the FDA and foreign regulatory **regulators** authorities , which may impact the timing of development for our COVID - 19 vaccines. We may experience delays in producing variant- specific vaccines. Further, different **Different** regulators **have in the past and** may **in the future** issue differing **varying** guidance regarding vaccine composition or populations who should receive a vaccine. If our efforts to develop variant- specific vaccines against future variants are **not as** unsuccessful - **successful as** , we are slower than competitors to develop such vaccines or **our** our vaccines prove less effective than competitors' vaccines , we could suffer reputational harm, loss of market share and adverse financial results. Additionally, we

may expend significant resources adapting our vaccines or conducting clinical trials to protect against variants, but a market for our adapted vaccines may fail to develop or demand may not align with our projections or cost expenditures. The commercial success of our products ~~will depend~~ **depends** on the degree of market acceptance by physicians, patients, third- party payors and others in the medical community ~~. The commercial success of our products will depend in part on the medical community, patients and third- party or governmental payors accepting mRNA medicines, and our products in particular, as medically useful, cost- effective and safe~~ . The degree of market acceptance of our products will depend on numerous factors, including: • ~~the~~ **efficacy and** potential ~~efficacy and~~ advantages over alternative treatments; • the ~~ability to offer products at competitive prices; • the~~ duration of protection provided by our products compared to those of **our** competitors; • acceptance of mRNA products generally and the availability of competing non- mRNA medicines that may be preferred by the medical community or the public; • **safety and** the prevalence and severity of any side effects, including any limitations, restrictions (including for use together with other medicines) or warnings contained in a product' s approved labeling; • the prevalence and severity of any side effects resulting from checkpoint inhibitors or other products or therapies with which our products are co- administered; • relative convenience and ease of administration; • the willingness of the target patient population to try, and physicians to prescribe, new therapies; • the strength of marketing and distribution support and timing of market introduction of competitive products; • whether our product presentation meets customer demand (e. g., for single- dose presentations, or combination vaccines); • publicity **and health authority communications** concerning our products or competing products and treatments; and • **product cost and** sufficient third- party insurance coverage or reimbursement, and patients' willingness to pay out- of- pocket in the absence of third- party coverage or adequate reimbursement. Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance will be unknown until after it is launched. Our efforts to educate the medical community and third- party payors on the benefits of our products may require significant resources ~~, especially due to the complexity of our programs,~~ and may never be successful. Sales of pharmaceutical products depend on the availability and extent of reimbursement from third- party payors, and we may be adversely impacted by changes to such reimbursement policies or rules. Sales of pharmaceutical products in general depends to a significant extent on adequate coverage, pricing and reimbursement from third- party payors. When a new product is approved, the availability and extent of government and private reimbursement, and the pricing, for that product may be uncertain. ~~For example, it is uncertain whether any combination respiratory vaccine we develop, if approved, would qualify for coverage under Medicare Part B.~~ Additionally, pricing and reimbursement for any product we develop may be adversely affected by **various** ~~a number of~~ factors, including: • changes in, and implementation of, federal, state or foreign government regulations or private third- party payors' reimbursement policies; • pressure by employers on private health insurance plans to reduce costs; and • consolidation and increasing assertiveness of payors seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value. Our ability to set the price for any product we develop will vary significantly by country. Our inability to obtain and maintain adequate prices in a particular country may limit the revenues from our products within that country and adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. This may create the opportunity for third- party cross- border trade or influence our decision whether to sell a product, thus adversely affecting our geographic expansion plans and revenues. Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co- pay or co- insurance obligations and limitations on patients' use of commercial manufacturer co- pay payment assistance programs. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers. Additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products, particularly our therapeutic products or those that are individualized for a particular patient. Coverage and reimbursement by a third- party payor may depend **on various** ~~upon a number of~~ factors, including the third- party payor' s determination that use of a product is a covered benefit under its health plan, safe, effective and medically necessary, appropriate for the specific patient, cost- effective and neither experimental nor investigational. Additionally, target patient populations for some of our product candidates may be small (e. g., for rare genetic diseases) or require individual customization (e. g., for our INTs). The pricing and reimbursement of our medicines, if approved, must be adequate to support commercial infrastructure. If we cannot obtain adequate levels of reimbursement, we may be unable to successfully market and sell our products. The manner and level at which reimbursement is provided for services related to our products (e. g., for administration to patients) is also important. Inadequate reimbursement for such services may discourage physicians from prescribing or recommending our products, adversely affecting our ability to market or sell those products. The market opportunities for our products and product candidates may be smaller than we believe, or we may be unable to successfully identify clinical trial participants. We focus certain of our research and product development activities on treatments for severe rare genetic diseases, where the patient populations are difficult to ascertain or small. Additionally, ~~we expect to initially seek approval of our INT and intratumoral immuno- oncology product candidates for use by patients with relapsed or refractory advanced disease, i. e., the populations the FDA often approves new therapies for initially. If any such medicines prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first- line therapy. There is no guarantee that~~ our products **may only** ~~, if approved, would~~ be approved for ~~earlier~~ **certain populations or** lines of **treatment** ~~therapy and, prior to any such approvals, we may have to conduct additional clinical trials~~ . Our estimates of addressable patient populations are based on our beliefs, and have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may

change the estimated incidence or prevalence of these diseases. The number of trial participants may be lower than expected and potential clinical trial participants or patients may not be otherwise amenable to treatment with our product candidates or products, or new clinical trial participants or patients may become increasingly difficult to identify or gain access to. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, these medicines may never be profitable. **Furthermore, the size of markets that we target may be impacted by health authority recommendations regarding who should receive our products, which may be impacted by the new U. S. federal government administration.** Risks related to our pipeline, product development and regulatory review **If we cannot obtain** ~~Preclinical development is lengthy and uncertain~~ , ~~especially for~~ - **or** ~~mRNA medicines~~ **are delayed in obtaining** , **regulatory approvals** and **advisory committee recommendations, we will be unable to effectively commercialize,** ~~our~~ - **or** ~~preclinical programs~~ **will be delayed in commercializing,** ~~or~~ **our** product candidates ~~may be delayed or terminated~~ . ~~Much of our pipeline is in~~ **Any products we may develop are subject to comprehensive regulation by the FDA and comparable foreign regulators. To obtain required regulatory approvals to commercialize any product candidate, we must demonstrate through extensive** preclinical **studies** ~~development,~~ and ~~these programs could be delayed or not advanced into the clinic. Before we can initiate~~ clinical trials **that our products are safe and effective** for **their intended use. In addition, regulators conduct pre- approval inspections and negative findings may lead to delay in approval and failure to commercialize** a product candidate ~~, we must complete extensive preclinical studies, including IND- enabling good laboratory practice (GLP) toxicology testing~~ . **Even once approved** ~~We must also complete extensive work on Chemistry~~ , **products may** ~~Manufacturing, and Controls (CMC) activities to~~ be ~~included in~~ **subject to recommendations from advisory committees, such as the ACIP, before or after they** ~~an~~ **can** ~~IND submission~~ **be brought to market** . ~~CMC activities~~ **To date, we have only received regulatory approvals** for **our COVID** ~~mRNA medicines require extensive manufacturing processes~~ and ~~analytical development~~ **RSV vaccines** , ~~which is uncertain~~ and **our current or** ~~lengthy. We have had and may in the~~ future ~~have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our~~ product candidates **may never obtain regulatory approval** ~~. If we must produce new batches, our~~ - **or advisory committee recommendations** ~~preclinical studies could be delayed~~ . We ~~cannot be certain of the timely completion of our preclinical testing and studies, whether the FDA or other regulators will accept the results or if the outcome of our preclinical testing, studies and CMC activities will ultimately support further development of our programs. As a result, we~~ may **need** ~~be unable~~ to ~~submit INDs or similar~~ **rely on third parties to assist us in making** applications for ~~our~~ **marketing approvals.** ~~preclinical~~ **Preclinical studies** ~~programs on the timelines we expect, if at all,~~ and ~~such applications may not result in the FDA or other regulators allowing~~ clinical trials **conducted in one country may not be accepted by regulators elsewhere, and regulatory approval in one country does not guarantee approval in another. Regulators may require that we conduct additional clinical trials** to ~~begin~~ **support our applications for** approval **beyond our clinical development plans,which may result** in **increased expense and delays** ~~one country does not guarantee regulatory approval~~ in ~~another~~ **bringing our products to market** .Additionally,the process of obtaining marketing approvals ~~,both in the United States and abroad,~~ is expensive,time- consuming and uncertain,and can vary substantially based **on many** ~~upon a variety of~~ factors,including the type,complexity and novelty of the product candidates involved.Changes in marketing approval policies during the development period,changes in law or changes in regulatory review may delay the review of a submitted product application.The FDA and ~~comparable~~ foreign regulators have substantial discretion in the approval process and may refuse to accept any marketing approval application or may decide that our data are insufficient for marketing approval and require additional preclinical,clinical or other studies.In addition,varying interpretations of the data obtained from preclinical and clinical testing could delay,limit or prevent marketing approval of a product candidate.Additional delays or non- approval may result if an FDA ~~Advisory~~ **advisory** ~~Committee~~ **committee** or other ~~regulatory~~ - **regulator** ~~authority~~ recommends non- approval or restrictions on approval ~~.~~ . Clinical development is lengthy and uncertain, and our clinical programs may be delayed or terminated, or may be more costly to conduct than we anticipate. Clinical testing is expensive, complex and lengthy, and its outcome is inherently uncertain. Most product candidates that commence clinical trials are never approved as products. **Although we** ~~We may be unable to initiate, may experience delays in or may~~ have ~~to~~ **demonstrated historical success with our platform technology, we may not** ~~discontinue~~ --- **continue to realize the same levels of success with** clinical trials **in the future** ~~for our product candidates~~ . We and our strategic collaborators also may experience unforeseen events during, or as a result of, any clinical trials that we or they conduct that could delay or prevent us or them from successfully developing our product candidates and gaining approval from regulators. Events that might prevent us from proceeding with clinical trials could include: • regulators, Institutional Review Boards (IRBs) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective contract research organizations (CROs); • changes to the scale or site of our manufacturing could cause significant delays or changes in our clinical trial designs; • the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results; • we may be unable to establish or achieve clinically meaningful endpoints for our studies; • if we make changes to our product candidates after clinical trials have commenced (which we have done in the past), we may be required to repeat earlier stages or delay later stages of clinical testing; • clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs; • our product candidates, or other medicines in the same class as ours, may ~~have~~ **cause significant adverse events or other** undesirable side effects, such as the immunogenicity of the LNPs or their components, the immunogenicity of the protein made by the mRNA or degradation products, any of which could lead to serious adverse events, or other effects ~~; • administration of our LNPs could lead to systemic side effects related to the components of the LNPs and could contribute to immune reactions, infusion~~

~~reactions, complement reactions, opsonization reactions, antibody reactions or reactions to PEG- lipids; • significant adverse events or other side effects could be observed in our clinical trials~~; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the applicable clinical trial protocol or withdraw from the applicable clinical trial, which may require that we add new clinical trial sites; • regulators may impose a complete or partial clinical hold on a clinical trial **(or a trial of another company working on mRNA medicines)** , or we or our investigators, IRBs or ethics committees may suspend or terminate clinical research or trials for various reasons, including **quality events,** noncompliance with regulatory requirements or a finding that participants are being exposed to an unacceptable benefit- risk ratio ~~; • regulators may impose a complete or partial clinical hold on clinical trials of other companies working on mRNA medicines; • the cost of preclinical or nonclinical testing and studies and clinical trials of product candidates may be greater than anticipated~~ ; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate; • safety and efficacy concerns regarding our product candidates will be considered by us and by the FDA and other regulators as we pursue clinical trials of new product candidates, develop effective informed consent documentation and work with IRBs and scientific review committees (SRCs); • safety or efficacy concerns could arise from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; • adverse side effects could be observed in future clinical trials where our product candidates are administered in combination with other therapies (such as the co- administration of our INT product candidate, mRNA- 4157); **• delays in developing assays acceptable to the FDA or other regulators;** and • a lack of adequate funding to continue a particular clinical trial ~~. Before commencing later~~ **, including due to higher** ~~- stage clinical trials for our programs, we must develop assays to measure and predict the potency of a given dose of our product candidates. Any delay in developing assays that~~ **than - anticipated costs** ~~are acceptable to the FDA or other regulators could delay the start of future clinical trials~~ . Additionally, we have conducted and may conduct in the future " open- label " clinical trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate, an approved drug or a placebo. The results from an open- label clinical trial may not be predictive of future clinical trial results from a controlled environment with a placebo or active control. Further, the FDA or other regulators may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Significant preclinical or nonclinical testing and studies or clinical trial delays for our product candidates could allow our competitors to bring products to market before we do and could harm our business ~~, financial condition and prospects significantly~~ . There are risks ~~that are~~ unique to each of our programs and modalities and risks ~~that are~~ applicable across programs and modalities **, which** . ~~These risks~~ may ~~impair~~ **delay or prevent** our ability to advance one or more of our programs in clinical development, obtain regulatory approval or commercialize our products ~~, or cause us to experience significant delays in doing so~~ . Certain features in our product candidates, including those related to mRNA, chemical modifications, surface chemistries, LNPs and their components, may result in risks that apply to some or all of our programs and modalities. As our product candidates progress, we or others may determine that certain of our risk allocation decisions were incorrect or insufficient, we made platform- level technology mistakes, individual programs or our mRNA science in general has technology or biology risks that were unknown or under- appreciated, our choices on how to develop our infrastructure to support our scale will result in an inability to manufacture our product candidates for clinical trials or otherwise impair our manufacturing or we have allocated resources in such a way that we cannot recover large investments or rapidly re- direct capital. We utilize earlier programs in a modality to understand the technology risks within the modality, including the program' s manufacturing and pharmaceutical properties. Even if our earlier programs in a modality are successful in any phase of development, **other programs may fail at that stage, and** any program may fail at a later phase of development ~~, and other programs within the same modality may fail at any phase of development, including at phases where earlier programs in that modality were successful~~ . This may be a result of technical challenges or biology risk unique to that program. The biology risk across **much** ~~the majority~~ of our pipeline represents targets and pathways not clinically validated by one or more approved drugs, and the risk that the targets or pathways that we have selected may not be effective will continue to apply across ~~the majority of~~ our current and future programs. As we progress our programs through clinical development, new technical challenges may arise that cause an entire modality to fail. Additionally, any portfolio- spanning risks, whether known or unknown, such as an increased risk of a particular type of side effect, if realized in any one of our programs, would have a material and adverse effect on our other programs and on our **overall** business ~~as a whole~~ . There are also specific additional risks to certain of our modalities and programs. For example, prophylactic vaccines typically require clinical testing in up to tens of thousands of healthy volunteers to define an approvable benefit- risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Even if we observe positive safety, tolerability and levels of immunogenicity in early clinical trials, we may not observe acceptable safety or efficacy profiles in later- stage trials required for approval of these programs. There are many clinical and manufacturing challenges specific to our INT product candidates and any other neoantigen cancer vaccines we may develop. These risks include a rapid production turn- around time measured in weeks in order to supply patients in our clinical trials before further progression and mutation of their tumors, the significant costs incurred in making individualized medicines and potential lack of immune responses due to the biology of the tumor or immune status of the patient. These risks apply to our INT product candidates and other neoepitope investigational medicine programs. Additionally, there may be challenges in delivering an adequate quantity of active pharmaceutical ingredient (API) required to drive efficacy due to the limitation in volume of API that can be delivered to a specific location, like a tumor or injured tissue. Our investigational therapies for local injections often require specialized skills for conducting a clinical trial that could delay clinical trials or slow or impair commercialization of a product due to the poor adoption of injected local therapeutics ~~or intratumoral therapies~~ . In addition, the uncertain translatability of target selection from preclinical animal models, including mouse and non- human primate models, to successful clinical trial results may be impossible, particularly for ~~immuno-~~

~~oncology and~~ systemic therapies ~~,~~ and cancer vaccines. In general, several biological steps are required for delivery of mRNA to translate into therapeutically active medicines. These processing steps may differ between individuals or tissues, potentially leading to variable levels of therapeutic protein, variable activity, immunogenicity or variable distribution to tissues for a therapeutic effect. Gene therapies and mRNA medicines may activate one or more immune responses against any and all components of the drug product (e. g., the mRNA or the delivery vehicle, such as an LNP) as well as against the encoded protein, giving rise to potential immune reaction related adverse events. Eliciting an immune response against the encoded protein may impede our ability to achieve a pharmacologic effect upon repeat administration or a side effect. ~~These risks apply to all of our programs, including our systemic secreted therapeutics and systemic intracellular therapeutics modalities.~~ We may experience delays in enrolling participants in our clinical trials. Enrolling participants in our clinical trials is critical to our success. Difficulties or delays in enrolling a sufficient number of clinical trial participants ~~, or those with required or desired characteristics,~~ may result in increased costs or affect the timing or outcome of our planned clinical trials, which could prevent trial completion and adversely affect our ability to advance the development of and obtain regulatory approval for our product candidates ~~. We may slow enrollment in a trial to focus on achieving greater diversity in the subject population, as we did in the Phase 3 clinical trial of our original COVID- 19 vaccine~~ . Participant enrollment is affected by many factors, including: • severity of the disease under investigation; • complexity and design of the clinical trial protocol; • size of the patient population; • eligibility criteria for the clinical trial in question, including age- based eligibility criteria limiting subject enrollment to adolescent or pediatric populations; • proximity and availability of clinical trial sites for prospective trial participants; • availability of competing therapies and clinical trials; • patient referral practices of physicians; • ability to monitor trial participants adequately during and after treatment; • ability to recruit qualified clinical trial investigators; • clinicians' and trial participants' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; • adverse results or other adverse safety signals in our trials or related to other product candidates, and the resulting negative publicity, could discourage potential clinical trial participants and their doctors from participating in our trials; and • our ability to obtain and maintain participant informed consent. Additionally, we may have limited or no ability to influence enrollment in clinical trials where ~~we have entered into strategic alliances pursuant to which~~ our collaborators control clinical development. Even if we or our strategic collaborators can enroll clinical trial participants, there is no guarantee that such participants will ultimately be dosed as part of, or complete, a clinical trial. mRNA drug development has substantial clinical development and regulatory risks due to the novel nature of this new class of medicines, and the negative perception of the efficacy, safety or tolerability profile of any product candidates that we or others develop could adversely affect our ability to conduct our business, advance our product candidates or obtain regulatory approvals. Very few mRNA medicines have been authorized or approved to date by the FDA or other regulators, and efficacy, safety and immunogenicity data and real- world evidence with respect to mRNA medicines continue to accumulate. We may observe new, more frequent or more severe adverse events in subjects participating in ongoing clinical trials or among individuals vaccinated with **mRNA** ~~our COVID- 19 vaccine~~ **vaccines** . For example, some studies have suggested that our COVID ~~- 19~~ vaccine may be associated with higher rates of myocarditis and pericarditis in young males compared to other COVID ~~- 19~~ vaccines. If similar observations are made in recipients of our other products or product candidates, or if other unexpected safety issues arise, we could suffer significant damage to our reputation and that of our mRNA platform. Such events could lead to other issues, including delays in our other programs, the need to re-design our clinical trials and the need for significant additional financial resources. In addition, the FDA and other regulators may interpret data from our clinical trials differently than we do and such agencies may require us to conduct additional studies or analyses, which could delay or prevent us from obtaining full regulatory approvals in certain jurisdictions or for certain demographics. For example, in October 2021, the FDA requested that we explore a lower dosage for our COVID ~~- 19~~ vaccine in adolescents, which extended the length of clinical trials in this population prior to receiving regulatory authorization **. In addition, local legislatures may attempt to regulate or restrict the use of mRNA medicines in their jurisdictions** . Successful discovery and development of mRNA medicines by us or our strategic collaborators is highly uncertain and depends on many factors beyond our or their control. We constantly make business decisions and take calculated risks to advance our development efforts and pipeline, including those related to mRNA technology, delivery technology and manufacturing processes, which ultimately may be unsuccessful. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic, experience clinical holds or fail to reach the market for many reasons, including: • nonclinical or preclinical study, or clinical trial, results may show potential mRNA medicines to be less effective than desired or to have harmful or problematic side effects or toxicities; • adverse results in our clinical trials, or in those of others developing similar products, or adverse effects relating to mRNA, or our LNPs, may lead to negative publicity or delays in or termination of our programs; • the efficacy or safety of a combination vaccine product candidate could be less than that seen with the administration of the vaccines separately, which could prevent the combination product from obtaining regulatory approval; • adverse events related to products that are perceived to be similar to mRNA medicines, such as those related to gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our product candidates and less demand for any product that we may develop; • the insufficient ability of our translational models to reduce risk or predict outcomes in humans, particularly given that each component of our product candidates may have a dependent or independent effect on safety, tolerability and efficacy, which may be species- dependent; • manufacturing failures or insufficient supply of **current Good Manufacturing Practice (** cGMP **)** materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make mRNA medicines commercially unattractive; • changes that we make to optimize our manufacturing, testing or formulating of cGMP materials could impact the safety, tolerability and efficacy profile of our product candidates; • pricing or reimbursement issues or other factors that delay clinical trials or make any mRNA medicine

uneconomical or noncompetitive with other therapies; • our large pipeline of product candidates could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole; • failure to timely advance our programs or a failure or delay in receiving necessary regulatory approvals due to, among other factors, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, preparation of a BLA ~~,~~or the equivalent application, discussions with the FDA or EMA, a regulatory request for additional nonclinical or clinical data or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; • new legislation or regulations passed by U. S., state or foreign governments in response to negative public perception of mRNA medicines; and • the proprietary rights of others and their competing products and technologies that may prevent our mRNA medicines from being commercialized. Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other ~~regulatory~~ **regulators** ~~authorities~~ may not consider the endpoints of our clinical trials to provide clinically meaningful results. There are no pharmacologic therapies approved to treat the underlying causes of many diseases that we are currently attempting to address or may address in the future. For instance, for many of the rare diseases for which we are developing treatments, few clinical trials have been attempted, and there are no approved drugs to treat these diseases. As a result, the design and conduct of clinical trials of product candidates for the treatment of these disorders ~~and other disorders~~ may take longer, be more costly or be less effective due to the novelty of development in these diseases. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre- specified endpoint to a degree of statistical significance in ~~any~~ **our** pivotal or other clinical trials ~~we or our strategic collaborators conduct~~ . Further, even if we achieve the pre- specified criteria, our clinical trials may produce unpredictable or inconsistent results compared against the more traditional efficacy endpoints in the trial. The FDA could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and may view the efficacy results in the context of safety as not being supportive of licensure. Regulators in other countries may make similar findings with respect to these endpoints. Certain mRNA therapies are classified as gene therapies by the FDA and the EMA. The association of our ~~medicines~~ **products** with gene therapies could result in increased regulatory burdens, impair the reputation of our **products** ~~investigational medicines~~ or negatively impact our platform or our business. There are only a few approved gene therapy products in the United States or foreign jurisdictions, and there have been well- reported significant adverse events associated with their testing and use. Regulatory requirements governing gene therapy products have evolved and may continue to change in the future, and the implications for mRNA therapies are unknown. For example, the FDA has established an office, now called the Office of Therapeutics Products (OTP), within its Center for Biologics Evaluation and Research (CBER) to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the EU, certain mRNA therapies have been characterized as gene therapy medicinal products, which falls within a broader category known as Advanced Therapy Medicinal Products (ATMPs), which are subject to additional regulatory requirements. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us; for example, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification of mRNA therapies. Notwithstanding the differences between mRNA medicines and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the ~~United States~~ **U. S.** , the EU and potentially other countries could adversely impact our ability to develop our product candidates. For instance, a clinical hold on gene therapy products may apply to our mRNA product candidates irrespective of the differences between gene therapies and mRNA. Adverse events reported with respect to gene therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapies caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our clinical trials or impose additional testing for long- term side effects. Any new requirements and guidelines promulgated by regulatory agencies may negatively affect our business by lengthening the regulatory review process, requiring us to perform additional or larger studies or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our product candidates, or lead to significant post- approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our product candidates. Our work in genomic editing is subject to all risks associated with gene therapies. ~~Although there have been significant advances in recent years in fields of gene therapy and genome~~ **Genome** ~~editing, in vivo CRISPR- based genome~~ editing technologies are relatively new and their therapeutic utility is largely unproven. Public perception and related media coverage of potential therapy- related efficacy or safety issues, as well as ethical concerns related specifically to genome editing, may adversely influence the willingness of subjects to participate in clinical trials. In addition, any review conducted by an institutional biosafety committee may result in delay or prevent initiation of a gene therapy clinical trial. Additionally, if any such therapeutic is approved, physicians and patients may be slow or fail to accept these novel and personalized treatments. Physicians, health care providers and third- party payors often are slow to adopt new products, technologies and treatment practices, particularly those that may also require additional upfront costs and training. Physicians may not be willing to undergo training to adopt these novel and potentially personalized therapies, may decide the particular therapy is too complex or potentially risky to adopt without appropriate training and may choose not to administer the therapy.

Further, due to health conditions, genetic profile or other reasons, certain patients may not be candidates for the therapies. In addition, responses by federal and state agencies, congressional committees and foreign governments to negative public perception, ethical concerns or financial considerations may result in new legislation, regulations or medical standards that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. Based on these and other factors, health care providers and payors may decide that the benefits of these new therapies do not or will not outweigh their costs . If we cannot obtain, or....., our business would be adversely impacted . Our products are, and any future products will be, subject to regulatory scrutiny. Even if we obtain regulatory approval in a jurisdiction, we may remain subject to significant restrictions on the indicated uses or marketing of our product and ongoing requirements for potentially costly post- approval studies- such as those required under an accelerated approval by the FDA or other similar type of approval- or post- market surveillance. For example, the holder of an approved BLA must monitor and report adverse events and monitor and report any failure of a product to meet the specifications in the BLA, as well as submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Additionally, pharmacovigilance obligations under the regulatory regimes of the jurisdictions where our products are distributed require us to collect, process, analyze and monitor safety data and to identify and evaluate adverse reactions to our products as they are administered in those jurisdictions. If we or any of our partners assisting us in meeting these obligations cannot comply with relevant regulations, we may be subject to sanctions, increased costs and reputational harm, or our regulatory authorizations to distribute our vaccines in the relevant jurisdiction may be revoked or curtailed. Furthermore, advertising and promotional materials must comply with FDA rules and regulations and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. We are required by the FDA to conduct post- marketing studies for our COVID ~~-19~~ vaccine (mRNA- 1273) **, including** to ~~further~~ assess the ~~risks~~ **risk** of myocarditis and pericarditis **and** ~~following vaccination. Additionally, we have committed~~ to ~~conducting additional~~ **evaluate outcomes in pregnant women and infants** post- **vaccination** ~~marketing safety studies, including conducting a study to evaluate pregnancy and infant outcomes after receipt of mRNA- 1273 during pregnancy~~ . We or others could identify previously unknown side effects, or known side effects could be observed as being more frequent or severe than in clinical trials or earlier post- marketing periods. If we, our contract manufacturers or other strategic collaborators fail to comply with applicable post- approval regulatory requirements, a ~~regulatory~~ **regulator** ~~agency~~ may issue a warning letter asserting that we are in violation of the law, seek an injunction or impose civil or criminal penalties or monetary fines, suspend or withdraw regulatory approval or revoke a license, suspend any ongoing clinical trials, refuse to approve a pending BLA or supplements to a BLA submitted by us, seize or recall products or product candidates, or require field alerts to physicians, pharmacists and hospitals or refuse to allow us to enter into supply contracts. We could also be required to conduct additional nonclinical studies or clinical trials, or implement changes in labeling or to our manufacturing processes, specifications or facilities. Initiation of any government investigation or lawsuit, including class- action lawsuits, would require us to expend significant time and resources in response and would likely generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our COVID ~~-19~~ vaccine, or any future approved products, and generate revenues **. Our COVID vaccine is still subject to an emergency use authorization (EUA) for pediatric populations, and this EUA could be revoked for a variety of reasons, including if the FDA determines that the underlying health emergency no longer exists or warrants such authorization** . Additionally, the FDA or other foreign regulators could require us to adopt Risk Evaluation and Mitigation Strategies (REMS) for any product to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including the suspension or withdrawal of approvals and licenses, the addition of warning labels, changes to the way a product is administered, the requirement to conduct further clinical trials, lawsuits or increased liability for harm to patients and their children and reputational harm to us. Any of these events could prevent us from achieving or maintaining market acceptance of any products we develop ~~and~~ **. Additionally, the U. S. Supreme Court' s June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision** could **result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rule- making process. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed. Preclinical development is lengthy and uncertain, especially for mRNA medicines. Much of our pipeline is in preclinical development, and these programs could be delayed or not advanced into the clinic. Before we can initiate clinical trials for a product candidate, we must complete extensive preclinical studies, including IND-enabling good laboratory practice (GLP) toxicology testing. We must also complete extensive work on Chemistry, Manufacturing, and Controls (CMC) activities to be included in an IND submission. CMC activities for mRNA medicines require extensive manufacturing processes and analytical development, which is uncertain and lengthy. We** have **had and may in the future have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our product candidates. If we must produce new batches, our preclinical studies could be delayed.**

We cannot be certain of the timely completion of our preclinical testing and studies, whether the FDA or other regulators will accept the results or if the outcome of our preclinical testing, studies and CMC activities will ultimately support further development of our programs. As a ~~material adverse impact~~ **result, we may be unable to submit INDs or similar applications for our preclinical programs** on ~~our business~~ **the timelines we expect** , ~~financial condition~~ **if at all** , **and such applications may not** ~~results~~ - **result** ~~of operations and prospects~~ **in the FDA or other regulators allowing clinical trials to begin** . Risks related to the manufacturing of our commercial products and product candidates ~~Our mRNA products and product candidates are based on novel technologies and are complex and difficult to manufacture.~~ We or our third- party manufacturers may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping for any of our products. The manufacturing processes for our mRNA medicines are novel and complex. We and our collaborators have experienced and may continue to encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping, including delays as our supply chain expands and grows more complex. We ~~could~~ **may** experience ~~issues~~ **difficulties effectively managing and executing the complexities of a larger and multi-product supply plan, including those** resulting from complexities of producing batches at larger scale, equipment failure, human error, choice and quality of raw materials and excipients, analytical testing technology and product instability. Further, mRNA medicines encapsulated in LNPs must be developed and manufactured under well- controlled conditions, or pharmacological activity can be adversely impacted. In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This has in the past and may in the future result in our having to resupply batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our product candidates could materially delay our ~~or our strategic collaborators'~~ ability to continue clinical trials or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply. Our high rate of innovation causes a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure or may adversely affect third- party relationships. In many cases, we may need to utilize multiple batches of drug substance and drug product to meet the supply requirement of a single preclinical study or clinical trial. Failure in our ability to scale up batch size or failure in any batch, which we have experienced in the past, may lead to a substantial delay in our clinical trials or in the commercialization of any approved product. For example, the changes we make as we continue developing new manufacturing processes for our drug substance and drug product may impact specification and stability of the drug product, and may lead to failure of batches, resulting in a substantial delay in delivery of commercial product or conduct of our clinical trials. Our mRNA product candidates may prove to have a stability profile that leads to a lower than desired shelf life of the final approved medicine. This poses risk in supply requirements, wasted stock and higher cost of goods. We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our medicines. If we encounter unexpected performance issues with such equipment, we could encounter delays or interruptions to clinical and commercial supply. Due to the number of different programs, we may have cross contamination of product candidates inside of our factories, CROs, suppliers or in the clinic that affect the integrity of our product candidates. As we scale the manufacturing output for commercial production and particular programs, we plan to continuously improve yield, purity and the pharmaceutical properties of our products and product candidates from IND- enabling studies through commercial launch, including shelf- life stability, and solubility properties of drug product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after a change in process, more time will be required for pharmaceutical property testing, such as 6 or 12 month stability testing. That may require resupplying clinical material or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed. We ~~are utilizing~~ **utilize** a number of raw materials and excipients that have a single source of supply, are new to the pharmaceutical industry and are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our products or product candidates. We have established several analytical assays and may have to establish several more to assess the quality of our mRNA product candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release mRNA product candidates until the manufacturing or testing process is rectified. As we grow as a commercial company and our drug development pipeline increases and matures, the increased demand for clinical and commercial supplies from our facilities and third parties may impact our ability to operate. We rely on third- party service providers, all of whom have inherent risks in their operations. ~~We have limited experience at larger scale production necessary to support large- scale clinical trials and commercial sales.~~ Completion of our trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our vaccine candidates at sufficient yields and at commercial scale. We expect to continue to make significant investments in our manufacturing capacity and commercial network as we continue to expand our commercial launch efforts. We ~~are building regional~~ **expect to bring** manufacturing ~~capability globally~~ **plants online in Australia, Canada and the United Kingdom in 2025** and are subject to risks associated with ~~building and operating in foreign jurisdictions~~ **operationalizing these facilities, including with respect to plant licensures** . To supplement our internal manufacturing infrastructure, we have entered into agreements for the production, as well as for commercial fill- finish manufacturing, of our products to supply markets globally. We may need to engage additional third parties in the future to meet our capacity needs. If we cannot enter into such arrangements on favorable terms, or at all, our ability to develop, manufacture and distribute our

products would be adversely affected. Further, efforts to establish these capabilities may not meet initial expectations as to scheduling, scale- up, reproducibility, yield, purity, cost, potency or quality. If we are unable to institute necessary controls related to product development, manufacturing and quality, we may encounter difficulties producing our products on the timelines and in the quantities set forth in our supply agreements or to meet potential future demand. We currently utilize, and expect to continue to utilize, third parties to, among other things, manufacture raw materials, components, parts, and consumables and to perform quality testing. If the field of mRNA and other nucleic acid medicines continues to expand, we may encounter increasing competition for these materials and services. Demand for third- party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third- party manufacturers capable of producing sufficient quantities of such raw materials, components, parts and consumables required to manufacture our mRNA product candidates. The use of service providers and suppliers could expose us to risks, including: • termination or non- renewal of supply and service agreements in a manner or at a time that is costly or damaging to us; • disruptions to the operations of these suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the supplier or service provider; and • inspections of third- party facilities by ~~regulatory~~ **regulators** ~~authorities~~ that could have a negative outcome and result in delays to or termination of their ability to supply our requirements. Our reliance on third- party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third- party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial scale, replacement of a manufacturer may be expensive and time- consuming and may cause interruptions in the production of our vaccine. ~~Regulatory~~ **Regulators** ~~authorities~~ may also require us to register our facilities or those of another supplier if we terminate an existing third- party manufacturer relationship, which could lead to delays or our inability to supply a particular market. A third- party manufacturer may also encounter difficulties **, delays or interruptions** in production, including: • difficulties with production costs, scale up and yields; • availability of raw materials and supplies; • quality control and assurance; • shortages of qualified personnel; • compliance with strictly enforced regulations that vary in each country where products might be sold; and • lack of capital funding. ~~Any delay or interruption could adversely affect our business, financial condition or results of operations.~~ We are subject to operational risks associated with the physical and digital infrastructure at our manufacturing facilities and those of our external service providers. Our manufacturing facilities incorporate a significant level of automation of equipment with integration of several digital systems **, including those that may utilize artificial intelligence (AI),** to improve efficiency of operations. The digitization of our facilities exposes us to the risk of process equipment malfunctions. These risks include potential system failures or shutdowns due to internal or external factors including ~~,~~ design issues, system compatibility or potential cybersecurity compromises, incidents or breaches. Upgrades or changes to our systems, infrastructure or the software that we implement, use, or upon which our business relies, may result in the introduction of new cybersecurity vulnerabilities and risks. Our facilities and infrastructure or those of our contract manufacturers or other third- party providers may also be subject to attacks or acts of sabotage by outside actors, contractors or employees. Any disruption in our or our contract manufacturers' manufacturing capabilities could ~~cause delays~~ **delay** ~~in~~ **scaling up** production capacity for our drug substances or products or **shut down** ~~a shutdown of~~ facilities, ~~could~~ impose additional costs, cause us to fail to meet certain product volume or delivery timing obligations, or may require us to identify, qualify and establish an alternative manufacturing site, ~~the occurrence of~~ which could adversely affect our business ~~, financial condition, results of operations, and prospects~~. As we expand our development and commercial capacities, we have and expect that we will continue to establish additional manufacturing capabilities in the United States, as well as in other countries, such as Australia, Canada and the United Kingdom. This expansion may lead to regulatory delays or prove more costly than anticipated. If we fail to select suitable locations, complete construction in an efficient manner, engage effectively with local regulators, recruit the required personnel or manage our growth effectively, the development and production of products or our product candidates could be delayed or curtailed ~~. We will require significant additional investments in our manufacturing processes as we expand our manufacturing infrastructure~~. Our products and product candidates are sensitive to shipping and storage conditions, which, in some cases, requires cold- chain logistics and subjects them to risk of loss or damage. Our products and product candidates are sensitive to temperature, storage and handling conditions, and we could lose medicines if the product or product intermediates are not stored or handled properly. Shelf life for our products and product candidates is variable, and they may expire prior to use. Cold- chain logistics are required for certain of our products and product candidates. If we or third- party distributors do not maintain effective cold- chain supply logistics, then we may experience returned or out of date products and product may be rendered unusable. This has led and could lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or commercial sale. In addition, the cost associated with such transportation services and the limited pool of vendors could cause supply disruptions. ~~We are subject to significant regulatory oversight regarding manufacturing our products and product candidates.~~ Our manufacturing facilities or those of our third- party manufacturers or suppliers may ~~not~~ **fail to** meet regulatory requirements. Failure to meet ~~current Good Manufacturing Practice (~~ cGMP ~~)~~ requirements could ~~result in significant delays~~ **delay** ~~in any~~ approval of ~~and~~ **or increase production** costs ~~of~~ **for** our products. The manufacturing of medicines for clinical trials or commercial sale is subject to extensive regulation, and components of such products must be manufactured in accordance with cGMP requirements, which are enforced, in the case of the FDA, in part through its facilities inspection program. The regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive. Such production process issues include: • critical deviations in the manufacturing process; • facility and equipment failures; • contamination of the product due to an ineffective quality control strategy; • facility contamination as assessed by the facility and utility environmental monitoring program; • raw material

failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers; • ineffective product stability; • ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and • failed or defective components or consumables. ~~Regulatory~~ **Regulators** ~~authorities~~ typically require representative manufacturing site inspections to assess adequate compliance with cGMP and manufacturing controls. If we or one of our third- party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by ~~regulatory~~ **regulators** ~~authorities~~ may occur at any time during the development or commercialization ~~phase~~ of products **and may be unannounced** . The inspections may be product specific or facility specific ~~for broader cGMP inspections~~ , or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes **, such as failure to comply with cGMP requirements,** may negatively impact the ability of our third- party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs. The manufacturing process for our products is subject to ~~the FDA and foreign~~ regulatory ~~authority~~ approval ~~process~~ . If we or our third- party manufacturers are unable to reliably produce products or product candidates to specifications acceptable to ~~regulatory~~ **regulators** ~~authorities~~ , we or our strategic collaborators may not obtain or maintain the approvals needed to commercialize such products. Even if regulatory approval is obtained for any of our mRNA medicines, there is no assurance that either we or our CMOs will be able to manufacture the approved medicine to specifications acceptable to the FDA or other ~~regulatory~~ **regulators** ~~authorities~~ . Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods, which, in turn, could have an adverse effect on our business ~~, financial condition, results of operations and prospects~~ . In addition, we may not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Our contract manufacturers supply or manufacture materials or products for other companies and their failure to meet applicable regulatory requirements may affect the regulatory status of their facilities. In addition, to the extent that we rely on foreign contract manufacturers, we are subject to additional risks, including the need to comply with import and export regulations. The FDA, the EMA and other foreign ~~regulatory~~ **regulators** ~~authorities~~ may require us to submit product samples of any lot of any approved product, together with the protocols showing the results of applicable tests, at any time. In some cases, regulators may prohibit us from distributing a lot or lots until it authorizes release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may cause unacceptable changes in the product, resulting in lot failures or product recalls. Our third- party contract manufacturers have experienced lot failures resulting in product recalls of our COVID ~~-19~~ vaccine. Lot failures have caused, and lot failures or product recalls in the future with respect to product produced by either our own or our third- party manufacturers' facilities could cause, us and our strategic collaborators to delay clinical trials or product launches ~~, which could harm our business, financial condition, results of operations and prospects~~ . We and our manufacturing partners also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes and operations or those of our manufacturing partners, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Additionally, we may not be able to control for or detect intentional sabotage or negligence by any employee or contractor. Our INT product candidates are uniquely manufactured for each patient using a novel, complex manufacturing process and we may encounter difficulties in production. We custom design and manufacture INTs ~~that are unique and~~ tailored ~~specifically~~ for each patient. Manufacturing unique lots of INTs is susceptible to product loss or failure due to issues with: • logistics associated with the collection **and shipping** of a patient' s tumor, blood or other tissue sample ~~; • shipping such samples to a facility for genetic sequencing~~ ; • next- generation sequencing of the tumor mRNA **and** ~~; •~~ identification of appropriate tumor- specific mutations; • the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient- specific mRNA, which software must be maintained and secured; • effective design of the patient- specific mRNA that encodes for the required neoantigens; • batch specific manufacturing failures or issues that arise due to the uniqueness of each patient- specific batch; • quality control testing failures; • unexpected failures of batches placed on stability; • shortages or quality control issues with single- use assemblies, consumables or critical parts sourced from third- party vendors that must be changed out for each patient- specific batch; • significant costs associated with individualized manufacturing that may adversely affect our ability to continue development; • successful and timely manufacture and release of the patient- specific batch; • shipment issues encountered during transport of the batch to the patient site of care; and • the ability to define a consistent safety profile at a given dose when each participant receives a unique therapy. We have built and installed custom manufacturing equipment for INTs incorporated into a dedicated unit at our Norwood, Massachusetts facility. This equipment may not function as designed, resulting in deviations in the drug product produced, which could lead to increased batch failure and the inability to supply patients enrolled in a clinical trial. Additionally, as we continue our current Phase 3 INT trials, expand to additional tumor types and prepare for commercialization, we anticipate an increase in manufacturing demand for our INTs that will require ongoing investments. Some of the additional equipment that will be required will be custom- made for us, which will lead to long lead times and expedited procurement to meet our timelines. In addition, it may take longer than anticipated to scale up our facilities and to complete our Marlborough, Massachusetts facility (which we expect to dedicate to INTs) to meet commercial demand, if our INT product candidate is approved. This expansion and addition of new facilities could also lead to product comparability issues, which could further delay introduction of new capacity. Because our INTs are manufactured for each individual patient, we are required to maintain a chain of identity with respect to each patient' s tissue sample, sequence data derived from such tissue sample, results of analysis of such patient' s genomic analysis and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so has resulted and may in the future result in product mix up, adverse patient outcomes, loss of product or regulatory action, including withdrawal of any approved products from the market. Further, as our

INTs are developed through clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery process will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our INTs to perform differently than we expect, potentially affecting the results of clinical trials. Risks related to our reliance on third parties We are dependent on single- source suppliers for some of the components and materials used in, and the ~~processes required to develop, our products and product candidates. We depend on single- source suppliers for some of the components and materials used in, and~~ manufacturing processes required to develop and commercialize, our products and product candidates. We cannot ensure that ~~these~~ -- **the** suppliers **we rely on** will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that will cease working with us. Our use of single- source suppliers exposes us to several risks, including disruptions in supply, price increases, late deliveries or business interruptions. There are, in general, few alternative sources of supply for substitute components. If we **must** ~~have to~~ switch suppliers, the manufacture and delivery of our products or product candidates could be interrupted for an extended period. Establishing additional or replacement suppliers for any of the components or processes used in our products or product candidates, if required, may not be accomplished quickly, if at all. Any replacement supplier (or us, if we produced directly) would need to be qualified and may require additional regulatory ~~authority~~ approval, resulting in further delay. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our products or product candidates. Additionally, as part of the FDA' s approval of our product candidates, the FDA will review the manufacturing processes and facilities of our single- source suppliers. We have entered ~~into~~, and ~~in the future~~ may enter into, strategic alliances with third parties for ~~the~~ **product** development and commercialization ~~of products and product candidates~~. If these ~~strategic~~ alliances are ~~not successful~~ **unsuccessful**, our business could be adversely affected. We have entered into strategic alliances with collaborators that have provided, and may in the future provide, funding, intellectual property licenses and other resources for developing, manufacturing and commercializing our product candidates. Additionally, we have entered into, and ~~expect to~~ **may in the future** enter into ~~future~~, strategic alliances where we agree to provide funding, intellectual property licenses and other resources to third parties. Our existing and any future strategic alliances may pose a number of risks, including: • strategic collaborators may not perform their obligations as expected; • strategic collaborators may ~~not pursue~~ **cease or deprioritize** development ~~and~~ **or** commercialization of ~~any~~ **our** products **due** ~~that achieve regulatory approval or may elect not~~ to **unfavorable** ~~continue or renew development or commercialization of programs based on~~ clinical trial results, changes in ~~the~~ **their** ~~strategic collaborators'~~ focus or ~~available~~ funding **,** or ~~external~~ **other** factors that divert **their** resources or create competing priorities **, such as potential competition with their own products or candidates** ; • strategic collaborators may delay ~~clinical trials~~, **stop or** provide insufficient funding or resources for clinical trials (whether as a result of a business decision or necessitated by financial difficulties of such collaborator) ~~, stop a clinical trial, abandon a product candidate or repeat or conduct new clinical trials; • products or product candidates developed in strategic alliances with us may be viewed by our collaborators as competitive with their own products or product candidates, which may cause them to cease to devote resources to development or commercialization~~ ; • a strategic collaborator with marketing and distribution rights to one or more of our products may commit insufficient resources to the marketing and distribution of any such product; • disagreements with strategic collaborators, including over proprietary rights, contract interpretation or the course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, lead to additional responsibilities for us with respect to such product candidates or result in litigation or arbitration, any of which would be time-consuming and expensive; • strategic collaborators may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our IP or proprietary information; • disputes may arise with respect to the ownership of IP developed pursuant to our strategic alliances; • strategic collaborators may infringe the IP rights of third parties, exposing us to potential litigation and liability; • future relationships may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing ~~stockholders~~ **shareholders** or disrupt our management and business; • any equity investments we make in collaborators could decrease in value or become worthless; and • our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in the United States. Our strategic collaborators generally may materially amend or terminate their agreements with us, which has happened in the past. If any collaboration agreement is terminated, we may not receive anticipated future research or development funding or milestone, earn- out royalty, profit share or other contingent payments and the research or development of our product candidates may be delayed or discontinued. It may also be difficult to attract new strategic collaborators to continue development or commercialization of the applicable product candidate, and our reputation could be adversely affected. All the risks relating to product development, regulatory approval and commercialization described elsewhere in these Risk Factors apply to our strategic collaboration activities. We may seek to establish additional strategic alliances and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our strategic alliance agreements may restrict our ability to develop certain products. Our development programs and the potential commercialization of our product candidates will require substantial ~~additional~~ cash to fund expenses. We may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of some of our product candidates, and we face significant competition in seeking appropriate strategic collaborators. Our ability to establish additional strategic alliances will depend, among other things, on our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed strategic alliance and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or ~~similar~~ foreign ~~regulatory~~ **regulators** ~~authorities~~, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to trial participants, the

potential of competing drugs, the existence of uncertainty with respect to our or the proposed collaborator' s ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. We are also restricted under some of our existing strategic alliance agreements from entering into agreements on certain terms with potential strategic collaborators to pursue other targets on our own. These restrictions on working with targets, polypeptides, routes of administration and fields could limit our ability to enter into strategic collaborations with other collaborators or to pursue certain potentially valuable product candidates. Strategic alliances are complex and time- consuming to negotiate and document. If we cannot enter into new strategic alliances on a timely basis, on favorable terms or at all, we may need to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. We ~~rely on and~~ expect to continue to rely on third parties to conduct aspects of our research, preclinical studies, protocol development and clinical trials ~~for our product candidates~~. If these third parties do not perform satisfactorily ~~,~~ **or** comply with regulatory requirements ~~or meet expected deadlines~~, we may ~~not~~ be ~~able~~ **unable** to obtain regulatory approval for or commercialize our product candidates. We rely on third parties such as CROs to help manage certain preclinical work and our clinical trials, and on medical institutions, clinical investigators and CROs to assist in the design and review of, and to conduct, our clinical trials, including enrolling qualified patients. In addition, we engage third- party contractors and collaborators to support numerous other research, commercial and administrative activities, which reduces our control over these activities but does not relieve us of our responsibilities, such as ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocols. Moreover, the FDA requires us to comply with GLPs and good clinical practices for conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that in the case of clinical trials the rights, integrity and confidentiality of trial participants are protected. Such standards will evolve and subject us and third parties to new or changing requirements. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we may need to replace them, which could ~~cause a~~ delay ~~of~~ the affected clinical trial, drug development program or applicable activity. If clinical trials are not conducted in accordance with our contractual expectations or regulatory requirements, action by ~~regulatory~~ **regulators** ~~authorities~~ may significantly and adversely affect the conduct or progress of such trials or even require a clinical trial to be redone. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates could be delayed. In addition, failure of any third- party contractor to conduct activities in accordance with our expectations could adversely affect the relevant research, development, commercial or administrative activity. Failure of any third- party contractor to timely provide access to our data in a format ~~that is~~ acceptable to us may result in delays or impediments to our regulatory submissions or other development activities. Risks related to our intellectual property We may be unable to obtain and enforce patent protection for our discoveries and the intellectual property rights therein, or protect the confidentiality of our trade secrets. Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other IP laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. Because certain U. S. patent applications are confidential until the patents issue, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, if at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. We therefore may be unable to secure desired patent rights, thereby losing exclusivity. In the past, we have obtained licenses under third- party patents to market our products or conduct our research and development or other activities, and we may do so in the future if necessary. If licenses are not available to us on favorable terms, we may not be able to market the affected products or conduct the desired activities. The process of obtaining and enforcing patent protection is expensive and time- consuming and our pending patent applications may not result in issued patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent applications may fail to result in valid enforceable patents, or our patent protection could be reduced or eliminated, for non- compliance with these requirements. If we or our strategic collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business may be adversely affected. Despite our and our strategic collaborators' efforts to protect our proprietary rights, unauthorized parties may obtain and use information that we regard as proprietary. While issued patents are presumed valid, they may not survive a validity challenge and could be held unenforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, adjudged unenforceable or circumvented by parties seeking to design around our IP. Also, third parties or the USPTO may commence patent office proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation, or circumvention of, our patents or patent applications, would be costly, would require significant time and attention of our management, could reduce or eliminate royalty payments to us from third- party licensors and could have a material adverse impact on our business. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and foreign countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. ~~For example, the America Invents Act included a number of changes to the patent laws of the United States. If any of the enacted changes prevent us from adequately protecting our discoveries, including our ability to pursue infringers of our patents to obtain injunctive relief or for substantial damages, our business could be adversely affected.~~

One major provision of the America Invents Act changed U. S. patent practice from a first- to- invent to a first- to- file system. If we fail to file an invention before a competitor files on the same invention, we no longer **can** ~~have the ability to~~ provide proof that we were in possession of the invention prior to the competitor' s filing date, and thus would not be able to obtain patent protection for our invention. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. We also rely to a certain extent on trade secrets, know- how and technology, which are not protected by patents, to maintain our competitive position. We also rely on non- disclosure agreements and invention assignment agreements ~~entered into~~ with our employees, consultants and third parties. If any trade secret, know- how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected. Failure to obtain and maintain all available regulatory exclusivities and broad patent scope and to maximize patent term restoration or extension on patents covering our products may lead to loss of exclusivity and early biosimilar entry resulting in a loss of market share or revenue. In addition, we may choose not to enforce our IP rights in certain circumstances or for certain periods of time. For example, in March 2022, we announced that we will not enforce our patents for COVID ~~- 19~~ vaccines against companies manufacturing in or for the Gavi COVAX Advance Market Commitment **(AMC)** countries, provided that the manufactured vaccines are solely for use in the AMC 92 countries. In addition, we are willing to license our IP for COVID ~~- 19~~ vaccines to manufacturers, but **licensing** ~~we may never enter into such licenses~~ of our IP **may be limited** , and our business may be otherwise adversely impacted if we are unable to enforce our IP. Uncertainty over IP in the pharmaceutical and biotechnology industry has been the source of litigation and other disputes, which is inherently costly and unpredictable and can have adverse financial and freedom- to- operate consequences. mRNA medicines are a relatively new scientific field and, as the field continues to mature, patent applications are being processed by national patent offices globally. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. Litigation is ongoing over the underlying technology to mRNA medicines between many mRNA market participants. It is likely that there will continue to be significant litigation and patent office proceedings in various patent offices relating to patent rights in the mRNA field. We have issued patents and pending patent applications in the United States and in key markets around the world that claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of mRNA medicines and our delivery technology, including LNPs. Oppositions and inter partes review petitions have been filed against some of our patents, and we expect that further proceedings will be filed in the European Patent Office (EPO), USPTO and elsewhere relating to patents and patent applications in our portfolio. In many cases, the possibility of appeal exists for any party, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. We cannot be certain that any patent will survive or that the claims will remain in the current form. Even if our rights are not directly challenged, disputes could lead to the weakening of our IP rights. In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U. S. patents and opposition proceedings against European patents owned by third parties in the field of mRNA medicines. We have a number of these proceedings ongoing against third- party patents. If we are unsuccessful in narrowing or invalidating such third- party patents, those third parties may attempt to assert those patents against our products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products or product candidates may be subject to claims of infringement of the patent rights of third parties. We have invested billions of dollars in creating our patented mRNA platform, which is integral to the development of our mRNA medicines, and we are involved in various intellectual property litigation as described under Part I, Item 3, " Legal Proceedings. " We expect to expend substantial financial and managerial resources in connection with these legal proceedings, and the ultimate outcome of each proceeding is uncertain. We are, and may in the future become, involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and product candidates, and third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires. Defense of infringement and other claims, regardless of their merit, ~~would involve~~ **involves** substantial litigation expense and ~~divert~~ **diverts** employee resources from our business. In the event of a successful **infringement** claim ~~of infringement~~ against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense. In addition, any such licenses are likely to be non- exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate

revenues or achieve profitability, which could jeopardize our ability to sustain our operations. Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our IP may be offset by amounts paid by our collaborators to third parties who have competing or superior IP positions in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations. In addition, in connection with certain license and strategic alliance agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to IP rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to IP rights, even if resolved in our favor, could be substantial, and litigation would divert our management' s efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could delay our research, development and commercialization efforts and limit our ability to continue our operations. If third-party owners of any patent rights that we license do not properly or successfully obtain, maintain or enforce the patents underlying such licenses, our competitive position and business prospects may be harmed. We may become ~~a~~ party to licenses that give us rights to third- party IP ~~that is~~ necessary or useful for our business **and** ~~. In such a case,~~ our success may depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed IP. Our licensors may ~~not~~ **fail to** successfully prosecute the patent applications we license ~~. Even if patents issue in respect of these patent applications~~ , ~~our licensors may~~ fail to maintain these patents, ~~may~~ determine not to pursue litigation against other companies that are infringing these patents or ~~may~~ pursue such litigation less aggressively than we would. Without protection for the IP we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third- party licenses to our strategic collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our strategic alliance agreements or result in termination of an agreement by one or more of our strategic collaborators. If we fail to comply with our obligations in the agreements under which we license IP rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We license IP, which involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. We are a party to certain IP license agreements and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license and may be subject to additional liabilities. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our strategic collaborators. Disputes may arise regarding IP subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether our technology and processes that are not subject to the licensing agreement infringe on IP of the licensor; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of IP by our licensors and us and our strategic collaborators; and • the priority of invention of patented technology. If disputes over IP that we have licensed prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of IP that we license as we are for IP that we own. If we or our licensors fail to adequately protect this IP, our ability to commercialize products could suffer. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. From time to time, we are subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed IP, including trade secrets or other proprietary information, of third parties, including our employees' former employers. Litigation may be necessary to defend against these claims. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable IP rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may be subject to claims challenging the inventorship or ownership of our patents and other IP. We may be and have been subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other IP. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights, including exclusive ownership of, or right to use, valuable IP. Such an outcome could have a material adverse impact on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract management and other employees, and could impact or patenting strategy. Changes in U. S. patent and regulatory law could impair our ability to protect our products. Our success is heavily dependent on IP, particularly patents. U. S. patent law continues to evolve, and certain U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have increased uncertainty ~~with regard~~ **regarding** ~~to~~ our ability to obtain patents in the future, as well as with respect to the value of patents, once obtained. Depending on **actions or** decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the

future. We may be unable to protect our IP rights throughout the world. Filing, prosecuting and defending patents in every country would be prohibitively expensive, and our foreign IP rights can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect IP rights to the same extent as U. S. federal and state laws. Consequently, we may be unable to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection or may export infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. Many companies have encountered significant problems in protecting and defending IP rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other IP protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our IP rights around the world may be inadequate to obtain a significant commercial advantage from the IP that we develop or license. Additionally, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, during the COVID ~~-19~~ pandemic, certain countries threatened steps to facilitate compulsory licenses to permit the distribution of a COVID ~~-19~~ vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired ~~, and our business, financial condition, results of operations and prospects may be adversely affected~~ . Our reliance on government funding and collaboration from governmental and quasi- governmental entities for certain of our programs adds uncertainty to our research and development efforts with respect to those programs and may impose requirements related to **IP** ~~intellectual property~~ rights and requirements that increase the costs of development, commercialization and production of any programs developed under those government- funded programs. Contracts and grants funded by the U. S. government and its agencies, including our agreements funded by BARDA and DARPA and our collaboration with NIAID, include provisions that reflect the government' s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to: • terminate agreements, in whole or in part, for any ~~reason~~ or no reason; • reduce or modify the government' s obligations under such agreements without ~~the~~ **our** consent ~~of the other party~~ ; • claim rights, including IP rights, in products and data developed under such agreements; • audit contract- related costs and fees, including allocated indirect costs; • suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations; • impose U. S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements; • suspend or debar the contractor or grantee from doing future business with the government; • control and potentially prohibit the export of products; • pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and • limit the government' s financial liability to amounts appropriated by the U. S. Congress on a fiscal- year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period. We may not have the right to prohibit the U. S. government from using certain technologies developed by us and we may be unable to prohibit other companies, including our competitors, from using those technologies in providing products and services to the U. S. government. The U. S. government generally takes the position that it has the right to royalty- free use of technologies that are developed under U. S. government contracts. In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example: • specialized accounting systems unique to government contracts and grants; • mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent; • public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and • mandatory socioeconomic compliance requirements, including labor standards, non- discrimination, and affirmative action programs and environmental compliance requirements. Further, under these agreements we are subject to the obligations to and the rights of the U. S. government set forth in the Bayh- Dole Act of 1980 (Bayh- Dole Act). As a result, the U. S. government may have rights in certain inventions developed under these government- funded programs, including a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as " march- in rights. " Any exercise of the march- in rights by the U. S. government could harm our competitive position, business, financial condition, results of operations and prospects. In December 2023, the Biden administration released a proposed framework specifying for the first time that price can be a factor in considering whether an invention is sufficiently available to the public. The proposed framework could potentially enable march- in rights to be used as a tool to regulate drug pricing. The potential inclusion of price as a factor in a march- in determination is expected to draw extensive criticism and challenge, and the ultimate impact is currently unknown. If the U. S. government exercises such march- in rights, we may receive compensation ~~that is~~ deemed reasonable by the U. S.

government in its sole discretion, which may be less than what we might be able to obtain in the open market. IP generated under a government- funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. ~~As~~ **We have significant contracts with the U. S.** ~~an~~ **and** ~~organization~~ **other governments** , ~~we~~ **and as such** are **subject** ~~relatively new~~ to ~~government contracting and the~~ related regulatory compliance obligations. If we fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts. Risks related to our financial condition and results of operations We incurred net losses in **2024 and** 2023 **,** and ~~we may~~ **expect to** incur **additional** losses ~~again~~ in the future; we ~~have a limited history of recognizing revenue from product sales and~~ may **not** ~~be unable to~~ achieve long- term sustainable profitability. We incurred ~~a~~ net ~~loss~~ **losses** of **$ 3. 6 billion and** $ 4. 7 billion in **2024 and** 2023 **, respectively** , and other than in **2022 and** 2021 ~~and 2022~~ , we have incurred net losses in each year since our inception. Currently, our COVID ~~- 19~~ **and RSV** ~~vaccine~~ **vaccines** ~~is~~ **are** our only commercial ~~product~~ **products and our RSV sales have been minimal** . While preparations are underway for additional potential product launches, ~~including our anticipated RSV launch in 2024,~~ the ultimate occurrence and timing of these launches is uncertain. Our ability to generate revenue and ~~maintain~~ **achieve** profitability depends on our ability to successfully develop and obtain the regulatory approvals necessary to commercialize our products. We have incurred, and expect to continue to incur, significant costs associated with commercializing our **products** ~~COVID- 19 vaccine~~ and our clinical ~~and preclinical~~ development activities. **Although** ~~In addition,~~ we ~~incurred significant~~ **continue to implement cost efficiency and prioritization measures, we may be unsuccessful in reducing our** costs in **line with** ~~2023 as we resized~~ our **expectations, which could require us** ~~manufacturing capacity. We may be unable~~ to **seek** ~~achieve long- term sustainable profitability and may need~~ additional funding to continue operations. **Our** ~~We anticipate that our~~ expenses ~~may~~ **could** increase ~~substantially~~ **for many reasons, including** if and as we: ~~• expand our research or development of our programs in preclinical development;~~ • initiate additional ~~preclinical,~~ clinical **trials** ~~or other studies for our product candidates~~ , particularly large pivotal trials; • continue to **build out** ~~invest in our platform to conduct research to identify novel mRNA technology improvements; • change or~~ **our** ~~add to internal~~ manufacturing capabilities ~~, or additional manufacturers or suppliers; • add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization; • attract and retain skilled personnel; • create additional infrastructure to support our product development and commercialization efforts, including new sites globally; • seek marketing approvals and reimbursement for our product candidates~~ ; • build out a sales, marketing and distribution infrastructure to commercialize any products; • acquire or in- license other product candidates and technologies ~~; • make milestone or other payments under any in- license agreements~~ ; and • experience any delays or encounter issues with any of the above. Our quarterly and annual operating results may fluctuate. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability, as well as our ability to exist as a standalone company. Our financial condition and operating results may fluctuate from quarter- to- quarter and year- to- year due to many factors, many of which are beyond our control. As such, a period- to- period comparison of our operating results may not be predictive of our future performance. In any particular quarter, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. Our stock price could be affected by events not necessarily tied to our actual operating results, including recommendations by securities analysts, the timing of certain public disclosures by us, our collaborators or our competitors and our ability to accurately report our financial results in a timely manner. Other factors relating to our business that may contribute to these fluctuations include those described in these Risk Factors and elsewhere in this Annual Report on Form 10- K. The investment of our cash, cash equivalents and investments is subject to risks which may cause losses and affect the liquidity of these investments. As of December 31, ~~2023~~ **2024** , we had approximately $ ~~13~~ **9** . ~~3~~ **5** billion in cash, cash equivalents and investments, which are subject to general credit, liquidity, market, inflation and interest rate risks. We may realize losses in the fair value of these investments. In addition, if our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These and other market risks associated with our investment portfolio may adversely affect our results of operations, liquidity and financial condition. Risks related to our business and operations We may encounter difficulties in managing the development and expansion of our company. ~~As~~ **We have expanded our scope** of **operations and number of** ~~December 31, 2023, we had approximately 5, 600 full- time~~ employees **rapidly over** ~~in 19 countries, and we may increase our number of employees and~~ the **last several years and** ~~scope of our operations. To manage this global expansion,~~ we must continue to implement and improve our managerial, operational and financial systems ~~, expand our facilities and recruit and train qualified personnel~~ . Our management may need to divert significant attention away from our day- to- day activities to manage these development activities. Successfully developing products for and fully understanding the regulatory and manufacturing pathways for the many therapeutic areas and diseases we seek to address requires significant depth of talent, resources and corporate processes to allow simultaneous execution across multiple areas. We may be unable to effectively manage this simultaneous execution and expansion of our operations or recruit and train qualified personnel, which could cause weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations, including the expansion of our Norwood and Marlborough campuses in Massachusetts and the construction of manufacturing facilities overseas, may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our development and expansion, our financial performance and ability to commercialize our products may be affected negatively ~~, and we may not be able to implement our business strategy~~ . We are subject to the risks of doing business outside of the United States. Our business is subject to risks associated with doing business outside of the United States ~~, and we have limited experience operating internationally~~ . We are not permitted to market or promote any of our product candidates before we receive regulatory approval or other authorization from an applicable authority, and we may never receive such approval. To obtain regulatory approval in various jurisdictions, we must comply with

numerous regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our product candidates, and we may fail to obtain approval. We have rapidly expanded our global operations, establishing commercial subsidiaries and entering into arrangements to support the worldwide manufacture and distribution of our products, which is a complex task. For example, we are building regional manufacturing facilities and investing in research and development in several countries. Our business may be adversely affected by many factors associated with our expanding global business, including: • efforts to develop an international commercial sales, marketing and supply chain and distribution organization, including efforts to mitigate longer accounts receivable collection times, longer lead times for shipping and potential language barriers; • our customers' ability to obtain reimbursement for our products in foreign markets; • our inability to directly control commercial activities because we rely on third parties; • different medical practices and customs in foreign countries affecting acceptance in the marketplace; • changes in a specific country' s or region' s political and cultural climate or economic condition; • an increased legal and compliance burden to establish, maintain and operate legal entities in foreign countries; • the burden of complying with complex and changing foreign regulatory, tax, accounting, reporting and legal requirements, including the European General Data Protection Regulation 2016 / 679 (GDPR); • the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute, and the difficulty of effective enforcement of contractual provisions in local jurisdictions; • inadequate IP protection in foreign countries and the existence of potentially relevant third- party IP rights; • trade- protection measures including trade restrictions, import or export licensing requirements such as Export Administration Regulations promulgated by the U. S. Department of Commerce and fines, penalties, or suspension or revocation of export privileges, the imposition of government controls and changes in tariffs; • the effects of applicable foreign tax structures and potentially adverse tax consequences; and • significant adverse changes in foreign currency exchange rates. We are also subject to extensive federal, state and foreign anti- bribery regulations, including the U. S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act and similar laws in other countries. Compliance with the FCPA is expensive and difficult, particularly in countries where corruption is a recognized problem. Additionally, the FCPA presents particular challenges to the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the United States, we will need to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs. **Additionally, in many jurisdictions outside the United States, we have or may become subject to additional industry- specific codes of conduct that impose additional compliance responsibilities on us. Failure to comply with these codes particularly as we enter new markets has, and could in the future, result in findings against us, which could result in financial sanctions or reputational harm.** We cannot guarantee that we, or our employees, consultants or third- party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our strategic collaborators and third- party contractors outside the United States may have inadequate compliance programs or fail to respect the laws and guidance of the territories where they operate, which may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Even if we are not determined to have violated these laws, government investigations typically require the expenditure of significant resources and generate negative publicity ~~, which could adversely affect our business, financial condition and results of operations~~ . Our failure to ~~upgrade and~~ maintain our enterprise resource planning (ERP) system could adversely impact our business and results of operations. **Any disruptions** ~~We are upgrading our~~ **or difficulties using our newly upgraded** global ERP ~~system to support our continued growth as a commercial operation. We have incurred substantial costs in implementing our ERP system, and any disruptions or difficulties in implementing or using our~~ system could adversely affect our controls, resulting in harm to our business, including our ability to forecast or make sales and collect our receivables. Significant delays in documenting, reviewing and testing our internal controls could cause our non- compliance with our SEC reporting obligations related to our management' s assessment of our internal control over financial reporting ~~. Moreover~~ , ~~such disruptions or difficulties could result~~ **resulting** in unanticipated costs and **the** diversion of management' s attention. Our success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends on our ability to attract and retain highly qualified managerial, scientific, technical, quality- control, manufacturing, medical, regulatory and commercial personnel. The turnover rate in our industry is high and we compete with other companies, as well as academic institutions, for individuals with certain skill sets. Failure to attract and retain personnel **, or to maintain relationships with key consultants, contractors and advisors,** could result in delays in production or difficulties in maintaining compliance with regulatory requirements. In addition, **negative business developments** ~~adverse publicity, including as the result of failure to succeed in clinical trials or obtain marketing approvals,~~ may make it difficult to recruit and retain qualified personnel. We are highly dependent on members of our management and scientific teams. Each of our executive officers and **key** employees ~~, including key scientists and clinicians,~~ are employed " at will, " **and** ~~meaning we or they~~ **the loss of** ~~may terminate the employment relationship at~~ any ~~time. The loss~~ of **their** ~~any of these persons'~~ services may adversely impact the achievement of our **business** ~~research, development, financing and commercialization~~ objectives. We do not have " key person " insurance on any of our employees. Several of our ~~key employees, including~~ executives ~~, have been with us for a long period of time, and~~ have valuable, fully vested stock options or other long- term equity ~~incentives~~ **awards. Additionally, significant declines in our stock price**

have in the past reduced, and may in the future reduce, the retentive power of equity awards for our executives or other key personnel . We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in Cambridge, Massachusetts. ~~In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to help us formulate our research and development, regulatory approval, manufacturing and commercialization strategies. These individuals may be employed by other employers and may have commitments under contracts with others that limit their availability to us. The loss of the services of these individuals might impede the achievement of our research, development, regulatory approval, manufacturing and commercialization objectives.~~ If we cannot maintain our corporate culture, we could lose the innovation, teamwork and passion that we believe contribute to our success. **It** ~~We invest substantial time and resources in building and maintaining our culture and developing our personnel; however, as we continue to expand, it~~ may be increasingly difficult to maintain our culture **, which we have invested substantial resources in building** . The dramatic growth of our workforce, coupled with recent shifts in workplace and workstyle, increase ~~the~~ **this** risk ~~of our ability to maintain culture~~ . Any failure to preserve our culture could negatively affect our future success, including our ability to retain and recruit personnel and to effectively pursue our strategic plans. Our internal computer systems and physical premises, or those of third parties with which we share sensitive data or information, may fail or suffer security breaches, including from cybersecurity incidents, which could materially disrupt our product development programs and manufacturing operations. Our internal computer systems and infrastructure and those of our strategic collaborators, vendors, contractors, consultants or ~~regulatory~~ **regulators** ~~authorities~~ with whom we share confidential, protected or sensitive data or information, or upon which our business relies, are vulnerable to damage from computer viruses, unauthorized access, misuse, natural disasters, terrorism, cybersecurity threats, war and telecommunication and electrical failures, as well as security compromises or breaches, which may compromise our systems, infrastructure, data or that of those with whom we share such data or information or upon which our business relies, or lead to data compromise, misuse, misappropriation or leakage. We have experienced, and may experience additional, cyber- attacks on our information technology systems and infrastructure by threat actors of all types (including nation states, criminal enterprises, individual actors or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by these threat actors. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, digital extortion, business email ~~compromise~~ **compromises** and denial- of- service attacks, social engineering **(including phishing attacks)** and other means to affect server reliability and threaten the confidentiality, integrity and availability of information, systems or infrastructure. If any such cyber- attack or physical intrusion against us or those with whom we share confidential, protected or sensitive data or information, or upon which our business relies, were to result in a loss of or damage to our data, systems or infrastructure, or interrupt our operations, such as a material disruption of our development programs or our manufacturing operations, or due to a loss of any of our proprietary or confidential information, it would have a material adverse effect on us. For example, the loss of clinical trial data could delay our regulatory approval efforts and increase our costs to recover or reproduce the data. In addition, because we run multiple clinical trials in parallel, any breach or compromise of our computer systems or infrastructure or physical premises may result in a loss of data or compromised data integrity across multiple programs in many stages of development. While we seek to take steps to address cybersecurity risks, our efforts may not wholly mitigate such risks. Further, our **contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our privacy and data** ~~cybersecurity~~ ----- **security obligations. Further, although we maintain cyber** liability insurance **, this insurance** may not **provide adequate** ~~cover~~ **coverage against potential liabilities related to** ~~all damages we would sustain based on~~ any **experienced cybersecurity incident or** breach ~~or compromise of our computer security protocols or cybersecurity attack~~ . Any data breach, security incident or compromise of confidential, protected or personal information, including any clinical trial participant personal data, may also **result in notification requirements or other disclosure obligations and may** subject us to civil fines and penalties, litigation, regulatory investigations or enforcement actions, or claims for damages under the GDPR and UK GDPR and relevant member state law in the EU, other foreign laws, and the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and other relevant state and federal privacy laws in the United States including the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the CCPA). We have from time to time received information that companies working on vaccine research and development may be a particular focus for those planning cyberattacks, including by nation states and affiliated cyber actors. To the extent that any disruption or security compromise incident or breach were to result in a loss of, or damage to, our data, systems, infrastructure or applications, or inappropriate use or disclosure of confidential or proprietary information, including information related to the research and manufacturing of our products, we could incur liability, our competitive and reputational position could be harmed and the further development and commercialization of our product candidates could be delayed. We may use our financial and human capital to pursue a particular research program or product candidate and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success. We pursue and fund the development of selected research programs or product candidates and may choose to forego or delay pursuit of other opportunities that could later prove to have greater commercial potential. For example, we **are currently focusing our efforts** ~~have focused a significant amount of resources~~ on **certain prioritized** ~~our COVID- 19 vaccines and other respiratory~~ programs ~~,~~ **that we expect to file** for **approval over the next several years** ~~which preparations are underway for multiple vaccine launches. Additionally, we are increasing our investments in our INT programs~~ . Our resource allocation decisions, or our contractual commitments to provide resources to our strategic collaborators, may cause us to fail to capitalize on certain **other** commercial products or profitable market opportunities. ~~Our~~ **Additionally,** spending on research and development programs for product candidates may not yield commercially viable products. We may also seek to enter into strategic collaborations or financing arrangements pursuant to which we may relinquish valuable rights to product candidates, including the rights to a portion of future revenues, through a strategic alliance, licensing or other royalty arrangements in cases

where it would have been more advantageous for us to retain sole development and commercialization rights. Additionally, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a strategic alliance. If we are not successful in discovering, developing and commercializing additional products, our ability to expand our business and achieve our strategic objectives would be impaired. A key element of our **longer- term** strategy is to discover, develop and commercialize products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our drug discovery efforts, exploring potential strategic alliances for the development of new products and in- licensing technologies. Identifying new product candidates requires substantial technical, financial and human resources. We may fail to identify promising candidates or to successfully develop and commercialize products for many reasons, which would impair our potential for growth. Our business could be harmed if we suffer damage to our reputation, including as a result of a product recall. The FDA or foreign regulators could require the recall of our products. The FDA has authority to recall a biologic product if it finds that a batch, lot or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, foreign governmental bodies may require the recall of any products in the event of material deficiencies or defects in design or manufacture. Manufacturers may independently recall a product if a material deficiency in a product is found. A government- mandated or voluntary recall by us or our strategic collaborators could occur **because** ~~as a result~~ of manufacturing errors, design or labeling defects or other deficiencies and issues, as occurred with the recall in 2021 of certain batches of our COVID ~~- 19~~ vaccine shipped to Japan that were found to contain foreign particulate. Recalls of any of our products would divert managerial and financial resources and adversely affect our financial condition and results of operations. A recall announcement could harm our reputation and negatively affect our sales. Our reputation could be further impacted by public discourse regarding our business and perception of our business strategy. Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our products. We are exposed to product liability risk related to the development, testing, manufacturing and marketing of our products and product candidates in clinical trials. Product liability claims and related cross- claims and claims for indemnification may be brought against us by patients, healthcare providers or others using, prescribing, selling or otherwise coming into contact with our products or product candidates. For example, we may be sued if any product or product candidate allegedly causes injury or is found to be otherwise unsuitable during clinical trials, manufacturing or, if approved, marketing, sale or commercial use. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. We could also face product liability claims relating to the worsening of a patient' s condition, injury or death alleged to have been caused by our products or product candidates. Any such claims may include allegations of defects in manufacturing or design, a failure to warn of dangers inherent in the product, including **due to** ~~as a result of~~ interactions with alcohol or other drugs, knowledge of risks, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims might not be fully covered by product liability insurance. For any marketed products, product liability claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, suspension or withdrawal of approvals or license revocation. Regardless of the merits or eventual outcome, liability claims may cause decreased demand for our products, injury to our reputation and significant negative media attention, costs to defend the related litigation, withdrawal of clinical trial participants, loss of revenue, a diversion of management' s time and our resources, substantial monetary awards to trial participants, patients or their family members, payments to indemnify clinical trial sites and other clinical trial partners and a decline in our stock price. On occasion, large judgments have been awarded in individual, mass tort and class- action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. With respect to our COVID ~~- 19~~ vaccine, although the U. S. and certain foreign governments ~~have~~ contractually agreed to indemnify us or make statutory immunity available to us **for sales during the pandemic public health emergency** , such indemnification or statutory immunity may be unavailable to cover potential claims or liabilities resulting from the research, development, manufacture, distribution or commercialization of the vaccine. Additionally, other foreign governments that we contract with ~~may~~ **have** not ~~provide~~ **provided** us with similar contractual indemnity or statutory immunity, and we ~~will~~ **generally** ~~not~~ **no longer** have the benefit of such indemnities or immunities **for** ~~in the~~ future **sales of our** ~~as the COVID- 19 vaccine market transitions to a~~ commercial **products** ~~market in the United States and elsewhere~~ . Substantial claims arising from the vaccine outside the scope of or in excess of U. S. or foreign government indemnity or statutory immunity could harm our financial condition and operating results. Moreover, any adverse event or injury for which we are liable, even if fully covered under an indemnity or immunity, could negatively affect our reputation. We may be unable to maintain our product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition. Federal legislation and actions by federal, state and local governments may permit reimportation into the United States of drugs from foreign countries where the drugs are sold at lower prices. We may face competition in the United States for our products from therapies sourced from foreign countries with price controls on pharmaceutical products. For example, in October 2020, the FDA published a final rule that would allow for the importation of certain prescription drugs from Canada, where there are government price controls. In January 2024, the FDA approved Florida' s request to import certain lower- priced medications from Canada. While the full implications of the final rule are currently unknown, legislation or regulations allowing the reimportation of drugs could decrease the price we receive for any products we

may develop and adversely affect our future revenues and potential profitability. Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business. In the United States, federal and state legislatures, health agencies and third- party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the ACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the PHSA. Additionally, the Inflation Reduction Act of 2022 includes several provisions such as drug pricing controls and Medicare redesign that are likely to impact our business to varying degrees, but its ultimate effect on our business and the healthcare industry in general is not yet known. See " Business —- Government Regulation- Current and future healthcare reform legislation. " We may face uncertainties **due to** ~~as a result of~~ efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. There is no assurance that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. There is increasing public attention on the costs of prescription drugs and there have been, and are expected to continue to be, legislative proposals to address prescription drug pricing, which could have significant effects on our business. These actions and the uncertainty about the future of the ACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs. There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs or that would allow for importation of pharmaceutical products from lower cost jurisdictions outside the United States. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding limitation on prices and reimbursement for our products, if approved. In the EU and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government- sponsored health care system. Many countries have announced or implemented measures, and may in the future implement new or additional measures, to reduce health care costs to limit the overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower- cost countries. These measures may adversely affect our revenues and results of operations. We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and false claims laws. If we cannot comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third- party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained **during** ~~in the course of~~ patient recruitment for clinical trials. See " Business —- Government Regulation —- Other healthcare laws. " 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. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, is time- and resource- consuming and can divert a company' s attention from the business. If our operations are found to violate any of these laws or any other regulations, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting 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. Furthermore, if any physician or other healthcare provider or entity with whom we do business is found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management' s attention from the operation of the business. In addition, the approval and commercialization of any product candidate we develop outside the United States will subject us to foreign healthcare laws. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU and the UK. The provision of benefits or advantages to induce or reward improper performance generally is also governed by the national anti- bribery laws of EU Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. The EU

Directive (2001 / 83 / EC, as amended) governing medicinal products for human use provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often are the subject of prior notification and approval by the physician' s employer, his or her competent professional organization, or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. We are subject to various and evolving laws and regulations governing the privacy and security of personal data, and our failure to comply could result in fines or criminal penalties and damage our reputation. Privacy and data security are significant issues in the United States, Europe and many other jurisdictions where we operate or collect personal information. We are subject to data privacy and security laws and regulations in various jurisdictions that apply to the collection, storage, use, sharing and security of personal data, including health information, and impose significant compliance obligations. In addition, numerous other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection and privacy laws, govern the collection, use, disclosure and security of personal information. The GDPR and UK GDPR impose stringent obligations on us with respect to our processing and the cross- border transfer of personal data, including higher standards of obtaining consent or ensuring another appropriate legal basis or condition applies to the processing of personal data, more robust transparency requirements, data breach notification requirements, requirements for contractual language with our processors and stronger individual data rights. Different EEA Member States have interpreted the GDPR differently and many have imposed additional requirements, adding to the complexity of processing personal data in the EEA. The GDPR and UK GDPR also impose strict rules on the transfer of personal data to countries outside the EEA that are not considered to provide " adequate " protection to personal data, including the United States, and permits data protection authorities to impose large penalties for violations. Compliance with the GDPR and UK GDPR is a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices. We could be subject to fines and penalties, litigation and reputational harm in connection with any activities falling within the scope of the GDPR or UK GDPR. In the United States **, at the federal level, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. In addition, certain state laws govern privacy and security of personal information. For example** , California has passed the CCPA and numerous other states have passed their own similar comprehensive consumer privacy laws. There are also states that are specifically regulating health information. Further, a small number of states have passed laws that regulate biometric data specifically. In addition, numerous states and the federal government are actively considering proposed legislation governing the protection of personal data. State laws are changing rapidly and there ~~is~~ **have been** ~~discussion~~ **discussions** in the U. S. Congress of ~~a~~ new comprehensive federal data privacy ~~law~~ **laws** to which we **could** ~~may likely~~ become subject, if enacted. Additionally, many foreign jurisdictions have passed data privacy legislation and others are considering various proposals for new privacy and data protection laws. Data privacy remains an evolving landscape at the domestic and international levels, with new laws and regulations being considered and coming into effect and continued legal challenges. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and regulatory agencies, creating additional uncertainty, and ~~we may fail~~ **any failure or perceived failure** to comply with the evolving data protection laws **could** ~~, which may~~ expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions and potential significant penalties if we are found to be non- compliant. Some of these laws and regulations also carry the possibility of criminal sanctions. For example, we could be subject to penalties, including criminal penalties, if we knowingly obtain or disclose individually identifiable health information from a HIPAA- covered health care provider or research institution that has not complied with HIPAA' s requirements for disclosing such information. Furthermore, the number of government investigations related to data security incidents and privacy violations continues to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and our reputation. The Clinical Trials Regulation (EU) No. 536 / 2014 (the Clinical Trial Regulation) and the EMA policy on publication of clinical data for medicinal products for human use both permit the EMA to publish clinical information submitted in **marketing authorization approvals (** MAAs **)** . The ability of third parties to review or analyze data from our clinical trials may increase the risk of commercial confidentiality breaches and result in enhanced scrutiny of our clinical trial results. Such scrutiny could result in public misconceptions regarding our drugs and drug candidates. These publications could also result in the disclosure of information to our competitors that we might otherwise deem confidential, which could harm our business. Our use of GenAI and other AI technologies presents certain risks and challenges given the emerging nature of AI technologies. The development and use of GenAI and other AI technologies (collectively, AI Technologies), along with an uncertain regulatory landscape, pose risks that could harm our reputation, expose us to liability or **otherwise** adversely affect our business. The integration of AI Technologies into our and our vendors' systems (potentially without the vendor disclosing such use to us) subjects us to the risk that the providers of AI Technologies may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection. ~~This~~ **Further, bad actors around the world use increasingly sophisticated methods, including the use of AI technologies, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. These factors** may lead to breaches of security or privacy, reduced levels of service or experience, loss of intellectual property or exposure of confidential or proprietary information. Sophisticated cyber- attacks, including those using AI, could exacerbate these risks. Additionally, GenAI' s potential for producing false or

misleading outputs, reflecting biases or generating content that may not be subject to **IP** ~~intellectual property~~ protection or that infringes proprietary rights of others, poses additional risks to our business. Regulatory changes or reinterpretations could introduce new compliance risks, including potential government enforcement actions or civil lawsuits. Our competitors' faster or more effective adoption of AI could also disadvantage us. We could be adversely affected by outbreaks of epidemic, pandemic or other contagious diseases. In the event of a future epidemic or pandemic, our clinical trials could be paused or delayed due to restrictions (such as quarantines or travel limitations) or reprioritization of resources. Travel limitations could also create challenges and potential delays in our development and production activities, increasing the expense and timelines for producing our products and product candidates. We utilize third parties to, among other things, manufacture raw materials, components, parts and consumables, perform quality testing and ship our products. If these third parties were to experience delays or disruptions in providing their services in response to an epidemic or pandemic, our supply chain could be disrupted, limiting our ability to manufacture and sell our products and manufacture product candidates for our clinical trials, as well as negatively impacting our research and development operations. Such delays or disruptions could adversely impact our strategic collaborators' ability to fulfill their obligations, which could affect the clinical development or regulatory approvals of product candidates under joint development. In addition, during a global health crisis, one or more government entities could take actions (such as via the Defense Production Act in the U. S.) that diminish our rights or economic opportunities with respect to our products. Our third- party service providers could be impacted by government- imposed restrictions on services they might otherwise offer. Any such action could cause us to experience delays in the development, production, distribution or export of our products and product candidates and increased expenses. Engaging in acquisitions, joint ventures or strategic collaborations may increase our capital requirements, dilute our ~~stockholders~~ **shareholders** and cause us to incur debt or assume contingent liabilities. We may engage in acquisitions, joint ventures and collaborations, including licensing or acquiring complementary products, IP rights, technologies or businesses. Such transactions and relationships may entail numerous risks, including: • increased operating expenses and cash requirements; • assimilation of operations, IP and products, including difficulties associated with integrating new personnel; • the diversion of management' s attention from our existing product programs and initiatives; • the loss of key personnel and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and • our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. If we undertake acquisitions **in the future** , we may utilize cash, issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, if we cannot locate suitable acquisition or strategic collaboration opportunities, our ability to grow or obtain access to technology or products that may be important to the development of our business may be impaired. The illegal distribution and sale by third parties of counterfeit or stolen versions of mRNA products ~~, or the unauthorized donation or re- sale of mRNA products,~~ could negatively impact our financial performance or reputation. Third parties could illegally distribute and sell, especially online, counterfeit versions of mRNA products that do not meet the rigorous cGMP manufacturing and testing standards. Counterfeit medicines may contain harmful substances or the wrong dose, are frequently unsafe or ineffective and could be life- threatening. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit products, increased levels of counterfeiting or unsafe mRNA products could materially affect patient confidence in our mRNA products. Adverse events caused by unsafe counterfeit or other non- mRNA products could mistakenly be attributed to our mRNA products. In addition, thefts of inventory at warehouses, plants or while in- transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business. **The** ~~Public~~ **public could** ~~loss~~ **lose** ~~of~~ confidence in the integrity ~~in~~ **of** mRNA products **because** ~~as a result~~ of counterfeiting, theft or improper manufacturing processes ~~could have a material adverse effect on our business, results of operations and financial condition. Further, the unauthorized donation or resale of our product could adversely affect our ability to sell in a particular territory, and have other adverse effects on our business, results of operations and financial condition~~ . Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations and financial condition. We are exposed to physical risks (such as rising temperatures, flooding and severe storms), risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in customer behavior and cost and availability of raw materials) and social and human effects (such as population dislocations and harm to health and well- being) associated with climate change. These risks can be either acute (short- term) or chronic (long- term). Climate- related physical risks to our facilities and those of our suppliers could disrupt our operations and supply chain, which may result in increased costs. New legal or regulatory requirements may be enacted to prevent, mitigate or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could subject us to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, investments in data gathering and reporting systems, upgrades of facilities to meet new building codes and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy we use. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us, which may affect our ability to procure raw materials or other supplies required to operate our business at the quantities and levels we require. Our aspirations, goals and disclosures related to environmental, social and governance (ESG) matters expose us to numerous risks. **Many** ~~Institutional~~ **institutional** and individual investors **use** ~~are increasingly using~~ ESG screening criteria to determine whether we qualify for inclusion in their investment portfolios. We are frequently asked by investors and other stakeholders to set ~~ambitious~~ ESG goals and provide new and more robust disclosure on goals, progress toward goals and other matters of interest to ESG stakeholders. In response, we have adapted the tracking and reporting of our corporate responsibility

program to various evolving ESG frameworks, and we have established and announced goals and other objectives related to ESG matters. Statements about these goals reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these goals and objectives, including with respect to environmental and diversity initiatives, are subject to numerous risks, many of which are outside of our control, which could have a material negative impact, including on our reputation and stock price **. Additionally, the increased focus on ESG matters by policymakers, regulators and investors has in some instances resulted in diverging expectations and standards, which could make it more difficult to comply with ESG- related regulations across our global business** . Further, the standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. Our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in a lack of consistent or meaningful comparative data from period to period. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our attractiveness as an investment, business partner or acquiror could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill our goals, targets and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could also have similar negative impacts and expose us to government enforcement actions and private litigation. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous and flammable materials and wastes, including chemicals and biological materials. We generally contract with third parties for the disposal of these materials and waste products, and we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines, penalties or other sanctions for failure to comply with such laws and regulations. We may also incur substantial costs to comply with such laws and regulations, and these laws and regulations could impair our research, development or production efforts. Our workers' compensation insurance may not provide adequate coverage against potential liabilities due to injuries to our employees resulting from the use of hazardous materials. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Risks related to ownership of our common stock The price of our common stock has been volatile, which could result in substantial losses for ~~stockholders~~ **shareholders** . Our stock price has been, and is expected to continue to be, subject to substantial volatility. Since our IPO in December 2018, our stock price has ranged from a high of $ 497. 49 to a low of $ 11. 54 per share. **Over the last several years** ~~Since we began our COVID- 19 vaccine development efforts in early 2020~~ , our stock has experienced pronounced and extended periods of volatility, which could cause our ~~stockholders~~ **shareholders** to incur substantial losses. Public statements by us, government agencies, the media, competitors, financial analysts or others ~~relating~~ **, including those related** to COVID- 19 **,** have resulted, and may result, in significant fluctuations in our stock price. Information in the public arena ~~on this topic~~ , whether or not accurate, has had and will likely continue to have an outsized impact (positive or negative) on our stock price. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies, and you may not be able to sell your shares at or above your initial purchase price. The market price for our common stock may be influenced by many factors, including: • our **product** ~~COVID- 19 vaccine~~ sales and anticipated product revenue **; • our ability to effectively reduce costs** ; • the commercial launch of any additional products; • timing and results of clinical trials or progress of our product candidates or those of our competitors **; • the exclusion or removal of our stock from market indices** ; • the success of competitive products or technologies; • the emergence or decline of new or existing variants of the SARS- CoV- 2 virus; • developments regarding our manufacturing, regulatory and commercialization efforts, or information regarding such efforts by competitors; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • expenses related to any of our products or clinical development programs; • the results of our efforts to discover, develop, acquire or in- license additional product candidates; • actual or anticipated changes in estimates of financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in the structure of healthcare payment systems; • economic, industry and market conditions generally, and in the biopharmaceutical sector specifically; and • announcement by us or our competitors of the commencement or termination of significant acquisitions, strategic partnerships, joint ventures or capital commitments. Securities class- action litigation often has been instituted against companies following periods of volatility in their stock price. ~~If such~~ **In 2024, class action and derivative** ~~litigation~~ **litigations** were ~~instituted~~ **filed** against us ~~, we~~ **related to statements made about our RSV vaccine. See Item 3. " Legal Proceedings. " We** could incur substantial costs in defense **of such litigation, or in defense of any future lawsuits that may be filed against us,** and management' s attention and resources could be diverted ~~, which could adversely affect our business, financial condition and results of operations and prospects~~ . Our principal ~~stockholders~~ **shareholders** and management own a significant percentage of our stock and will be able to exert significant control over matters subject to ~~stockholder~~ **shareholder** approval. As of February ~~16~~ **14** , ~~2024~~ **2025** , our executive officers, directors and affiliated ~~stockholders~~ **shareholders** owned, directly or indirectly, approximately ~~12~~ **8** % of our outstanding common stock. In addition, non- affiliated five percent or greater ~~stockholders~~ **shareholders** owned approximately 27 % of our outstanding common stock. These ~~stockholders~~ **shareholders** will have the ability to influence us through their

ownership positions. For example, if they were to act together, they could exert significant influence over matters such as elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our ~~stockholders~~ **shareholders** may believe to be in their best interests. Provisions in our organizational documents, as well as provisions of Delaware law, could make it more difficult or costly for a third party to acquire us or remove our current management, even if doing so would benefit our ~~stockholders~~ **shareholders** . Our ~~amended and~~ restated certificate of incorporation (charter), **second** amended and restated by- laws (by- laws) and Delaware law contain provisions that could delay or prevent a hostile takeover or change in control of us or changes in our management. Our charter and by- laws include provisions that: • authorize " blank check " preferred stock, which could be authorized for issuance by our board of directors without ~~stockholder~~ **shareholder** approval and may contain voting, liquidation, dividend and other rights superior to our common stock; • create a classified board of directors whose members serve staggered three- year terms; • ~~specify that~~ **limit shareholders' ability to call a** special ~~meetings~~ **meeting** of **shareholders to shareholders representing at least 20 %** ~~our stockholders can be called only by our board~~ of ~~directors~~ **our outstanding shares** ; • prohibit ~~stockholder~~ **shareholder** action by written consent; • establish an advance notice procedure for ~~stockholder~~ **shareholder** approvals to be brought before an annual meeting of our ~~stockholders~~ **shareholders** , including proposed nominations of persons for election to our board of directors; • provide that our directors may be removed only for cause; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; • specify that no ~~stockholder~~ **shareholder** is permitted to cumulate votes at any election of directors; • expressly authorize our board of directors to modify, alter or repeal our by- laws; and • require supermajority votes of the holders of our common stock to amend specified provisions of our charter and by- laws. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of ~~stockholders~~ **shareholders** owning in excess of 15 % of our outstanding voting stock to merge or combine with us. Any provision of our charter, by- laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our ~~stockholders~~ **shareholders** to receive a premium for their shares, and could also affect the price that some investors are willing to pay for our common stock. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business or to return cash to shareholders through share repurchases. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Our by- laws designate the Court of Chancery of the State of Delaware or the U. S. District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our ~~stockholders~~ **shareholders** , which could limit our ~~stockholders~~ **shareholders** ' ability to obtain a favorable judicial forum for disputes with us. Pursuant to by- laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our ~~stockholders~~ **shareholders** , (3) any action asserting a claim against us or any of our current or former directors, officers, employees or ~~stockholders~~ **shareholders** arising pursuant to any provision of the Delaware General Corporation Law or our by- laws or (4) any action asserting a claim governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our by- laws further provide that the U. S. District Court for the District of Massachusetts is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the Federal Forum Provision). Our by- laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision. The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on ~~stockholders~~ **shareholders** in pursuing any such claims, particularly if the ~~stockholders~~ **shareholders** do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our by- laws may limit our ~~stockholders~~ **shareholders** ' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our **shareholders** ~~stockholders. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision~~ . The Federal Forum Provision may also impose additional litigation costs on ~~stockholders~~ **shareholders** who assert that the provision is unenforceable or invalid, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs in resolving such matters. The Court of Chancery of the State of Delaware and the U. S. District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a ~~stockholder~~ **shareholder** considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our ~~stockholders~~ **shareholders** . General risk factors Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators leading our clinical trials and consultants. Such misconduct could include failures to comply with FDA regulations or similar regulations in other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad ~~or~~ **, comply with industry codes of conduct,** report financial information or data accurately **,** or disclose unauthorized activities to us. Such misconduct also could involve improper use of

information obtained during clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and serious harm to our reputation. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter employee misconduct, and we may fail to control unknown or unmanaged risks or losses or take steps that protect us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including through the imposition of significant fines or other sanctions. **We could face** ~~Unfavorable~~ **unfavorable** U. S. or global economic conditions, including as a result of disease outbreak, war, conflict or other political instability, or geopolitical risks ~~, 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 disruptions caused by pandemic, war, conflict or other political instability, including **related to** Russia' s invasion of Ukraine and resulting sanctions against Russia or conflict in the Middle East. Adverse macroeconomic conditions, and perceptions or expectations about current or future conditions, such as inflation, slowing growth, rising interest rates **, the imposition of tariffs (either on imports or exports, which may impact us directly or indirectly through increased costs in our supply chain)** , rising unemployment and recession, could negatively affect our business and financial condition. Additionally, global events, including war, conflict, political instability or other adverse economic conditions have and may in the future cause governments to divert spending away from healthcare, negatively impacting the ~~marketability of~~ **market for** our products. Any severe or prolonged economic downturn could create a variety of risks to our business, including weakened demand for our medicines, and negatively ~~impacting~~ --- **impact** our ability to raise additional capital or financing ~~when~~ **if** 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 the ways in which the current economic climate and financial market conditions could adversely impact our business. Additionally, geopolitical tensions could adversely impact our business and our commercial plans. For instance, restrictions by the U. S. government on the export of mRNA technology or our products to certain markets, or restrictions on the establishment of manufacturing in certain foreign jurisdictions, may prevent us from seeking commercial growth opportunities in a manner that harms our competitive position. Employee litigation and unfavorable publicity could negatively affect our future business. Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. Recently, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment- related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm. ~~Any employment- related claim could negatively affect our business.~~ Ineffective internal controls could adversely impact our business and operating results. Our internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, failure or interruption of information technology systems, the circumvention or overriding of controls, or fraud. Even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, our business and operating results could be harmed and we could fail to meet our financial reporting obligations **. Inadequate funding for the FDA, CDC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely. Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U. S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, CDC and other agencies may also slow the time necessary for new product candidates to be reviewed or approved, or for recommendations on use to be developed. If a prolonged government shutdown occurred, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions** . Changes in tax law could adversely affect our business and financial condition. We are subject to evolving and complex tax laws in the jurisdictions in which we operate. The rules dealing with U. S. federal, state, local and non- U. S. income taxation are constantly under review by legislative and tax authorities. Changes to tax laws (which could apply retroactively) could adversely affect us and our ~~stockholders~~ **shareholders** . In recent years, such changes have been made and changes are likely to occur in the future, which could have a material adverse effect on our business, cash flow, financial condition and results of operations. The increasing use of social media platforms presents risks and challenges. Social media is increasingly being used to communicate about our research, product candidates, commercial products and the diseases our products and product candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not

always clear. This uncertainty creates risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may be unable to defend our business in the face of political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.