
RISK FACTORS

An investment in the H Shares involves various risks. You should consider carefully all the information set out in this document and, in particular, the risks described below before making an investment in the H Shares.

The occurrence of any of the following events could materially and adversely affect our business, financial position, results of operations or prospects. If any of these events occurs, the trading price of the H Shares could decline, and you may lose all or part of your investment. This document also contains forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below. You should seek professional advice from your relevant advisors regarding your prospective investment in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT AND REGULATORY APPROVAL OF OUR VACCINE CANDIDATES

We may fail to obtain regulatory approval for our vaccine candidates under tightening regulatory requirements, and any refusal or delay of such approvals would postpone, or even discontinue the development and commercialization of our vaccine candidates.

To obtain approval for the commercialization of our vaccine candidates in China, we are required to submit to the NMPA preclinical studies or clinical data that sufficiently demonstrate the safety and potency of our vaccine candidates for their intended indications. The timeline for obtaining NMPA approval is inherently uncertain and may span several years following the initiation of preclinical studies and clinical trials. The approval process is subject to numerous factors and remains largely within the discretion of the NMPA.

Our vaccine candidates may fail to secure NMPA regulatory approval for various reasons, including divergence on the design, conduct or data interpretation of preclinical studies or clinical trials; disagreement regarding the specifications and standards applicable to new vaccines; failure to demonstrate the safety, efficacy or potency of our vaccine candidates for their indications, or to prove that their benefits outweigh the associated safety risks, including side effects; insufficient clinical trial data for NDA or other filing submissions; findings by regulatory authorities of deficiencies in our manufacturing processes or facilities; regulatory changes rendering existing data inadequate for approval; and regulatory requests for additional information, such as more preclinical or clinical data.

Even if approval is obtained, regulatory authorities may grant approval for fewer or more limited indications than requested, impose costly post-marketing clinical trial requirements, or approve labeling that is not conducive to successful commercialization. Furthermore, regulatory changes during ongoing clinical trials may necessitate modifications to trial protocols, which could increase costs, extend timelines, or reduce the likelihood of obtaining regulatory approval for our vaccine candidates.

The development of new vaccine products is complex, time-consuming and costly, with no assurance that we will be able to achieve scale-up production, secure supply chain readiness or implement sales and marketing strategies, even after obtaining regulatory approval.

Our success depends, in part, on our ability to develop new vaccine products, which is inherently complex, uncertain, time-consuming and costly. Whether we can successfully develop new vaccine products will depend on our ability to accurately assess emerging trends, diseases, technologies and market needs; maintain strong R&D capabilities and retain sufficient experienced R&D personnel; apply technological advances to the development and production of new vaccine products; conduct and complete compliant, timely and cost-effective preclinical and clinical trials; and obtain all requisite approvals for our preclinical studies, clinical trials and manufacturing activities.

RISK FACTORS

Moreover, early or even interim encouraging trial results may not be predictive of future success, and significant setbacks may occur at any stage. Numerous unexpected events during or resulting from these trials could delay or prevent commercialization, including negative or inconclusive clinical trial results requiring additional trials or program abandonment; higher-than-anticipated subject requirements, slow or insufficient enrollment, or unexpectedly high subject dropout rates; CRO regulatory or contractual non-compliance or delays; deficient preclinical or clinical safety of our vaccine candidates, including unacceptable health risks; regulatory suspension or termination of clinical research, including for non-compliance; unexpectedly higher clinical trial costs; and insufficient or inadequate supply or quality of materials necessary for clinical trials.

Delays in clinical trials may increase development costs and shorten the period during which we retain exclusive commercialization rights. Competitors’ earlier product introductions may also impair our commercialization. Thus, we cannot assure effective or timely new vaccine development.

The data and information that we gather in our R&D process could be inaccurate or incomplete.

We collect, aggregate, process, and analyze data from our preclinical studies and clinical trials. Vaccine industry data is often fragmented in origin, inconsistent in format and incomplete, creating significant data quality challenges, including missing or omitted data. Errors in data capture, input, or analysis could materially impair vaccine candidate development and damage our reputation.

As part of the regulatory approval process, we manage and submit data to governmental authorities. Our regulatory data submissions require complex processing and validation. Interim, top-line, or preliminary data that we announce or publish from time to time are subject to audit and verification, potentially resulting in material changes to the final data. In such cases, regulatory authorities may determine that our storage, handling, submission or display of health information or other data was inaccurate or non-compliant. Even unsuccessful claims could incur substantial costs and divert management time and resources; uninsured/under-insured claims could also hurt our business.

In addition, we engage CROs to monitor and manage data for certain preclinical and clinical programs and only control certain aspects of their activities. If CROs or other third parties fail to meet our data accuracy and completeness standards, data integrity could be compromised, delaying or preventing regulatory approval or commercialization of our vaccine candidates.

We may engage third parties to monitor, support and/or conduct clinical trials of our vaccine candidates.

We engage academic institutions, organizations conducting serologic analysis, CROs, hospitals and clinics, which are beyond our direct control, to monitor, support and conduct pre-clinical and/or clinical studies of our vaccine candidates. We also engage third parties to perform clinical trials when our vaccine candidates reach that stage. As a result, we have less control over the quality, timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials entirely on our own. Specifically, in line with industry practice, we outsource certain clinical trial-related activities to CROs which are Independent Third Parties. CROs assist us in selecting and working with clinical trial institutions to implement trial protocols, execute clinical trials and prepare materials for CTA filings.

If we are unable to enter into acceptable agreements with third parties, or if any such engagement is terminated, our planned clinical trials and R&D testing may be disrupted. Furthermore, as these third parties and their personnel are not our employees, we face risks that they may not devote sufficient time, resources and oversight to our ongoing clinical programs. Their failures to meet deadlines, promptly transfer regulatory information, adhere to protocols, comply with regulatory/contractual obligations (including maintaining clinical trial information), or

RISK FACTORS

otherwise perform inadequately can compromise project quality and data accuracy, potentially leading to trial extensions, delays or termination, and regulatory data or approval rejection by authorities like the NMPA. In addition, such outsourcing requires us to disclose proprietary information, increasing misappropriation risk.

Meanwhile, we remain responsible for ensuring that each study complies with applicable protocols and legal, regulatory and scientific standards, including GCP, GLP, GMP and human and animal testing regulations, as enforced by the NMPA. The NMPA conducts periodic inspections of trial sponsors, investigators and clinical trial sites, and our engagement of CROs does not relieve us of these regulatory obligations. Non-compliance by us or third parties may deem clinical data unreliable, necessitate additional trials required by the NMPA, and delay or prevent approval. We cannot assure you that regulatory authorities will determine that our clinical trials comply with all requirements.

We may enter into collaboration or licensing arrangements for the development and commercialization of certain vaccine candidates in the future, and any suspension, termination or underperformance of such arrangements could increase our R&D costs, delay our development timelines and adversely affect our ability to develop new products.

Our strategy may involve collaboration agreements, strategic partnerships or licensing arrangements with third parties to obtain rights under patents and technologies or co-develop vaccine candidates. While these arrangements offer resources, they also entail significant risks and uncertainties.

Collaborations and licensing arrangements may require us to incur non-recurring charges, increase near- and long-term expenditures, issue securities that dilute existing shareholders, or disrupt our management and operations. We also face intense competition in identifying suitable partners, and negotiations can be time-consuming and complex. Once established, such arrangements are subject to numerous risks that could delay our development, increase costs, reduce efficiency and compromise our competitive position, including collaborators exercising significant discretion over their efforts and resources; collaborators breaching confidentiality obligations; collaborators developing competing products independently or with third parties; collaborators failing to protect or misusing our intellectual property, exposing us to costly legal proceedings and liability; conflicts of interest among collaborators’ personnel limiting their capacity to fully deliver; disputes delaying or terminating our efforts or resulting in costly litigation or arbitration; and collaborators’ co-ownership of intellectual property limiting our exclusive commercialization rights.

Importantly, if any collaboration or licensing arrangement is suspended, terminated or underperforms, we may need to assume full responsibility and fund development activities ourselves, which could require additional expertise and capital that may not be available on acceptable terms or at all. Failure to maintain or replace such arrangements could materially and adversely affect our ability to develop and commercialize vaccine candidates.

Even if our vaccine candidates obtain regulatory approval, we will remain subject to ongoing and additional regulatory obligations and continuous regulatory review, which may lead to significant extra costs.

If the NMPA or any comparable regulatory authority approves any of our products, the manufacturing processes, labeling, packaging, storage, adverse event reporting, advertising, promotion, sampling, record-keeping and post-marketing studies of such vaccines will remain subject to extensive and ongoing, or additional, regulatory requirements. These requirements include, among others, the submission of safety and other post-marketing information and reports, registration, random quality control testing, adherence to chemistry, manufacturing and control standards, continued compliance with GMPs, GCPs, good storage practices and good vigilance

RISK FACTORS

practices, as well as potential post-approval studies for the surveillance and monitoring of the safety and efficacy of the vaccines. Such requirements, in particular post-approval studies, may result in significant additional expenses for us.

Moreover, any regulatory approvals that we receive for our products may be subject to limitations on the approved indications for which the vaccines may be marketed or to the fulfilment of certain conditions. Failure to maintain strict compliance with any of the above regulatory requirements may result in the loss of regulatory approvals that we have already obtained.

If we experience difficulties in enrolling participants in our clinical trials, our clinical development activities may be delayed or otherwise adversely affected.

Enrolling enough participants and retaining them until the completion of a clinical trial are critical for timely trial completion, but various factors introduce uncertainty into our trial outcomes, including the size of the study population required to analyze the trial’s primary endpoints; the design and eligibility criteria of the relevant clinical trial; our ability to recruit clinical trial investigators with appropriate competencies and experience; the failure of enrolled participants to complete the trial; our ability to obtain and maintain participants’ consents; the age of participants, which may require parental consent; the level of public awareness of infection rates of the targeted infectious diseases and the size of the population at risk of infection; and the availability of approved vaccines that are non-inferior or even superior to our vaccine candidates.

In addition, our clinical trials may compete with those conducted by our competitors for vaccine candidates targeting the same preventive areas. Such competition may reduce the number and types of participants available to us, as some participants may choose to enroll in trials conducted by our competitors instead of ours. Even if we could enroll enough participants, delays in enrollment may result in increased costs or affect the timing or outcome of the planned clinical trials, preventing trial completion and adversely affecting our ability to advance our vaccine candidates’ development.

We devote substantial resources to R&D to advance our vaccine candidates and enhance our technology platforms. However, we may not be able to continue identifying, discovering, developing, or securing regulatory approval for vaccine candidates that are suitable and commercially viable.

The vaccine industry is constantly evolving, and we must keep pace with new technologies and platforms to maintain our competitive position. While we expect to continue investing significant human and capital resources, we cannot assure you that we will be able to continually and successfully develop, improve or adapt to new technologies and platforms, and identify new vaccine candidates.

Even if we succeed in identifying potential new vaccine candidates, we cannot guarantee that we could develop and bring additional enhanced, safe, and effective vaccines, or vaccines that compare favorably with other commercially available alternatives, to market. The vaccine candidates may ultimately prove unsuitable for clinical development, and be unlikely to obtain sufficient or any intellectual property protection, timely marketing approval, market acceptance or qualification for reimbursement under relevant PRC government policies. The reasons may include insufficient resources for the acquisition or discovery of additional vaccine candidates; the failure of vaccine candidates in preclinical or clinical testing; a lack of safety, low immunogenicity or other characteristics revealed in further studies that render candidates ineffective or non-compliant; competitors developing alternatives that make our candidates obsolete or less attractive; and a lack of acceptance of our vaccine candidates by patients or the medical community.

If any of these events occur, we may be forced to abandon development efforts for one or more programs, rendering our efforts obsolete and making us unable to commercialize additional vaccine candidates.

RISK FACTORS

We may not be able to achieve our anticipated development objectives within the time frames we announce or expect, or at all.

Similar to many other companies in the vaccine industry, we set goals for our objectives and currently have a series of vaccine candidates at different development stages. However, the successful implementation of our product development programs is subject to significant business, economic and competitive uncertainties, including product development risks, availability of funding, competition, regulatory requirements and government policies, and the continued growth of the vaccine market. The actual timing of these milestones may vary significantly due to factors beyond our control, such as delays or failures in clinical trials, uncertainties inherent in the regulatory approval process and delays in establishing manufacturing or marketing arrangements for commercialization.

We cannot assure you that our preclinical studies or clinical trials will be completed as planned, that we will make regulatory submissions or obtain approvals on schedule, or that we will be able to adhere to our anticipated timelines for product launches.

RISKS RELATING TO THE SALES AND MARKETING OF VACCINE PRODUCTS AND COMMERCIALIZATION OF VACCINE CANDIDATES

We currently derive substantially all of our revenue from a limited number of vaccine products, and any decrease in their revenue would adversely affect our business, financial condition, results of operations and prospects.

During the Track Record Period, our revenue was derived from the sale of four vaccine products covering two disease areas, among which an even fewer number of products contributed to the majority of our revenue. For example, in 2025, our lyophilized human rabies vaccine (Vero cell) and trivalent split influenza vaccine collectively accounted for 95.7% of our total revenue. We expect sales of certain of these products to continue to account for a significant portion of our revenue in the foreseeable future. However, any decrease in demand for, or pricing of, these products could cause our revenue and profitability to decline. Factors that could lead to such decline include, among others, increased competition; the introduction of new comparable or superior products by market entrants or competitors; the cost of vaccines relative to alternative treatments; the results, timing and procedures of lot release that determine whether we can market our products; the outcomes of public tenders that determine whether we can sell in designated markets; market acceptance of our products by local CDCs and vaccine recipients and their willingness and ability to purchase; PRC government-imposed pricing constraints or guidance; new and stringent regulatory requirements on licensing and qualifications; disruptions in manufacturing or sales; media coverage and public opinion on vaccination side effects or the discovery of previously unknown adverse reactions; and newly discovered safety issues, including those relating to product quality or quality control.

Our sales are subject to seasonal variations, which may result in fluctuations in our operating results.

Our sales performance is, and will likely remain, subject to seasonal fluctuations, as part of our revenue during the Track Record Period was derived from the sales of our influenza vaccines, and will likely continue to be. For example, as influenza vaccines are seasonal vaccines targeting major circulating viruses during each flu season, our sales and returns are affected by seasonal fluctuations in demand, which in turn depend on the timing and severity of flu outbreaks and the prevalence of circulating strains. Accordingly, our manufacturing activities of influenza vaccines tend to peak between February and September. However, given that the sales of influenza vaccines primarily occur in the influenza season around autumn to spring, we have limited control over the eventual sales of influenza vaccines produced, especially considering that the execution of our manufacturing plan takes months to complete and factors in the industry practice of producing surplus influenza vaccines to be better prepared in case of need, which may lead to excess inventory.

Considering the significant seasonal fluctuations, comparing our results of operations across different periods within a given year or from year to year may not provide a meaningful indication of our performance and should not be relied upon as a predictor of future results. Furthermore, our operations may be disrupted or adversely affected by unpredictable events during peak flu vaccination seasons.

RISK FACTORS

If our bids in the public tender process are not successful, or we fail to secure subsequent product orders and provincial CDC access, our business may be adversely affected.

In China, we are required to participate in public tender processes organized by provincial-level CDCs to sell our Category II vaccine products. We generally compete with other market participants on factors such as technical specifications, registration classification, bid price, clinical effectiveness, product quality and reputation. Winning a public tender allows us to become eligible to sell vaccine products to CDCs. See “Business — Sales and Marketing — Public Tenders.”

However, our bids in public tenders may not be successful, and our vaccine products, including any future commercialized products, may not be selected for reasons such as uncompetitive pricing, perceived inferior clinical product effectiveness, perceived substandard service quality or other operational aspects, and reputation adversely affected by unforeseeable events. If we fail to participate in or win any public tender, we will not be able to sell our products to the relevant CDCs, which would negatively impact our sales volume.

Even if we win a public tender, we cannot guarantee that we will secure purchase orders from local CDCs. For Category II vaccines, winning a provincial tender only grants market entry into that province. We are still required to participate in local selection processes organized by CDCs to sell our products in specific jurisdictions. Thus, winning a provincial tender does not guarantee actual sales. If we fail to secure subsequent product orders from local CDCs after winning at the provincial level, our sales volume and results of operations could be materially and adversely affected.

Our sales to CDCs may expose us to uncertainties associated with government funding, budgeting, and decision-making processes.

During the Track Record Period, substantially all of our customers were CDCs at various levels in the PRC, which are government agencies responsible for public health administration. This exposes us to certain public authority business risks. For example, although we enter into contracts with CDCs for the sale of our vaccine products, we have little or no control over their procurement decisions or payment cycles. Changes in CDC personnel may lead to changes, delays or cancellations of purchase commitments due to differing policy priorities or budgetary agendas. Any such actions by CDCs could affect our expected earnings, or require us to revise downward our sales estimates.

In addition, many remedies available to us when dealing with private parties, such as pursuing claims for breach of contract or initiating legal proceedings, may not be practicable in our dealings with CDCs. For example, in the event of a dispute with a CDC, we may determine that it is not in our best interest to pursue legal action and may instead seek to resolve the matter through negotiations or third-party mediation. We cannot assure you that the outcome of such processes will be as favorable to us as those we might have obtained through legal proceedings.

We may experience delays in receiving payments from CDCs or other government-funded customers, or encounter credit risks related to our trade receivables from CDCs.

We are exposed to certain risks in collecting payments from CDCs or other customers. Demand for and ability to pay for our products may be affected by their budgetary cycles, availability of funds and changes in government procurement policies, and the actual recovery period can be significantly longer due to multi-level internal review and approval procedures within CDCs. See “Business — Our Customers” and “Financial Information — Selected Balance Sheet Items — Trade Receivables”.

Our employees are responsible for collecting amounts due from CDCs. We cannot assure you that CDCs will settle trade receivables in a timely manner, or that we can properly assess and respond to changes in their credit profile and financial condition. Delays in receiving payments could adversely affect our cash flow and working capital, our ability to meet payment obligations or fund vaccine production, R&D and other planned business activities.

RISK FACTORS

Our vaccine products may become subject to national or other third-party reimbursement policies, pricing regulations or other policies that are intended to reduce healthcare costs.

The level of reimbursement available from PRC government health authorities, private health insurers and other organizations will affect the extent to which we can successfully commercialize an approved vaccine candidate. None of our approved vaccine products or vaccine candidates are currently covered under the PRC national reimbursement scheme. As a result, if an approved vaccine product or vaccine candidate is not perceived as addressing a high-risk condition affecting a large population, individuals may elect not to receive the vaccination. Conversely, if our vaccine is not covered by reimbursement from any third-party payor while a competitor’s vaccine targeting the same indication is covered, vaccine recipients may choose the competitor’s product over ours.

Historically, PRC government authorities and third-party payors have sought to control costs by limiting coverage and reimbursement amounts for certain vaccines. We cannot assure you that reimbursement will be available for our approved vaccine products or any future approved vaccine candidates, or, if available, what the level of reimbursement will be. Obtaining or maintaining reimbursement for vaccine products may be particularly challenging, and there may be delays in obtaining reimbursement or coverage may be more limited than expected.

Moreover, eligibility for reimbursement does not guarantee that vaccines will be paid for in all cases or at rates sufficient to cover our costs, including research, development, manufacturing and sales. Payment rates may vary depending on the clinical setting, may be based on lower-cost alternatives already reimbursed, or may be incorporated into bundled payments for other services. We may not be able to promptly obtain coverage and favorable payment rates from government-funded or private payors for our approved vaccine products and any future approved vaccine candidates.

The PRC government may also launch a national tendering scheme for public medical institutions concerning our products, which uses minimum procurement quantities to secure larger volumes of pharmaceutical products at lower prices. If our competitors participate in and win bids under this scheme while we fail to do so, demand for our products may decrease, which could adversely affect our revenue, profitability, and market share.

Our pricing for vaccine products may restrict market acceptance and lead to lower sales.

Under the Vaccine Administration Law, Category II vaccine companies are required to adhere to reasonable pricing principles, which are generally understood by market participants as setting prices with reference to market factors and CDC purchase demand. For our vaccines, we participate in provincial-level centralized bidding processes, and prior to bidding, we determine our bid prices independently and in a reasonable manner. If we win the bid, the bid price becomes the selling price of the product in the respective province. Bid price is one of the key factors considered by provincial CDCs.

As Category II vaccines are paid for by vaccine recipients, our pricing is primarily market-driven. If our bid price is high, we may fail to win the tender. Even if we win, if multiple manufacturers are selected and our product is priced higher, vaccine recipients may choose lower-priced alternatives. Moreover, even without competing products, vaccine recipients may still consider our product expensive and not get inoculated. Any of these factors could limit market acceptance of our products and reduce sales.

Further, our pricing approach may attract increased regulatory scrutiny and adverse pricing regulations, driven by healthcare cost reduction pressures. Competitors may also challenge our pricing strategy by offering similar vaccines at lower prices to capture market share and erode our competitive position. If we fail to effectively communicate the value and benefits of our vaccine products to the market, our ability to maintain expected sales volumes and achieve projected revenues could be compromised.

RISK FACTORS

If we fail to obtain regulatory approval in any of our targeted jurisdictions outside China, we will be unable to market our products in those jurisdictions.

We intend to market certain of our vaccine candidates, if approved, in jurisdictions outside of China. In 2026, we plan to submit product registration applications in various jurisdictions, together with any required GMP inspection applications. Overseas market entry requires additional varied jurisdictional regulatory approvals and compliance with diverse requirements, potentially involving additional testing requirements, significantly different timelines compared to NMPA approval, and price approvals for our vaccines in certain jurisdictions outside China. NMPA approval does not guarantee approval by regulatory authorities in other jurisdictions, and vice versa. The foreign regulatory approval process may involve all risks associated with obtaining NMPA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Consequently, we may not be able to file for or obtain the necessary approvals to commercialize our vaccines in any overseas market.

Our business and operations rely on our experience in launching and marketing vaccine products, and if we fail to maintain adequate marketing and sales capabilities, we may be unable to generate sustainable revenue and profit.

To expand current product sales and commercialize new candidates, we must maintain and further develop our sales and marketing capabilities, either through our own resources or in collaboration with third-party marketing service providers. Building and expanding our sales and marketing team will require significant time and financial resources and could delay product launches. There are many vaccine companies that have established, experienced and well-funded sales and marketing operations, with whom we will need to compete with to recruit, train and retain qualified personnel. If we fail to sustain or expand our sales and marketing team, we may be unable to compete effectively.

In addition, to build a sales network that can timely deliver our products, we engage third-party marketing service providers with local resources, proven industry experience, expertise and a track record of regulatory compliance to assist our sales efforts. We must negotiate and secure appropriate arrangements on acceptable terms; otherwise, commercialization of approved vaccine candidates could be prevented, delayed or limited. We typically enter into agreements with third-party marketing service providers for a term of one to two years. However, third-party marketing service providers may choose not to renew their agreements or may terminate their business relationships with us for various reasons. If a significant third-party marketing service provider or a substantial number of third-party marketing service providers suspend or terminate their relationships with us, or fail to achieve the sales targets we set, we may not be able to maintain our sales volume effectively.

Under our marketing agreements, third-party marketing service providers are required to maintain applicable qualifications, comply with regulatory requirements governing marketing activities and adhere to our sales policies. We cannot assure you that they will consistently meet our policies, as their actions remain beyond our direct control. If third-party marketing service providers fail to meet our standards, we could be exposed to product liability claims, potential litigation, governmental investigations and penalties.

Even if one of our vaccine candidates obtains regulatory approval, it may still fail to gain the broad acceptance from CDCs, local vaccination sites and clinics, physicians, vaccine recipients and others necessary for commercial success.

Even if one of our vaccine candidates obtains regulatory approval, its commercial success will depend significantly on broad acceptance by CDCs, local POVs, healthcare professionals, vaccine recipients and other stakeholders. The degree and speed of adoption of our current or future vaccine candidates, if approved, will depend on numerous factors, including the approved clinical indications and the demand for vaccines targeting those indications; the comparative safety and efficacy profiles of our vaccines; the prevalence and severity of side effects; the time required for

RISK FACTORS

manufacturing and lot release; the availability and adequacy of reimbursement coverage under China’s national or third-party schemes; acceptance by physicians, POV operators and recipients as safe and effective; proper training and administration by physicians and medical staff; vaccine recipients’ satisfaction with the results and experience, such as dosing regimen convenience; the cost of treatment relative to alternative options; limitations or warnings contained in the NMPA-approved labeling; the effectiveness of our sales and marketing efforts; adverse publicity about our products or favorable publicity about competing products; and potential product liability claims.

We cannot assure you that our current or future vaccine candidates, if approved, will achieve broad market acceptance among physicians or vaccine recipients.

Our products may cause, or may be perceived to cause, severe side effects or adverse events following immunization.

As an inherent risk of our business, our vaccine products may cause side effects or adverse events following immunization due to various factors, many of which are beyond our control. Such factors include potential side effects or adverse reactions not identified or managed in clinical trials; rare but severe side effects or adverse reactions in isolated cases; product defects undetected by the quality management system; improper storage by hospitals or clinics; or inappropriate handling, prescribing, or administration by physicians.

The side effects range from minor reactions to severe outcomes, including death, with varying frequency. Our products may be perceived to cause severe side effects or adverse events following immunization if a conclusive determination of the cause is not, or cannot be, obtained; if other vaccine manufacturers’ products (targeting the same diseases, applying the same technology, or using the same culture cells or raw materials as our products) cause or are perceived to have caused severe side effects or adverse events following immunization; or if one or more regulators (such as the NMPA) or international institutions (such as the WHO) determine that products applying the same technology or using the same culture cells or raw materials as our products could cause or lead to severe side effects or adverse events following immunization.

Unacceptable side effects during development could lead to trial suspension or termination, NMPA-ordered cessation, or approval denial for targeted indications, or hinder participant recruitment. For the side effects identified after commercialization, we may face additional risks, including recall or withdrawal of products, suspension of commercialization of the affected vaccines, withdrawal of regulatory approvals for products or production facilities, imposition of additional warnings on product labels, required post-market studies to assess new safety risks, exposure to product liability claims, and reputational damage, decreasing the demand for, and sales of, our products.

Moreover, under PRC law, as a vaccine manufacturer, we may be required to compensate vaccine recipients who suffer adverse events following immunization of Category II vaccines, where the immunization causes damage to organs or physiological functions or results in severe injuries or death during or after the administration of a qualified vaccine, and no party is at fault during the process. As a result, we may be required to provide compensation even if such damages do not necessarily have a causal relationship with the quality of our vaccines.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the relevant vaccine candidate and result in significant revenue loss. Furthermore, if one or more of our vaccine candidates prove unsafe, our entire pipeline could be adversely impacted.

RISK FACTORS

Failure to maintain and accurately forecast inventory and finished goods levels in line with demand for our vaccine products could result in lost sales or expose us to excess inventory risks and holding costs.

For effective business operation and CDC customer satisfaction, we are required to maintain a certain level of finished goods to ensure timely delivery upon request, as well as an appropriate level of raw material inventory to support our commercial production. We maintain our inventory and finished goods levels based on internal forecasts, which are inherently subject to uncertainty, especially considering the significant variation in disease prevalence each year. If our forecasted demand is lower than actual demand, we may fail to maintain adequate inventory or finished goods levels or produce our products in a timely manner, which could result in lost sales and market share to competitors. Conversely, if our forecasted demand exceeds actual demand, we may be exposed to increased inventory risks due to excess raw materials or finished goods. Excess inventory could increase our holding costs and expose us to risks of inventory obsolescence or write-offs.

We are exposed to risks associated with product returns.

In line with industry practice according to Frost & Sullivan, we accept returns of (i) unused products that have expired or are about to expire; (ii) products that are defective or substandard; (iii) products with damaged packaging; and (iv) products that are otherwise unmarketable due to any fault on our part. As our influenza vaccines are seasonal vaccines targeting specific circulating viruses during each season, we also voluntarily accept unused influenza vaccines after the end of each influenza season. See “Business — Sales and Marketing — Return and Exchange of Products.”

We recognize a refund liability when we expect to refund some or all the consideration received from customers. Where the actual return rate differs from our original estimate, such difference will be adjusted in the subsequent period. See “Financial Information — Selected Balance Sheet Items — Other Payables and Accruals”

The estimation of sales returns involves significant judgment and assumptions. Given our limited experience in the commercialization of vaccine products, we cannot assure you accurate estimates. Any inaccuracy could further complicate our inventory and financial management strategies.

The market opportunities for our vaccine products and candidates may be smaller than we anticipate, not grow as projected, or at all.

We estimate the incidence and prevalence of target vaccinee populations for specific diseases based on various third-party sources, including scientific literature, clinic surveys, patient foundations and market research, as well as internally generated analyses. We rely on such estimates in formulating our vaccine development strategy, including determining which candidates to prioritize for preclinical or clinical trials. These estimates may prove inaccurate or be based on imprecise data. The total addressable market opportunity will depend on factors such as acceptance of our vaccines by the medical community, accessibility for vaccinees, vaccine pricing and reimbursement.

The actual number of vaccinees in the addressable markets may be lower than expected, vaccinees may not be receptive to treatment with our vaccines, or new vaccinees may become increasingly difficult to identify or reach. In addition, new studies may alter the estimated incidence or prevalence of the diseases targeted by our vaccine candidates, and the number of addressable vaccinees may in any case be lower than anticipated. In such circumstances, even if we achieve significant market share for our vaccine candidates, the potential target populations may be too small for us to achieve profitability without obtaining regulatory approval for additional indications.

RISK FACTORS

We face risks from government actions regarding vaccines for diseases of major public health concern, which may bring about substantial reputational damage in case of mishandling.

In response to a pandemic or the perceived risk of a pandemic, governments in China and other jurisdictions may implement measures to protect public health, including, among others, intellectual property expropriation, compulsory licensing and/or strict price controls. Such measures could limit our ability to control production and generate revenue from the sale of pandemic vaccines, or otherwise impose onerous regulatory requirements on our business. Moreover, we may be required by governmental or non-governmental authorities to reserve our vaccines for designated purposes or geographic areas, subject to specific supply allocation requirements. We may also face significant public scrutiny regarding our vaccine pricing policies.

If we obtain approval to commercialize our vaccines outside China, we will be subject to risks inherent in international operations.

We intend to market certain of our vaccine candidates, if approved, in jurisdictions outside of China. In the future, we plan to submit product registration applications in various jurisdictions, together with any required GMP inspection applications. We therefore expect to be subject to additional risks in commercializing our vaccine candidates outside China, including varying regulatory requirements for vaccines and biologics in foreign jurisdictions; delays or difficulties in obtaining, or weakened protection for, our intellectual property rights, or more aggressive enforcement of competitors’ intellectual property rights; unexpected interruptions or changes in collaborations with international entities; changes in tariffs, trade barriers or regulatory requirements; economic challenges, such as inflation, or political instability in certain foreign markets; risks of non-compliance with tax, employment, immigration and labor laws for employees residing or traveling abroad; foreign currency fluctuations and restrictions on remittances, which could increase operating costs and reduce revenues; workforce uncertainty in jurisdictions where labor unrest is more prevalent than in China; and business interruptions arising from geopolitical events, including war and terrorism, or natural disasters such as earthquakes, typhoons, floods and fires.

The recession or eradication of the infectious diseases targeted by our vaccines, as well as the emergence of alternative vaccines or treatment technologies, could adversely affect our sales.

If the diseases targeted by our vaccine products recede or are effectively eradicated, market demand for the relevant vaccine products would diminish. In addition, medical technologies continue to evolve and new vaccines or treatment modalities for diseases targeted by our vaccines may emerge. For example, several universal influenza vaccine candidates are under development to provide protection against a broad range of virus strains. If these competing vaccines or technologies are perceived by vaccinees to be more effective or to offer broader protection than our vaccines, demand for our products may decline.

RISKS RELATING TO THE MANUFACTURING AND SUPPLY OF VACCINE PRODUCTS

The manufacturing of vaccines is a highly precise and complex process that involves inherent risks in manufacturing.

Vaccine manufacturing is a highly complex and exacting process, primarily due to the inherent variability in industrial yields caused by biological mechanisms and the susceptibility of biological materials to contamination. During the Track Record Period and up to the Latest Practicable Date, all our vaccine products and vaccine candidates used in clinical trials were manufactured by our in-house manufacturing team. See “Business — Manufacturing — Manufacturing Facilities.” Our products and manufacturing are subject to applicable laws, regulations and GMP requirements, which govern manufacturing procedures such as record-keeping, operations and implementation of quality management systems to ensure the approved and investigational products quality. We have established a comprehensive quality control system throughout our production and sales processes.

RISK FACTORS

However, errors, defects or failures in manufacturing may still occur for various reasons, not only affecting our sales volume and revenue growth, but also potentially resulting in vaccinee injury or death. These reasons include equipment malfunction; failure to adhere to specific protocols and procedures; problems with raw materials; suspension of production or delays in our production schedule, such as delays related to the construction of new facilities; non-compliance with strictly enforced regulatory requirements and GMP standards; changes in product types; improper management of capacity, such as long downtime for GMP renewal and insufficient certified back-up capacity; physical limitations that may impede continuous supply; and human-made or natural disasters and environmental factors, such as power interruptions, water shortages, storms, fires, earthquakes, terrorist attacks and wars, as well as changes in governmental zoning plans.

If problems occur during the production of a batch, the affected batch may need to be discarded, resulting in product shortages, increased expenses, reduced revenue, damaged customer relationships, and significant time and resources spent investigating the root cause. Depending on the nature of the issue, similar losses could occur with other batches or products.

If we fail to detect and rectify quality defects in our products, prevent defective products from being released for sale, maintain the effectiveness of our quality control systems, or otherwise violate the manufacturing facility regulatory requirements, we may face operational suspension and sanctions, such as regulatory refusal to review pending production permit applications or supplements; withdrawal, revocation or non-renewal of approvals, licenses or permits; product recalls, seizure or confiscation; total or partial suspension of production; monetary penalties; and even criminal prosecution.

Moreover, if we fail to timely improve and optimize our manufacturing processes or techniques, or only make insufficient improvements, we may be unable to meet clinical demand for enhanced safety, immunogenicity and efficacy, or market demand for larger and faster supply. This could impair our competitiveness in the vaccine industry, and disrupt current sales and future regulatory submissions and/or commercialization of new vaccine products.

We may be subject to product liability claims.

We may face product liability claims arising from alleged design or manufacturing defects, improper labeling, inadequate risk disclosure, negligence, or breach of warranties. Defending against these claims is costly and diverts significant management resources. Actual or perceived liability could result in substantial monetary damages, clinical trial disruptions, product recalls, reputation damage, decreased vaccine demand, and a decline in the trading price of our H Shares.

While we are required to maintain product liability insurance post-approval, we cannot assure you that adequate coverage will be available on commercially acceptable terms, or at all. Any liability exceeding our policy limits or excluded from coverage must be borne by us, which could materially and adversely affect our business, financial condition, and results of operations.

Some of our equipment is under financing lease arrangements. If we breach such arrangements, we may lose access to essential equipment, face additional replacement costs, and experience operational disruptions.

Some of our equipment is subject to financing lease arrangements under which we pay annual rental fees and expect to acquire ownership through a buyback. If we fail to meet our payment obligations or complete the buyback, we may lose access to essential equipment required for our manufacturing operations, which could result in significant operational disruptions, delays in production and additional costs to replace such equipment. These arrangements also increase our liabilities and may adversely affect our financial position and ability to obtain additional financing. In addition, any failure to maintain access to such equipment could impair our ability to meet production schedules, and damage our relationships with customers and counterparties.

RISK FACTORS

We have pledged certain properties as collateral to banks for financing purposes, which exposes us to risks associated with foreclosure or enforcement actions in the event of default. Any disruption to our continuous use of these properties could adversely affect our business and results of operations.

We have pledged certain properties, including our self-owned land and buildings in Chengdu and Dalian, as collateral to banks for financing purposes. As a result, we are exposed to risks associated with foreclosure or enforcement actions in the event of default under the relevant financing arrangements. If we fail to meet our payment obligations or otherwise breach the terms of such arrangements, we may lose access to these properties which are critical to our manufacturing operations. Any disruption to our continuous use of these properties could result in suspension or delay of production, increased costs to relocate or replace facilities, and damage to our relationships with customers and counterparties. In addition, pledging these properties increases our leverage and may adversely affect our financial position and ability to obtain additional financing.

We use certain leased properties. Any disruption to our continuous use of these properties could adversely affect our business and results of operations.

We use certain leased properties for our business and operations. If we fail to maintain these lease arrangements or renew them on commercially reasonable terms, or if any of these properties become unavailable for use due to disputes, early termination, changes in ownership or other unforeseen circumstances, we may be required to relocate our operations or employees. Such relocation could result in significant costs, operational disruptions, delays in R&D activities, and adverse impact on employee productivity. In addition, we may not be able to secure alternative properties in a timely manner or on comparable terms, which could further affect our business continuity.

The expansion of our manufacturing facilities may be subject to delays, disruptions, cost overruns or may not produce expected benefits.

To meet future vaccine market demand, we are expanding our manufacturing facilities, in Chengdu and Dalian. See “Business — Manufacturing — Manufacturing Facilities.” However, we may face delays or other difficulties in constructing these facilities that require significant capital investment. Any failure in the completion, qualification or capacity ramp-up of our facility expansion on schedule and within budget could adversely affect our financial condition, production capacity and operational results.

Under PRC laws, construction projects in our industry are subject to extensive government supervision and approval processes, including project approvals, construction permits, occupational health and safety compliance, environmental approvals, and inspection and acceptance by relevant authorities. Importantly, all vaccine manufacturing facilities must obtain regulatory approval before commencing commercial production and are subject to inspection by regulatory agencies during operation. We cannot guarantee that we would obtain necessary approvals or permits in time, which may potentially disrupt or halt our expansion plans.

Furthermore, integrating new or acquired manufacturing facilities involves logistical and operational challenges, including recruiting skilled personnel, establishing reliable supply chains and implementing effective quality control measures. We may encounter difficulties in integrating these facilities into our operations or in bringing their processes up to our quality standards on a timely basis, which could result in operational inefficiencies, production delays or compromised product quality. In addition, if market demand falls short of our expectations, our capacity expansion may not generate the anticipated economic benefits, and the resulting excess capacity could increase our costs and reduce our profitability.

RISK FACTORS

We may be unable to source sufficient raw materials of required quality at commercially acceptable costs.

For our vaccine manufacturing, we must secure sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. While most of these raw materials are widely available from multiple suppliers across China, we cannot assure you that our suppliers will always provide them in the quantities, quality or at the prices we require. If any supplier fails to do so, we may incur additional time and costs to identify and qualify alternative suppliers, as onboarding new suppliers involves regulatory and procedural requirements. Our supply may also be disrupted if our suppliers fail to maintain the necessary licenses and permits or comply with applicable laws and regulations.

In addition, our raw material supply and prices may be affected by external factors such as changes in government policies or natural disasters. We cannot assure you that our raw material costs will not increase significantly, or that we will be able to pass on any such increases to our customers, which could adversely affect our profitability and results of operations. Furthermore, if we fail to detect quality issues in the raw materials we procure, and the quality of our products is compromised, we may be required to recall products, face product liability claims, suspend production and/or incur significant costs to rectify such issues.

Failure to maintain and expand an effective cold-chain network may expose our vaccine products, reputation and business to significant risks.

Vaccines are highly sensitive biological products, and temperature changes may compromise their potency. To maintain quality and efficacy, vaccines must be stored and transported under strictly controlled conditions through cold-chain logistics providers. Under the Vaccine Administration Law, vaccines are required to undergo cold-chain transportation and storage throughout the entire delivery process, with continuous temperature monitoring and a tracking system to record temperature data during transportation and storage. See “Regulations.”

For compliance, we engage logistics companies with cold-chain capabilities to transport our products. Our agreements with these companies require them to provide cold-chain transportation services equipped with tracking systems suitable for vaccines or medical products, deliver our products on time and assume responsibility for any losses or damages during transportation. Upon delivery, logistics companies must provide complete temperature monitoring records for the entire delivery process, and we are entitled to inspect their compliance with all applicable requirements. In addition, CDCs generally require logistics companies to provide relevant licenses demonstrating their eligibility to transport vaccines, and we conduct periodic audits to ensure service quality.

As of the Latest Practicable Date, our storage centers are all qualified for cold-chain storage. See “Business — Sales and Marketing — Vaccine Transportation and Storage.” However, if we or our third-party logistics providers fail to strictly adhere to cold-chain requirements, our vaccine products may be exposed to inappropriate temperatures or other improper conditions, resulting in diminished or lost potency. In such cases, entire batches may be compromised and require destruction.

Vaccine products are susceptible to contamination.

In vaccine manufacturing, the risk of contamination and cross-contamination runs through multiple stages of the production process. Manufacturing typically involves the cultivation of biological organisms and the use of substances of animal origin, which inherently increases the likelihood of introducing adventitious contaminants that may be progressively amplified during subsequent cultivation steps. In addition, as equipment and facilities are often shared across different product lines or batches, cross-contamination may readily occur in the absence of strict segregation and cleaning validation. Furthermore, vaccine production is frequently conducted in close proximity to other activities such as testing and research, which increases the channels through which contamination may spread.

RISK FACTORS

In the event of vaccine contamination or injury resulting from such contamination, we could be subject to liabilities for any resulting damages to vaccinees, product recalls, confiscation and/or destruction. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, contamination of our vaccine products could cause customers or other third parties with whom we conduct business to lose confidence in our products’ quality and the reliability of our manufacturing procedures, which could adversely affect our sales and profits. In addition, contaminated products that are unknowingly sold could result in harm on vaccinees, threaten the reputation of our vaccine products and expose us to product liability claims, criminal charges and administrative sanctions.

We handle potentially harmful biological and other hazardous materials that may cause environmental contamination or injury to others.

Our manufacturing operations and R&D activities involve controlled use of hazardous substances. The risk of accidental contamination of the environment or injury to our employees or others from the use, manufacture, storage, handling or disposal of these materials cannot be eliminated. For example, viruses and bacteria used in the production and testing of vaccines, if leaked, may pose significant risks to public health and the environment.

In the event of contamination or injury, we could be held liable for resulting damages, which may exceed the limits of any applicable insurance coverage. Also, governmental authorities may initiate investigations against us, resulting in fines, sanctions, revocation of operating permits, suspension of operations, closure of facilities or other penalties. Our reputation could be adversely affected.

In addition, laws and regulations governing the handling of harmful biological materials and hazardous substances, or more stringent environmental regulations that may be adopted in the future, could require us to implement additional protective measures and compliance procedures, incurring significant costs.

OTHER RISKS RELATING TO OUR BUSINESS

We rely on the continued efforts of our senior management and key scientific personnel.

Our future success depends significantly on the continued service of our key senior management and scientific personnel. If we lose the services of any of these individuals, we may be unable to identify or recruit suitable replacements in a timely manner. Moreover, as we compete for qualified personnel with other biotechnology companies and research institutions, retaining and attracting talent may require us to offer higher compensation and benefits, thereby increasing our operating expenses. Any failure to attract or retain key personnel could increase our recruitment and training costs, compromise our competitiveness, disrupt our operations and materially and adversely affect our business and prospects.

We may not be able to detect, deter or prevent all fraud or other misconduct by our employees or third parties.

We may be subject to fraud or other misconduct by our employees or third parties, which could result in financial losses, regulatory sanctions and damage to our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any fraud or misconduct by employees or third parties that had a material adverse impact on our business or results of operations. However, we cannot assure you that similar incidents will not occur in the future. While we believe our internal control policies and procedures are adequate, they may not be sufficient to prevent, detect or deter all instances of misconduct. Any such misconduct, whether previously undetected or occurring in the future, could materially and adversely affect our business, financial condition and results of operations.

RISK FACTORS

We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

We may from time to time be involved in claims, disputes or legal proceedings arising in the ordinary course of business. We may face disputes or litigation relating to many matters, including but not limited to intellectual property-related litigation, breach of contract, environmental issues and labor disputes. Any such claims, disputes or legal proceedings, whether initiated by us or brought against us and regardless of merit, could result in significant legal costs, diversion of management attention and resources, and, if unsuccessful, could materially harm our reputation. In addition, any adverse judgment or award against us could require us to pay substantial damages or assume other liabilities.

Furthermore, certain claims, disputes or legal proceedings may arise from actions taken by our counterparties, such as suppliers or service providers. Although we may seek indemnification from such counterparties, there is no assurance that they will indemnify us in a timely manner, or at all, for any costs or liabilities incurred as a result of such claims, disputes or legal proceedings.

We have limited insurance coverage, which may expose us to significant costs and business disruptions.

Insurance coverage available in China may not fully meet our business needs. Thus, we may not be able to obtain insurance for all risks associated with our operations. We maintain insurance policies required under PRC laws and regulations, as well as those we consider appropriate based on our operational needs and industry practice. Consistent with market practice in China, we maintain various types of insurance, including product liability insurance and clinical trial liability insurance. See “Business — Insurance.” However, our insurance policies are subject to coverage limits and exclusions. Accordingly, any uninsured loss, loss exceeding our coverage limits, litigation expenses related to potential product liability claims or business interruptions could result in significant costs and diversion of resources.

Increases in labor costs could slow our growth and adversely affect our financial condition.

Our operations rely on the technical expertise of our employees. Our success depends, in part, on our ability to attract, retain and motivate enough qualified personnel. We have implemented various initiatives to attract and retain competent staff, but facing intense competition for skilled personnel, we cannot guarantee that these measures will be effective or that the supply of skilled labor in local markets will meet our needs. Currently, substantially all our employees are based in China, where average labor costs have increased in recent years due to government-mandated wage hikes and changes in PRC labor laws. With China’s economic growth driving higher labor costs, competition for talent may require us to offer higher wages and benefits, further increasing our labor costs. Also, amendments to labor laws, rules or regulations may be introduced in the future, which may impose additional obligations on employers. If we fail to recruit and retain adequate talent, our planned preclinical studies or clinical trials could be delayed, regulatory approvals for the commercialization of our vaccine candidates could be postponed, or our expenses could exceed budgeted levels.

Natural disasters, epidemics, acts of war or terrorism or other factors beyond our control may have a material adverse effect on our business and operations.

The regions where we operate may be exposed to natural disasters such as typhoons, tornadoes, snowstorms, earthquakes, floods or droughts, as well as power shortages or outages. These regions may also be susceptible to epidemics (such as COVID-19), potential wars, terrorist attacks, riots, civil disturbances or strikes. Severe natural disasters could result in significant loss of life, injuries, destruction of assets and disruption of our operations. Widespread outbreaks of infectious diseases could lead to public health crises that materially disrupt business activities in affected areas. Acts of war, terrorism, riots or disturbances could also cause injuries or fatalities among our employees and disrupt our business network and operations. Any of these events, or other factors beyond our control, could negatively affect the overall business environment.

RISK FACTORS

Our internal IT systems or those of our service providers may fail or suffer security breaches.

Despite our implementation of security measures, our information technology systems, as well as those of our current or future service providers, remain vulnerable to various risks. These include cyber-attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power outages, terrorism, war, and telecommunication or electrical failures. Any such event could disrupt our operations and materially affect our R&D programs. For example, if data is not backed up in a timely manner, the loss of clinical trial data for ongoing or future trials of our vaccine candidates could delay regulatory approval processes and significantly increase the costs of data recovery or reproduction.

In addition, any disruption or security breach that results in data loss or damage, or unauthorized disclosure of confidential or proprietary information, could expose us to liability and delay the development of our vaccine candidates. A security breach involving personally identifiable information could have severe consequences, including disputes, regulatory investigations, litigation, fines, penalties and damages, as well as time-consuming and costly legal proceedings.

Any damage to our reputation or negative publicity regarding vaccine products or candidates could adversely affect our business and result in more stringent regulations.

From time to time, we, or our Shareholders, Directors, officers, employees, suppliers or other third parties we cooperate with or rely on, may be subject to negative media coverage or adverse publicity, which could harm public perception of our reputation and brand. Negative publicity may also undermine public confidence in vaccine products generally, reduce demand for vaccination, and lead to more stringent regulations, and thus demanding significant time and attention from our management team, diverting resources from business operations, and increasing compliance costs. We may be subject to the implications of negative publicity on vaccine products or the vaccine industry as a whole.

We may grow through acquisitions, partnerships, collaborations or other strategic arrangements, which may fail to deliver anticipated benefits and adversely affect our business.

For successful acquisitions, strategic partnerships, collaborations or alliances, we need to find suitable targets and partners on favorable terms. However, we may not be able to identify appropriate opportunities or successfully negotiate and complete such transactions. These activities may require significant management attention and resources, which could divert focus from our existing operations and adversely affect our ability to manage our business effectively.

We cannot assure you that we will realize the anticipated benefits or synergies from any acquisition, partnership, collaboration or alliance. Such transactions may involve risks and uncertainties, including integration challenges, difficulties in combining operations or technologies, diversion of management attention, loss of key employees or customers, exposure to litigation, unforeseen or hidden liabilities, ongoing financial obligations, and impairment charges if the transaction does not perform as expected.

We may not be able to effectively manage our growth or successfully expand our operations.

To achieve sustained growth, we may need to expand our development, regulatory, manufacturing, marketing and sales capabilities, or engage third parties to provide these services, as well as to manage additional relationships with those suppliers and other third parties, which may impose significant responsibilities on our management team.

Our future financial performance and ability to commercialize our vaccine candidates and compete effectively will depend, in part, on our capacity to manage growth efficiently. This includes overseeing development efforts and clinical trials, and recruiting, training and integrating additional management, administrative and sales and marketing personnel. We may not be able to achieve these objectives.

RISK FACTORS

Counterfeits of our products and illegal vaccines could negatively affect our sales and our reputation and expose us to liability claims.

Certain vaccines sold on the market may be manufactured without proper licenses or approvals, or fraudulently mislabeled regarding their content or manufacturer. These counterfeit products often resemble authentic vaccines in appearance but are generally sold at lower prices, which could quickly erode our sales of the affected products.

Counterfeit vaccines may differ in chemical composition from our products, making them less effective, entirely ineffective, or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, administrative penalties, fines, and even litigation. The existence of counterfeit or substandard vaccines in recent years has reinforced negative perceptions of pharmaceutical products manufactured in China, which may harm the reputation of companies like us.

Also, vaccines may be illegally imported into the PRC market at lower prices, competing with and reducing demand for vaccines legally manufactured and sold. Continued proliferation of counterfeit and illegal vaccines could adversely affect our sales and our reputation, and expose us to liability claims.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

We may not succeed in obtaining or maintaining adequate intellectual property protection for one or more of our vaccine products or candidates.

Our commercial success depends significantly on our ability to obtain and maintain adequate intellectual property protection for our vaccines and vaccine candidates. While we seek patent protection for certain technologies, many of our key product formulation and manufacturing processes are maintained as trade secrets and proprietary know-how. We may not seek patent protection for these technologies to preserve our competitive position in all jurisdictions where we operate or plan to operate, and we cannot assure you that competitors will not develop similar or related technologies and obtain patent protection that could restrict our ability to use such technologies or manufacture our products.

Even if we apply for patents, we cannot guarantee that our applications will be granted. Obtaining patent protection in China can be a lengthy and costly process, and we cannot assure you that our pending patent applications, or any future applications relating to other products or production processes, will result in granted patents. In addition, if we pursue license-in arrangements, patents licensed to us under such arrangements may not ultimately be granted, which could limit our protection.

Even if we obtain patent protection for our vaccines and vaccine candidates, such protection is limited and may not protect us against all potential risks or threats. Patent protection is subject to statutory terms and does not last indefinitely. For example, in the PRC, the term of an invention patent is generally 20 years from the filing date. Upon expiration of any issued patents or patents that may be granted from pending applications, we will no longer be able to assert such rights against competitors. Given the lengthy timelines required for development, clinical testing and regulatory approval of new vaccine candidates, patents covering such candidates may expire before or shortly after commercialization, limiting their commercial lifespan and value. As a result, our patents and applications may not provide sufficient protection to prevent others from developing or commercializing similar or identical products.

Further, as the patent landscape for vaccine companies is inherently uncertain with complex legal and factual considerations, we cannot guarantee that any issued patents we currently hold or may obtain in the future will be valid, enforceable, or provide sufficient and meaningful protection or a competitive advantage. Despite our protection measures, our patents may be interpreted

RISK FACTORS

narrowly, challenged, invalidated, or circumvented. The grant of a patent does not guarantee its inventorship, scope, validity or enforceability, and our patents may be challenged before courts or patent offices in various jurisdictions. We may face claims from former employees or third parties asserting interests in our patents or other intellectual property, or get involved in opposition, derivation, revocation, reexamination, post-grant review, inter partes review or interference proceedings.

If we are unsuccessful in any such proceedings or disputes relating to priority, validity or inventorship, we may lose valuable intellectual property rights, including exclusive ownership, or our patent claims may be narrowed, invalidated or held unenforceable. In some cases, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. Failure to obtain such licenses could force us to cease the development, manufacture or commercialization of our vaccine candidates. Loss of exclusivity or narrowing of patent claims could limit our ability to prevent others from using or commercializing similar products. Even if we prevail in such disputes, they could result in substantial costs and divert management attention.

Furthermore, to maintain adequate protection, we need to continuously comply with various procedural, regulatory and other requirements, which are subject to change and development, and our patent protection may be reduced or lost if we fail to comply. Periodic maintenance, renewal, annual, and other governmental fees must be paid to the CNIPA and other patent authorities at various stages throughout the life of a patent. These agencies also require strict compliance with procedural, documentary, and fee-related requirements during both the application and maintenance processes. While certain lapses can often be remedied by paying late fees or taking corrective measures under applicable rules, non-compliance in some cases may lead to the abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Such events may occur due to failure to respond to official actions within prescribed deadlines, non-payment of fees, or failure to properly legalize and submit required documents. If any of these occur, competitors may gain market access. Moreover, changes in patent laws or their interpretation across jurisdictions may increase uncertainty and costs, weaken our ability to protect our inventions, and reduce the scope or value of our patent rights. Any such developments could materially and adversely affect our intellectual property portfolio, our ability to protect and enforce patent rights, and ultimately our competitive position.

In addition to patents, we use trade secrets and proprietary know-how to protect our intellectual property. We have implemented measures such as confidentiality agreements with employees who have access to sensitive information. However, these measures may not offer enough protection or remedies for unauthorized use or disclosure. Third parties may independently develop information or techniques similar or alternative to ours, replicate our technologies without infringing our intellectual property rights, or otherwise gain access to our trade secrets.

Claims that our vaccine products or candidates infringe third-party patents or other intellectual property rights, or challenges to the ownership of our patents or other intellectual property, could result in costly litigation, require substantial time and resources to resolve, lead to significant liabilities, and prevent us from selling these products.

Our commercial success depends significantly on our ability to operate without infringing third-party intellectual property rights. Patent applications in China are generally published 18 months after filing, and China, like many other jurisdictions, adopts a first-to-file system. As a result, we may not be aware of pending applications filed by third parties while we are developing our products. Even after reasonable investigation, we cannot guarantee that our technologies do not infringe existing or future patents due to the complexity of patent claims and limitations of patent clearance searches in China. In addition, technologies licensed or acquired by us may be subject to infringement or misappropriation claims, which could affect our ability to rely on such technologies.

RISK FACTORS

If a third party claims that infringement upon its proprietary rights has taken place, any of the following may occur: we may become involved in time-consuming and expensive litigation, even if the claim is without merit; we may become liable for substantial damages for past infringement if a court decides that our technology infringes upon a third party’s patent; a court may prohibit us from producing, selling or licensing our product without a license from the patent holder, which may not be available on commercially reasonable terms, if at all, or which may require us to pay substantial royalties; and we may have to reformulate our product so that it does not infringe upon others’ patent rights, which may not be possible or could be very expensive and time-consuming.

To avoid or settle potential claims, we may need to obtain licenses and pay substantial fees or royalties, and such licenses may be non-exclusive, allowing competitors access to the same technology. Ultimately, we may be prevented from selling certain products or commercializing vaccine candidates, or be forced to cease some or all of our operations if licenses cannot be obtained on acceptable terms.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be costly, time-consuming and may not be successful, and any unfavorable outcomes in such litigation could restrict our R&D activities or our ability to commercialize our vaccine candidates, and may also result in negative publicity that harms our reputation and causes the market price of our H Shares to decline.

We may not be able to prevent infringement or misappropriation of our intellectual property rights, and enforcing such rights could be costly, uncertain and disruptive. Competitors or other third parties may infringe our patents or misappropriate our trade secrets and other intellectual property, and we may need to initiate litigation or other proceedings to enforce or defend our intellectual property, safeguard trade secrets, or determine the validity and scope of our rights. Such proceedings can be expensive, time-consuming, and may divert management and technical personnel from their core responsibilities.

There is inherent uncertainty in any litigation, including intellectual property disputes. We cannot assure you that we would prevail, even if claims against us are weak or flawed. If we are unsuccessful in defending allegations that we have infringed, misappropriated or otherwise violated third-party intellectual property rights, we may be required to pay substantial damages, cease sales of certain vaccines, or obtain licenses to continue our R&D programs or commercialize products. Such licenses may not be available on commercially reasonable terms, or at all. Failure to obtain necessary licenses could prevent us from using certain technologies, which may limit our ability to develop or commercialize our vaccine candidates or existing products.

Enforcement actions could also lead to counterclaims alleging that we infringe or misappropriate third-party intellectual property. For example, the defendant may counterclaim that the patent is invalid or unenforceable on grounds such as lack of novelty, obviousness, non-enablement or alleged misconduct during prosecution. If such challenges succeed, we could lose part or all the patent protection for a vaccine candidate. Even if unsuccessful, our patent claims may be construed narrowly, limiting enforcement against others. Many competitors have greater resources to defend and enforce their rights, which may put us at a disadvantage.

An adverse outcome in any litigation could result in our patents being invalidated, held unenforceable, or narrowly interpreted. Moreover, intellectual property litigation often involves extensive discovery, which may risk disclosure of our confidential information. Even if we ultimately prevail or settle early, litigation could burden us with substantial costs and distract our personnel. The uncertainties associated with litigation could also adversely affect our ability to raise funds, continue clinical trials, pursue internal research programs, in-license needed technology, or enter into strategic partnerships.

RISK FACTORS

Agreements with employees and third parties, such as confidentiality agreements or confidentiality provisions, may not prevent unauthorized disclosure or use of trade secrets and other proprietary information.

We use confidentiality agreements with employees and third parties to protect our intellectual property, including trade secrets, know-how, and other proprietary information. For example, such agreements are in place when we collaborate with CROs and with key employees. We also use invention assignment agreements and implement measures designed to protect our proprietary interests. However, we cannot guarantee that employees or third parties will not intentionally or inadvertently disclose our confidential information or these may otherwise be misappropriated. If competitors gain access to such information, they may use it to compromise our competitive position, despite any legal action we may pursue.

We sometimes engage individuals or research institutions to conduct research relevant to our business. While their ability to publish or disclose research data is subject to contractual restrictions, these provisions may not be sufficient to protect our confidential information. If we fail to apply for patent protection before such publication, or cannot otherwise maintain confidentiality, our ability to secure patent rights or protect trade secrets may be compromised, which could adversely affect our business.

We may face claims alleging that our employees have improperly used or disclosed trade secrets of their former employers, or asserting ownership of intellectual property that we consider our own.

Some of our employees, including members of senior management, were previously employed by other pharmaceutical companies, including our competitors or potential competitors. These employees may have been subject to proprietary rights, non-disclosure, and non-competition agreements with their former employers. As a result, we could face claims alleging that we or our employees have misappropriated or disclosed intellectual property, trade secrets, or other proprietary information belonging to such employers. Defending against these claims may require litigation. If we are unsuccessful, we could be required to pay damages, lose valuable intellectual property rights, or obtain licenses on terms that may not be commercially reasonable or available at all. Such outcomes could harm our business and impede the successful commercialization of our vaccine candidates. In addition, these claims or related litigation could lead to the loss of key personnel and negatively impact our ability to recruit or retain talent. Even if we prevail, litigation could be costly and divert the attention of our management and employees.

Furthermore, while we generally require individuals involved in the conception or development of intellectual property to enter into agreements assigning such rights to us, we may not succeed in obtaining such agreements from all contributors. Even when agreements are in place, assignments may not be self-executing or may be breached, resulting in disputes over ownership of intellectual property we consider ours. Also, individuals’ potential pre-existing or conflicting obligations to third parties, such as academic institutions, may render their assignment agreements ineffective. Failure to successfully prosecute or defend such claims could result in monetary damages and the loss of valuable intellectual property rights. Even if we succeed, litigation could still involve significant costs and distract our management and scientific personnel.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We recorded net losses during the Track Record Period and may continue to incur net losses in the foreseeable future.

We have incurred, and expect to continue incurring, substantial research and development, selling, administrative, and other operating expenses. For 2023, 2024 and 2025, we recorded a loss for the year of RMB35.9 million, RMB174.2 million and RMB71.3 million, respectively. See “Financial Information — Results of Operations” for further details on our financial performance during the Track Record Period.

RISK FACTORS

We expect to continue incurring significant expenses and losses for the foreseeable future, and our expenses are likely to increase substantially as we advance the clinical trials and preclinical studies of our vaccine candidates; initiate preclinical, clinical or other studies for new vaccine candidates; construct new manufacturing facilities; seek regulatory approvals to complete clinical development and commence commercialization; commercialize vaccine candidates that obtain marketing approval; attract and retain skilled personnel and grant equity-based awards under share incentive schemes; develop and expand our commercialization team for vaccine candidates that may receive regulatory approval; maintain, protect, expand and enforce our intellectual property portfolio; enforce and defend intellectual property-related claims; and acquire or in-license additional vaccine candidates, intellectual property assets and technologies.

Our future net profits and losses will depend, among other factors, on expenses incurred through our R&D programs and ongoing operations, the costs associated with commercializing any approved vaccine candidates, our ability to generate revenue, and the timing and amount of milestone or other payments made or received under arrangements with third parties. If any of our vaccine candidates fail during clinical trials, do not obtain regulatory approval, or, even if approved, fail to achieve market acceptance, our profitability may be materially affected. Also, even if we achieve profitability, we may not sustain it in subsequent periods. Our historical and anticipated future losses have adversely affected, and will continue to adversely affect, our working capital and shareholders' equity.

We recorded net current liabilities during the Track Record Period, which may expose us to liquidity risk.

As of December 31, 2023, 2024 and 2025, we had net current liabilities of RMB72.9 million, RMB435.1 million and RMB384.8 million, respectively, and we expect to continue incurring significant expenses, particularly for the expansion of our manufacturing facilities. We plan to fund near-term operations primarily through pre-[REDACTED] investments, cash generated from operations, existing cash and cash equivalents, bank borrowings, and [REDACTED] from the [REDACTED]. However, if there are changes to these funding sources or if our funding requirements increase, we will need to secure substantial additional financing through public or private equity offerings, debt financing, or other sources. Our ability to raise funds will depend on global financial, economic and market conditions and other factors beyond our control. If adequate funds are not available on a timely basis, we may be forced to reduce budgets for existing products or delay, limit, scale back, or terminate R&D activities, construction of production facilities, commercialization of our vaccine candidates, or sales and marketing efforts for our vaccine products.

We recorded net operating cash outflows during the Track Record Period and may need to obtain additional financing to fund our operations.

We had net cash flows generated from operating activities of RMB108.6 million in 2023, and net cash flows used in operating activities of RMB125.8 million and RMB258.6 million in 2024 and 2025, respectively. See “Financial Information — Cash Flows.” We expect to continue experiencing net cash outflows from operating activities in the near future. If we are unable to maintain sufficient working capital, we may default on our payment obligations, fail to meet capital expenditure requirements, be forced to scale back operations, and/or face other adverse operational impacts.

Our non-current assets, including goodwill, other intangible assets and property, plant and equipment, may become impaired.

We carry non-current assets that are subject to impairment assessments, including goodwill, other intangible assets and property, plant and equipment. See “Appendix I — Accountants' Report” for details. The recoverability of these assets depends on our management estimates and judgments, as well as the successful clinical development, regulatory approval and commercialization of our vaccine candidates. If our vaccine candidates fail to obtain approval or achieve anticipated market acceptance, if our expanded facilities are underutilized, or if market conditions otherwise

RISK FACTORS

deteriorate, we may be required to recognize material impairment losses, which could materially and adversely affect our financial condition and results of operations. Any impairment loss recognized for goodwill, moreover, cannot be reversed in subsequent periods. We cannot assure you that we will not recognize substantial impairment charges on our non-current assets in the future.

The expiration or termination of existing government incentives could adversely affect our profitability.

Our business benefits from certain government incentives, such as preferential tax treatment and government grants. The Company and Fosun Apexvac were accredited as a “High and New Technology Enterprise” under the relevant tax rules and regulations in 2023, and accordingly, was entitled to a reduced preferential CIT rate of 15% from 2023 to 2025. See Note 10 in the Accountants’ Report set out in Appendix I. In addition, we received government grants during the Track Record Period. Government grants recorded as other income and gains amounted to RMB1.1 million, RMB3.4 million and RMB3.0 million, respectively, representing 0.3%, 4.2% and 0.6% of our revenue in 2023, 2024 and 2025, respectively.

To continue qualifying for the above incentives, we must meet a number of financial and non-financial criteria. See “Regulations — Laws and Regulations Relating to Taxation — Enterprise Income Tax” for details. If we are no longer able to claim additional deductions on qualifying R&D expenditures, our effective income tax rate may increase. Furthermore, the government may decide at any time to eliminate or reduce the scope of such preferential tax policies. Similarly, the availability and amount of government grants depend largely on political and policy developments beyond our control. Government grants and subsidies are inherently non-recurring in nature. Any policy changes could significantly reduce or discontinue the government support we receive. In addition, effective January 1, 2026, our vaccine products ceased to be subject to the simplified VAT calculation method at 3% and are now subject to the standard VAT rate of 13% (with input VAT creditable accordingly). Although input VAT became creditable, we may be unable to fully pass on or offset the increased output VAT, which could increase our tax burden.

Even if we complete the [REDACTED], we may need to obtain additional financing to fund our operations.

During the Track Record Period, we funded our operations primarily through equity financing, bank borrowings, and cash generated from operations. We may require additional cash resources to meet ongoing operating needs in the future, particularly to support R&D activities. We expect to continue spending substantial amounts to advance the clinical development of our vaccine candidates and to commercialize any candidates that receive regulatory approval.

As our business and vaccine portfolio expand, we may need additional funding from existing shareholders or through public or private offerings, debt financing, collaborations, licensing arrangements, or other sources. However, we cannot guarantee that financing will be available in the required amounts or on commercially reasonable terms, if at all. We may also face challenges in obtaining or renewing bank loans and other borrowings. If we are unable to secure sufficient capital to meet future cash requirements, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

Our financial assets measured at amortized cost are subject to credit risk and may become impaired.

As of December 31, 2023, 2024 and 2025, we had financial assets measured at amortized cost of RMB478.2 million, RMB183.8 million and RMB658.5 million, respectively, consisting primarily of trade receivables, financial assets included in prepayments, deposits and other receivables, restricted bank deposits, time deposits and cash and cash equivalents. These financial assets are subject to impairment after initial recognition. If credit risk increases significantly since initial recognition, we may be required to increase the related loss allowances. Future impairment of our financial assets at amortized cost could result in material impairment losses.

RISK FACTORS

Share-based compensation will result in further dilution to our existing Shareholders and adversely affect our financial performance.

To incentivize and reward the eligible persons who have contributed or will contribute to the Group, we operate a share incentive plan which includes the share option scheme. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments. For details, see “Appendix IV — Statutory and General Information — Share Incentive Schemes.” In 2023, 2024 and 2025, we incurred share-based payments of nil, RMB4.5 million and RMB42.9 million respectively. For further incentivization, we may grant additional share-based payment in the future. Issuance of additional Shares with respect to such share-based payments may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payments may also increase our operating expenses.

RISKS RELATING TO GOVERNMENT REGULATIONS

Any failure to comply with applicable laws, regulations or industry standards, or to obtain required licenses and permits, or any changes in such laws and regulations could harm our reputation and adversely affect our business, results of operations and prospects.

We are subject to various laws and regulations and are governed by numerous governmental agencies and industry regulatory bodies in China that impose strict rules, regulations and industry standards on pharmaceutical and biopharmaceutical R&D activities, pharmaceutical manufacturing and vaccine circulation, including laws relating to biosecurity, data security and management, environmental protection, fire prevention and safety, occupational health and safety, anti-bribery and anti-corruption, and other compliance-related matters. These requirements continue to evolve and may differ across national, provincial and local levels, including variations in interpretation, implementation and enforcement which apply to us. We may not be able to always ensure full compliance. Any failure to comply could result in suspension or termination of ongoing research, administrative penalties, disqualification of data for regulatory submissions, and/or reputational damage.

We primarily conduct clinical trials for our vaccine candidates in China, and comparable foreign regulatory authorities may not accept data from such trials.

We primarily conduct clinical trials for our vaccine candidates in China and may conduct trials in other jurisdictions in the future. Acceptance of data from trials conducted outside a jurisdiction by its local regulatory authorities may be subject to conditions. In addition, such trials would be governed by the applicable laws and regulations of the jurisdictions where they are conducted. There can be no assurance that any foreign regulatory authority will accept data from trials conducted outside its jurisdiction. If such data is not accepted, we may be required to conduct additional trials, which would be costly and time-consuming, delay our business plans, and potentially prevent our vaccine candidates from obtaining approval or clearance for commercialization in the relevant jurisdiction.

We may face risks associated with managing human genetic resources and medical data of participants enrolled in our clinical trials.

Any changes in applicable privacy and data security laws and regulations could limit our ability to use medical data and expose us to liability for uses that were previously permitted. Compliance with these evolving requirements may result in significant operational costs or require us to modify our data processing practices. Our clinical trials often involve clinical sites and CROs working with our staff and participants, and we cannot guarantee that each party involved in clinical trials will consistently comply with applicable laws and regulations relating to human genetic resource management and personal information protection or our data protection measures. Any leakage or misuse of patient medical data or other negligence of compliance with such laws and

RISK FACTORS

regulations by the parties may be perceived as our fault or negligence. Noncompliance could lead to investigations or proceedings by related authorities, resulting in substantial fines, penalties, judgments, and negative publicity. We cannot guarantee that we could always comply with privacy obligations and human genetic resources management requirements, or prevent information security compromise leading to unauthorized disclosure or transfer of personally identifiable information or other patient data.

Failure by us, our employees or third-parties to comply with applicable anti-bribery laws could subject us to investigations, litigations, penalties or fines, which could harm our reputation and materially and adversely affect our business, financial condition and results of operations.

In the vaccine industry, the PRC government has implemented stringent anti-corruption and anti-bribery measures to curb improper practices, such as kickbacks, bribery, or other unlawful benefits offered by manufacturers to CDCs, medical institutions, physicians, or government authorities in connection with public tenders, vaccine procurement, or the issuance of licenses and permits. Any violation of these laws or involvement in such practices could result in fines, damages, suspension of licenses, or even criminal liability.

If our officers, employees, or third-party marketing service providers, whether knowingly or inadvertently, engage in bribery or other improper conduct in connection with the marketing, promotion, or sale of our products, or otherwise in the course of our business, it could harm our reputation and expose us to regulatory investigations, significant costs, and liabilities. We could also be held liable for misconduct by our employees or third-party marketing service providers.

Furthermore, if we become subject to criminal, investigational, or administrative proceedings for commercial bribery, we may be placed on the adverse record list maintained by provincial health and family planning authorities. Under the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry, the aforementioned record would prohibit public medical institutions and government-subsidized healthcare institutions within the relevant jurisdiction from purchasing our products for two years. See “Regulations — Laws and Regulations Relating to Vaccines — Anti-Corruption and Anti-Bribery” for details.

RISKS RELATING TO THE JURISDICTIONS IN WHICH OUR BUSINESS OPERATES

Changes in political, economic and industrial laws, regulations and policies in the jurisdictions where we operate could materially and adversely affect our business, financial condition, results of operations and prospects.

Substantially all our operations and revenue are based in the PRC. In recent years, the PRC government has introduced measures to promote market-driven reforms and strengthen corporate governance. These policies, however, may be adjusted across industries or regions, and overall economic growth remains subject to government regulations and policies relating to capital investment, monetary policy, financial services, and preferential treatment for certain sectors. We cannot predict future changes in China’s economic, political or social conditions, nor the impact of new government policies on our business and prospects.

Changes in the international trade policies may affect our business operations.

Governments worldwide may implement significant changes to trade policies or take actions that materially impact international trade, such as imposing tariffs or capital controls. Any unfavorable trade policies could affect demand for our vaccine products, our competitive position, the recruitment of scientists and other R&D personnel, and the import or export of raw materials for drug development, or even prevent us from selling our products in certain countries.

RISK FACTORS

Ongoing trade disputes may escalate, making certain goods, such as advanced R&D equipment, materials, and manufacturing equipment, significantly more expensive or even prohibited from export. Also, we cannot assure you that our existing or potential service providers or collaboration partners will not change their perception of us or their willingness to work with us due to trade tensions, geopolitical concerns, or other adverse shifts in political relationships among relevant countries or regions.

Payment of dividends is subject to restrictions under PRC law.

Under PRC law, dividends may only be paid out of distributable profits, which are calculated based on PRC GAAP after deducting accumulated losses and mandatory appropriations to statutory and other reserves. As a result, we may not have sufficient distributable profits to make dividend payments to our Shareholders, even in periods when we report net income. Any undistributed profit in a given year will be retained and may be available for distribution in subsequent years.

In addition, we must comply with dividend distribution rules prescribed by PRC regulatory authorities when determining our payout ratios. The relevant regulatory authorities may amend these rules in the future, which could significantly reduce the amount of capital available to fund our business development and growth.

We are subject to environmental protection, health and safety laws and regulations, and any failure to comply may result in fines, penalties or additional costs that could materially and adversely affect our business.

Delays or failures to comply with environmental, health and safety laws and regulations, including those governing environmental protection facility acceptance, the treatment and discharge of pollutants and the use of toxic or hazardous chemicals, could result in rectification orders, significant fines, monetary damages, or suspension of production, affecting our ability to develop, manufacture and commercialize our vaccine candidates as planned. If laws or regulations become more stringent, we may incur substantial costs for compliance, which could impair our research, development or production efforts.

We cannot fully eliminate the risk of accidental contamination, biological or chemical hazards, or personal injury at our facilities during discovery, testing, development or manufacturing, and we could be liable for damages and clean-up costs, which, if not covered by insurance or indemnification, could harm our business. Such liability could also result in reputational damage and may force us to temporarily or permanently close affected facilities.

Gains from the sale of H Shares and dividends on H Shares may be subject to PRC income tax.

Holders of H Shares who are non-PRC resident individuals or enterprises and whose names appear on our H Share register are subject to PRC income tax under applicable laws and regulations on dividends received from us and gains realized from the sale or transfer of our shares.

Under the PRC Individual Income Tax Law and its implementation regulations, effective January 1, 2019, non-PRC resident individuals are subject to a 20% tax on dividends and share transfer gains, which must be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the “**Arrangement**”), signed on August 21, 2006, when meeting certain requirements therein, the PRC may levy tax on dividends paid to Hong Kong residents, but such tax generally shall not exceed 10% of the total dividends.

Under the PRC Enterprise Income Tax Law, revised on December 29, 2018, and its implementation regulations, revised on April 23, 2019, non-resident enterprises without a presence in China, or whose income is not connected to such presence, are subject to a 10% enterprise income

RISK FACTORS

tax on income derived from China. Under the Arrangement, dividends paid to Hong Kong resident enterprises might be taxed either in Hong Kong or under PRC law, but the tax rate shall not exceed: (i) 5% if the Hong Kong enterprise directly owns at least 25% of our capital; or (ii) otherwise, 10%.

The interpretation and enforcement of PRC tax laws by the tax authorities, including whether and how income tax will be levied on non-PRC resident shareholders, will depend on laws and regulations in effect at the time. Non-PRC resident holders of our H Shares should be aware that they may be required to pay PRC income tax on dividends and gains from the sale or transfer of H Shares.

There are uncertainties in serving legal process, enforcing foreign judgments or initiating actions in China against us or our management under Hong Kong or other foreign laws.

Both our Company and our subsidiaries are incorporated under the laws of China, and substantially all of our assets are located in China. Substantially all of our Directors and senior management personnel also reside in China, and substantially all of their assets are located in China. As a result, it may not be possible for investors to effect service of process upon us or our Directors and senior management personnel in China.

On July 14, 2006, the Supreme People’s Court of PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**2006 Arrangement**”). Under the 2006 Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the 2006 Arrangement in which a Hong Kong court or a PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the 2006 Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the 2006 Arrangement remain uncertain.

On January 18, 2019, the Supreme People’s Court of PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which came into effect on January 29, 2024 and supersedes the 2006 Arrangement, seeking to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and PRC. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. As certain judgments are subject to case-by-case review by the relevant courts under the New Arrangement, there can be no assurance that all judgments rendered by the courts in Hong Kong will be recognized and enforced by PRC courts.

Furthermore, China has not entered into treaties or arrangements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries, and Hong Kong has no arrangement for the reciprocal enforcement of judgments with the U.S. As a result, recognition and enforcement in PRC or Hong Kong of judgment of a court in the U.S. or any other jurisdictions mentioned above in relation to any matter that is not subject to a binding arbitration provision may be difficult or impossible.

RISK FACTORS

Failure to comply with property-related laws and regulations in respect of certain owned and leased properties in China may adversely affect our business, financial condition and results of operations.

We occupy certain properties in the PRC in connection with our business operations. Some of these properties did not meet certain property-related requirements under PRC laws and regulations. As of the Latest Practicable Date, there were six self-built supporting properties for which the relevant construction project planning and construction permit procedures have not been processed and no property ownership certificates have been obtained. Also, as of the Latest Practicable Date, we had two leased supporting properties where the lessors failed to provide valid title certificates. We cannot assure you that we or the lessors will be able to complete all rectification measures in a timely manner, or at all. If the relevant authorities determine that any of our property arrangements do not comply with applicable PRC laws and regulations, we may be required to pay fines, suspend the use of certain properties, restore properties to their original condition, or otherwise incur liabilities, which could adversely affect our business, financial condition and results of operations.

In addition, as of the Latest Practicable Date, leasing agreements of our five leased properties for operation had not been registered and filed with the competent PRC government authorities as required by applicable PRC laws and regulations. We cannot assure you that the lessors will cooperate and complete the registration in a timely manner. Our PRC Legal Advisor has advised us that failure to complete the registration and filing of lease agreements will not affect the validity of such leases or impede our use of the relevant properties but could result in the imposition of fines up to RMB10,000 for each leased property that is unregistered if we fail to rectify the non-compliance within the time frame prescribed by the relevant authorities. See “Business — Properties — Owned Properties.”

Furthermore, substantially all of our self-owned properties have been mortgaged to financial institutions to secure our loans. Any failure on repayment may result in the disposal of our properties and adversely affect our business operations.

Third party payment arrangement on social insurance and housing provident fund may subject us to additional contributions, together with late payments and fines, under PRC laws and regulations.

During the Track Record Period, we engaged third-party agencies to make social insurance and housing provident fund contributions for certain employees. As of the Latest Practicable Date, approximately 27 employees of the Company and its PRC subsidiaries applied to have their social insurance and housing provident fund contributions made through third-party service providers. Pursuant to the PRC laws, we are required to pay social insurance premium and housing provident funds for our employees under our own accounts instead of making payments under third-party accounts, and an employer that fails to make such contributions in full and on time may be ordered to pay the outstanding amounts, together with a late payment fee of up to 0.05% per day for social insurance, failing which it may be subject to fines of one to three times the overdue amount or compulsory court enforcement. Although we did not receive any administrative penalties or notices of non-compliance from governmental authorities in this regard or had any dispute with related employees during the Track Record Period and up to the Latest Practicable Date, we cannot assure you that the competent authorities will not require us to pay outstanding amounts or impose late payment fees or fines in the future, which could increase our labor costs and materially and adversely affect our business, financial condition and results of operations.

RISK FACTORS

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares and there is no assurance that an active market will develop. The market price and trading volume of our H Shares may be volatile, which could result in significant losses for investors who purchase our H Shares in the [REDACTED].

Prior to the [REDACTED], no public market existed for our H Shares. The [REDACTED] has been determined between us and the Overall Coordinators, on behalf of the [REDACTED], and may not be indicative of the trading prices at which the H Shares will trade following the [REDACTED]. The trading price of the H Shares may fluctuate significantly in response to a number of factors many of which are beyond our control, and investors who purchase H Shares in the [REDACTED] may incur substantial losses.

Pursuant to applicable PRC laws and regulations, all Shares in issue as of the date of this document will be subject to a statutory lock-up period of one year from the [REDACTED]. The limited public float may constrain liquidity, heighten price volatility, and adversely affect the development of an active and orderly market in the H Shares.

There is no assurance that an active, liquid, and sustainable market for our H Shares will develop following the [REDACTED]. Even if such a market develops, it may not be maintained. The market price of the H Shares may fall below the [REDACTED], and investors may lose all or part of their investment.

You will experience immediate and significant dilution and may be subject to further dilution in the future.

Investors purchasing H Shares in the [REDACTED] will experience immediate and substantial dilution in the net tangible asset value per Share and may experience further dilution thereafter. The [REDACTED] of the H Shares is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. As a result, investors subscribing for H Shares in the [REDACTED] will incur an immediate dilution in the unaudited [REDACTED] net tangible asset value per H Share. Conversely, existing Shareholders will experience an increase in the net tangible asset value per Share of their Shares. For further details of the adjustments and assumptions, see “Unaudited [REDACTED] Financial Information” in Appendix II to this document.

Future sales, or the perception of sales, of our H Shares in the public market by major shareholders after the [REDACTED] could materially and adversely affect the market price of our H Shares.

Immediately after the [REDACTED], only a limited portion of our issued share capital will be freely tradable due to contractual lock-up arrangements and regulatory restrictions on disposal and new issuance. While these restrictions are expected to support market stability during the initial period following the [REDACTED], they will eventually lapse. Upon the expiry or waiver of these restrictions, significant sales of our H Shares by our existing Shareholders, particularly by major Shareholders, could increase the supply of H Shares available for trading and exert downward pressure on the market price of our H Shares. Even if actual sales do not occur, the market’s perception that substantial disposals may be contemplated by existing Shareholders could negatively impact investor sentiment and lead to a decline in the market price of our H Shares. Any such actual or perceived sales could also impair our ability to raise additional equity capital on favorable terms, or at all, in the future.

RISK FACTORS

Fluctuations in the RMB exchange rate and government regulations on currency conversion may materially affect our financial condition and limit our ability to make foreign exchange transactions, including dividend payments on our H Shares.

We derive all our revenue in RMB, which is not freely convertible into foreign currencies. Also, we are required to convert a portion of our RMB-denominated revenue into foreign currencies to meet our foreign currency obligations, including any dividend payments declared on our H Shares.

Under current PRC foreign exchange regulations, following completion of the [REDACTED], we are permitted to conduct current account foreign exchange transactions, such as the remittance of dividends in foreign currencies, without prior approval from SAFE, subject to compliance with prescribed procedural requirements. However, there is no assurance that such policies will remain in effect. Should the PRC government impose more restrictive foreign exchange controls, we may no longer be able to remit dividends to holders of our H Shares in foreign currencies.

Foreign exchange transactions under the capital account, including repayments of foreign-currency-denominated indebtedness, continue to be subject to significant restrictions and generally require prior SAFE approval. The PRC government may in the future introduce additional rules, administrative measures or policy adjustments that further restrict the availability, usage or conversion of foreign currency for both current account and capital account purposes.

Any such developments could adversely affect our ability to obtain foreign currency to pay dividends, service foreign currency obligations, fund capital expenditures or secure offshore financing.

We cannot assure you that we will make any dividend payments in the future.

We cannot assure you that we will declare or pay dividends in the future. We did not declare or pay any dividends during the Track Record Period, and our historical dividend record (or the absence of one) should not be regarded as indicative of our future dividend payments, if any. Even if our operations are profitable and our financial statements reflect positive results, we may not have sufficient distributable profits under applicable laws to declare dividends. Further, we cannot assure you that we will maintain the same dividend policy, if any, that we may adopt following the [REDACTED]. Whether dividends will be declared and the amount of any such dividends will depend on a range of factors, including our results of operations, financial condition, cash flow position, capital requirements, regulatory considerations, prevailing market conditions and other factors that our Board of Directors considers relevant at the time. See “Financial Information — Dividend Policy.”

Facts, forecasts and statistics in this document relating to the vaccine market may not be completely accurate or reliable.

This document contains facts, forecasts and statistics on the vaccine industry in and outside China derived from various sources, including government publications, industry reports, third-party databases and other publicly available information, which may not be prepared on a consistent basis or may be subject to significant limitations inherent in the collection, sampling or interpretation methodologies adopted by the relevant sources. Their methodologies may be flawed, outdated or not adequately disclosed, and market practice may also diverge from the assumptions underlying the published statistics. As a result, such information may be inaccurate, incomplete, internally inconsistent or not comparable across different markets or time periods.

While we believe that such information has been obtained from sources we consider reliable and that we have exercised reasonable care in the reproduction and presentation of such data, none of us, the Joint Sponsors, the Overall Coordinators, the [REDACTED], or any of their respective directors, officers, employees, advisors or agents have independently verified the accuracy or completeness of the official or third-party information set out in this document, and no

RISK FACTORS

representation or warranty, express or implied, is given as to the fairness, accuracy or reliability of such information. We cannot assure you that the facts, forecasts or statistics presented are compiled on the same basis as other data available in the public domain or with the same degree of precision as similar industry information included elsewhere. Accordingly, you should exercise caution in relying on such information and should not place undue reliance on them when considering an investment in our H Shares.

Forward-looking statements in this document involve risks and uncertainties.

This document contains forward-looking statements regarding our future plans, objectives, strategies, business outlook and anticipated financial performance, based on assumptions and information currently available to our management. However, whether we are able to implement those statements described in this document will depend on a number of factors, including changes in market conditions, our ability to execute our business strategies, our competitive environment, our operational and financial resources, regulatory developments, technological changes, and global, regional or local economic and financial conditions. Actual results may differ materially from those expressed or implied in our forward-looking statements. Accordingly, prospective investors should not place undue reliance on such forward-looking statements and should consider them in light of the risks described in this section and elsewhere in this document.

You should read this document in its entirety, and we strongly advise you not to rely on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this document and prior to the completion of the [REDACTED], there may be press or other media coverage regarding us, our business or the [REDACTED]. Such coverage may include financial information, operational data, industry commentary, valuations, forecasts, projections or other forward-looking statements relating to us or the [REDACTED]. We have no control over the dissemination of such information and have not authorized the disclosure of any such materials.

We make no representation as to the accuracy, completeness, fairness or reliability of any financial data, projections, valuations, views or analyses reported in the press or other media. Any such information may be inconsistent with, or conflict with, the information contained in this document. To the extent of any inconsistency or conflict, we disclaim responsibility for such information.

Prospective investors are cautioned that you should rely solely on the information contained in this document, the [REDACTED] materials and any formal announcements issued by us when making any investment decision regarding our H Shares. We do not accept any responsibility for the accuracy or completeness of media reports or for any forecasts, opinions or statements published by newspapers, other media outlets, analysts or commentators.

By applying to purchase our H Shares in the [REDACTED], you will be deemed to have acknowledged and agreed that you have relied only on the information in this document and the formal [REDACTED] documents, and not on any information from press articles, media reports or other unauthorized sources.

Our Controlling Shareholders exercise significant influence over our Company, and their interests may not align with those of holders of H Shares.

Our Controlling Shareholders exercise significant influence over our Company, including over matters such as management decisions, corporate policies, mergers and acquisitions, expansion strategies, asset sales, and the election of Directors. Their ability to control or substantially influence these decisions may not always align with the interests of our minority Shareholders. In some cases, this concentration of control could prevent us from pursuing transactions that might otherwise benefit our Company. It may also have the effect of discouraging, delaying, or preventing a change of control, which could deprive Shareholders of the opportunity to realize a premium on their Shares in connection with such a transaction and could adversely affect the market price of our H Shares. For further details, see “Relationship with Controlling Shareholders.”