

RISK FACTORS

An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this Document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the [REDACTED] our Shares could decline, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is subject to the cautionary statements in the section headed “Forward Looking Statements” in this Document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our business and industry, consisting of (a) risks relating to the development of our product candidates, (b) risks relating to commercialization of our product candidates; (c) risks relating to extensive government regulation; (d) risks relating to our intellectual property rights, and (e) risks relating to our reliance on third parties; (ii) risks relating to our financial position and need for additional capital; (iii) risks relating to our general operations; and (iv) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also have a material adverse effect on our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to Development of Our Product Candidates

Our future growth depends substantially on the successful development of our product portfolio. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business and financial prospects will be materially adversely affected.

Our business substantially depends on the successful development, obtaining and maintaining the necessary regulatory approvals and commercialization of our current and future product candidates. As of the Latest Practicable Date, we had commercialized the Brain Function Information Management Platform Software System (the “**System**”) for application

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in the assessment and treatment of cognitive impairment induced by vascular diseases, aphasia, Alzheimer’s disease, depression, schizophrenia, sleeping disorder, Attention Deficient Hyperactivity Disorder (the “ADHD”) and autism. Our System was under development for several other cognitive impairment indications in addition to the eight commercialized indications; we also had three additional products with regulatory approvals in China, one product with regulatory approval in the EU and six additional product candidates under different stages of preclinical and clinical development or registration process as of the Latest Practicable Date. See “Business—Our Product Pipeline” for more details on our complete product pipeline. We have invested a significant portion of our time and financial resources towards the development and commercialization of our products and product candidates. We incurred research and development expenses of RMB32.8 million, RMB67.6 million, RMB90.7 million, RMB34.4 million and RMB64.2 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. We incurred loss and total comprehensive expense for the year of RMB697.8 million, RMB502.5 million, RMB359.1 million, RMB234.6 million and RMB114.4 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. Whether we can generate profit from our operating activities largely depends on the successful commercialization of our System to more indications and of our other products candidates under development.

The success of our products and product candidates will depend on several factors, including but not limited to:

- successful enrollment of trial participants in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data resulting from our clinical trials and preclinical studies;
- obtaining and maintaining the necessary regulatory approvals, commercialization authorizations and successfully launching our product candidates effectively in target markets, if and when approved, in a timely manner;
- the performance by any third parties we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret and/or other intellectual property rights of third parties;
- appropriately pricing our products and timely collecting payments;
- enhancing our marketing and distribution capabilities in an efficient and cost-effective manner;

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- market and pricing competition with other cognitive impairment digital therapeutics (the “DTx”) products;
- keeping up with industry and technology developments; and
- continued acceptable safety profile and efficacy of our products and product candidates following regulatory approval, if and when received.

If we are not successful in one or more of these factors in a timely manner, or at all, we could experience significant delays or be unable to obtain the necessary approval for and/or to successfully expand commercialized indications of our System or to commercialize our other product candidates, which may have a materially adverse effect on our business and may result in us not being able to generate sufficient revenue and cash flow to continue our research, development and general business operations.

DTx industry is developing rapidly. If we are not able to develop and release new products that are competitive in the market, or develop successful enhancements or indication expansions of our System or any future products in a timely manner our products may become obsolete and our business, operating results and financial condition could be materially adversely affected.

DTx industry is new and rapidly evolving, and it is uncertain whether it will achieve and sustain high levels of demand and market adoption. Our future financial performance will depend on growth in this market and on our ability to adapt to emerging demands of our customers. It is difficult to predict the future growth rate and size of our target markets. The DTx industry is characterized by rapid technological change, frequent new product introductions and enhancements, changing customer demands, and evolving industry standards. Social trends and political policies on the DTx industry (including but not limited to ESG related matters over the industry) may further evolve, which could lead to changes in need for our products and the need for us to adapt our business model and our product pipelines. Our success therefore depends on our ability to accurately forecast the industry trends and continuously identify, develop and market more advanced products in a timely manner that address unmet clinical needs. Product designs can change with market conditions, as well as demand and preferences of hospitals and medical professionals. We cannot assure you that we will be able to successfully identify new technological opportunities, enhance or adapt to new technologies and methodologies, develop new products, or improve or expand the indication coverage of our existing products in a timely manner. Even if we develop new or improve our existing technologies and products, our ability to market our products could be limited by the need for regulatory clearance or approval, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other obstacles.

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Technological innovations often entail great uncertainty. A successful innovation cannot be a linear and regular method; rather, it has to take into account the randomness of the process and the industry participants' partial knowledge of the domain. We may not succeed in developing, marketing and delivering in a timely and cost-effective manner enhancements or improvements to our commercialized products or any new products that respond to continued changes in market demands, new customer requirements or achieve market acceptance. The timetable for the release of new products and enhancements to existing products is difficult to predict due to complexity in product development, and we may not offer new products and updates as rapidly as our users require or expect. Any new products that we develop or acquire may not be introduced in a timely or cost-effective manner, may contain errors or defects, or may not achieve the broad market acceptance necessary to generate significant or any revenue. In addition, technological innovations often require substantial time and investment before we can determine their commercial viability. We devote significant financial and other resources to our research and development activities, while our research and development efforts may not lead to new or improved technologies or products that will be commercially successful. Furthermore, we may not have the financial resources necessary to fund future projects. Even if we are able to successfully develop new products or improve or expand the indication coverage of existing products, we may not generate revenue in excess of the costs of development and procurement, or achieve the desired financial return. These products and relevant technologies may be rendered obsolete or less competitive due to changing customer preferences or the introduction by our competitors of products with newer technologies or features or other factors.

The introduction of new products by competitors, the development of entirely new technologies to replace existing DTx offerings or shifts in healthcare benefits trends could make our products obsolete or materially and adversely affect our business, financial condition and results of operations. We may experience difficulties with software development, industry standards, design or marketing that could delay or prevent our development, introduction or implementation of new products, indication coverage, additional features or capabilities. If patients and healthcare providers do not widely adopt our products, we may not be able to realize a return on our investment. If we do not accurately anticipate patient and physician demands or we are unable to develop, license or acquire new features and capabilities on a timely and cost-effective basis, or if such enhancements do not achieve market acceptance, it could result in adverse publicity, loss of revenue or market acceptance or claims by patients or healthcare providers brought against us, each of which could have a material and adverse effect on our reputation, business, results of operations and financial condition.

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Clinical development is a lengthy, expensive and uncertain process, and unsuccessful clinical trials or procedures relating to products and indications under development could have a material adverse effect on our prospects, including incurring additional costs, experiencing delays in completing, or ultimately being unable to complete the development and commercialization of our product if clinical trials fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities.

According to a catalog issued by the NMPA, medical devices are classified into three different categories, Class I, Class II and Class III medical device registration certificate, depending on the degree of risk associated with a particular medical device and the extent of control needed to ensure the safety and efficacy of such medical device. Our System has received its initial Class II Certificate from the Hunan MPA in September 2018. In June 2020, the System obtained an amended Class II medical device registration certificate from the Hunan MPA which includes the specific types of cognitive impairment covered by the System, making it possible for us to commercialize the System in China. In 2023, we successfully renewed the Class II medical device registration certificate which now expires in 2028. To obtain medical device registrations of Class II medical devices for commercialization in a particular indication, we need to conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate the safety and efficacy of our products.

Some of our current and future products may be classified or reclassified as Class III medical devices under relevant PRC laws and regulations. See “Regulatory Overview—PRC Regulatory Overview—Regulation Relating to Medical Devices—Registration and Record-Filing of Medical Devices” for more details. If this occurs, there may be more extensive regulatory requirements for the approval, manufacture, distribution and supervision of such products. These requirements may include additional clinical trials conducted under more stringent protocols than those required for Class II certifications, the need to obtain licenses to manufacture and distribute Class III medical devices and the establishment of an information management system to ensure traceability of all Class III medical devices that we manufacture and sell. Complying with the additional regulatory requirements for a Class III medical device may increase our research and development, regulatory, manufacturing and distribution costs, delay our research and development and commercialization timelines and have a material adverse effect on our business prospects, results of operations and financial condition.

Successful preclinical studies and early clinical trials do not necessarily mean that later clinical trials will also result in data that replicate the results of prior trials and preclinical studies and ultimately lead to regulatory approval. Our System was under development for several other cognitive impairment indications in addition to the eight commercialized indications; we also had three additional products with regulatory approvals in China, one product with regulatory approval in the EU and six additional product candidates under different stages of preclinical and clinical development or registration process as of the Latest

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Practicable Date. See “Business—Our Product Pipeline” for a detailed description of the development stages of our products and product candidates. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to obtain the necessary regulatory approval or commercialize our product candidates, including but not limited to:

- regulators or institutional review boards (“IRBs,” also known as independent ethics committees) may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- unanticipated protracted negotiations or an inability to agree on reasonable contractual terms with prospective CROs and hospitals for the provision of trial centers, which may lead to delayed commencement (if at all) of clinical studies for regulatory approvals;
- failure of our product to demonstrate superior results than competing or alternative products, if applicable;
- clinical trials of our product candidates may fail to demonstrate the primary or secondary endpoints as anticipated, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or subjects may drop out at a higher rate than we anticipate;
- our third-party contractors in connection with our clinical studies may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics; and
- the initial or interim results of the clinical trial may not be predictive of the final results; interim, “topline” and preliminary data from clinical trials of our product candidates under different indications may change as more patient data becomes available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

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There can be no assurance that the ongoing or planned clinical trials will be completed in a timely or cost-effective manner or result in a commercially viable product. If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates, the commercial prospects of that product candidate may be impacted, and our ability to generate revenue from any of those product candidates may be delayed. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development process and approval process, and jeopardize our ability to commercialize that product candidate. This may have a material adverse effect on business and financial condition. Clinical trials of our product candidates may produce negative or inconclusive results. Our future clinical trial results may not be favorable. Even if our future clinical trial results show favorable efficacy, not all users may benefit. We cannot assure you that our product candidates are able to suit the conditions of each clinical trial participant.

Our algorithms and methodologies are complex and may contain errors or may not operate properly, which could adversely affect our business, financial condition and results of operations.

Our algorithms and methodologies are crucial to our various types of DTx products. We feed training data into our algorithms, which typically include patient demographic information, clinical assessment information, and information collected when patients conduct training sessions at different difficulty levels, such as patient's performances, on, types of, and difficulty levels of previous training sessions. Leveraging such information, our neural networks (the "DNN") algorithms are constantly iterated and trained to timely adjust training session content in the System and introduce the appropriate training for patients' next-step intervention, in order to improve patients' cognitive functions. We cannot guarantee that the above working mechanism of our algorithms can function properly as designed. If our algorithms cannot access abundant and accurate information input to enable it to train and iterate properly, or if our DNN or other algorithms cannot achieve the intended training and iteration, the efficiency and efficacy of our System may be lower due to suboptimal task recommendation and poorly personalized training sessions, which could materially adversely affect our business operations and results of operations.

If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed, result in increased costs and longer development periods, or otherwise adversely affected.

Identifying, screening and enrolling of clinical trial participants are critical to our success. We may not be able to identify and enroll a sufficient number of trial participants with the required or desired characteristics in accordance with the eligibility criteria defined in our protocols to complete our clinical trials in a timely manner. The timing of our clinical trials depends on our ability to recruit participants to participate and remain in the trials until conclusion, as well as to complete follow-up periods, when required.

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Our clinical trials will likely compete with other clinical trials for comparable product candidates. This competition will reduce the number and types of trial participants available to us. For example, some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of trial participants available for our clinical trials at such clinical trial sites.

Any delays in enrolling trial participants in our planned clinical trials could result in increased costs, or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates or indication expansions of existing products.

If we experience delays in enrolling a sufficient number of participants in our clinical trials to meet relevant regulatory requirements or to generate meaningful statistical data, our clinical trial costs may increase or our clinical trial phases may not be completed on time, which may adversely affect our ability to advance the development of our product candidates and obtain the necessary regulatory approvals in accordance with our current planned timeline.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or result in significant negative consequences following regulatory approval, if any.

Although our products and current product candidates are mainly digital software systems that are unlikely to cause physical harm to human body, there is a possibility that the patients may suffer mental and emotional distress while using our products, even in a manner instructed by qualified physicians. Some patients may suffer from anxiety or sleeping disorder when and after using our System. If we or others identify undesirable side effects directly or indirectly caused by our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw clearance, authorization, or approvals of such product;
- regulatory authorities may require additional warnings for the product;
- we may be required to issue safety communications to patients or healthcare providers that outline the risks of such side effects;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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Any of these events could prevent us from achieving or maintaining market acceptance of the particular product or product candidate and, as a result of negative impacts to our reputation, our other products or product candidates and could significantly harm our business, results of operations and prospects.

Risks Relating to Commercialization of Our Product Candidates

We have relatively limited experience in marketing and sales of our products, and rely on our in-house marketing force to promote our products. If we are unable to develop and successfully maintain adequate sales and commercial distribution capabilities, our business and results of operations could be adversely affected.

We have relatively limited experience in launching, commercialization and marketing of our System. We started to commercialize the System in June 2020 when we amended the medical device registration certificate to include eight commercialized indications for the System. We rely on our in-house sales and marketing team and third-party service providers to market and promote our products. We incurred selling and distribution expenses of RMB10.8 million, RMB11.9 million, RMB38.4 million, RMB17.0 million and RMB25.4 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. The success of our marketing efforts depends on our ability to maintain and expand our relationships with qualified service providers, and our ability to attract, motivate and retain qualified and professional employees in our selling and distribution teams who have, among other things, the sufficient expertise in brain sciences, virtual human and AI technology, and clinical trials, and are able to communicate effectively with medical professionals. Competition for experienced selling and distribution personnel is intense. However, we would have little or no control over the selling and distribution efforts of third-party service providers. There can be no assurance that we will be able to develop and successfully maintain our in-house sales and commercial distribution capabilities or establish or maintain relationships with physicians, hospitals and other third parties to successfully commercialize our products. If we are unable to maintain and expand our relationships with qualified third-party service providers, or to attract, motivate and retain a sufficient number of qualified personnel to support our selling and distribution efforts, sales volumes or margin of our System and other products may be adversely affected and we may be unable to extend our market coverage and deepen our market penetration as contemplated.

In addition, we plan to continue to strengthen our cooperative relationship with hospitals and physicians for enhancing our product awareness in the market. However, such promotional activities may not be as effective as we expected, or may be impeded by unanticipated events, which may cause a decline of our sales revenue, and have a material adverse effect on our business, financial condition and results of operations.

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We mainly derived our revenue from services provided through our System. Failure to achieve the anticipated revenue related to the System may have a material adverse impact on our business and results of operations.

During the Track Record Period, a significant portion of our revenue was derived from services that allow customers to use our System. We expect that the System will continue to significantly contribute to our total revenue in the future. However, we cannot assure you that demand for our System and other DTx products and services will continue to grow as anticipated. There is also no assurance that we will be able to maintain our sales, which may be adversely affected by many factors outside of our control, including downward pricing pressure caused by changes in medical insurance coverage, binding pricing guidance, market competition, expiration of patent protection, introduction of substitute products marketed by our competitors, disruptions in sales, issues with respect to product quality or severe adverse events incurred, and disputes over intellectual property or other matters with third parties. If we are unable to maintain the sales volumes, pricing levels or profit margin of our medical products, our business, financial condition and results of operations may be materially and adversely affected.

The DTx market is relatively new. Failure to achieve broad market acceptance or maintain good reputation among physicians, hospitals, patients and other customers could have a material adverse impact on our business, results of operations and prospects.

If our products and any future approved product candidates fail to gain sufficient market acceptance by hospitals, physicians, patients and third-party payors, among others, the sales of our products may be adversely affected. In addition, hospitals, physicians, patients and third-party payors may prefer other novel products to ours. If our products do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our products and product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our products and product candidates are approved;
- perception by physicians, patients and hospitals of our products and product candidates as safe and effective, and physicians' willingness to recommend our products for the assessment and intervention of cognitive impairment patients;
- the actual and perceived advantages of our products and product candidates over alternative products;
- the prevalence and severity of any adverse effects or complications;
- the timing of market introduction of our products and product candidates as well as competitive products;

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- the cost of our products in relation to alternatives;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- the effectiveness of our sales and marketing efforts; and
- the operation smoothness of our System.

If any products that we commercialize fail to achieve market acceptance or if we fail to maintain good relationships with customers or potential customers, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies introduced are more favorably accepted by the market, more cost effective or render our products obsolete. In addition, the operations of our System and other DTx products and product candidates may encounter technical obstacles, and it is possible that we may discover additional technical glitches that prevent System from operating properly. If our System does not function reliably or fails to achieve expectations of our customers in terms of performance, we may be required to divert resources allocated for other business purposes to address these issues, may suffer reputational harm, lose or fail to grow our customer base, and may be subject to liability claims.

We believe that enhancing and maintaining awareness of our “BrainAu” brand is critical to achieving widespread acceptance of our cognitive impairment DTx products, gaining trust for our various products and related support services, strengthening our relationships with our existing customers and attracting new ones. Successful promotion of our brand depends largely on the quality of the Systems and our other products and product candidates and services and the effectiveness of our branding and marketing efforts. We expect that our branding and marketing efforts will require us to incur significant expenses and devote substantial resources. We cannot assure that our sales and marketing efforts will be successful. Brand promotion activities may not lead to increased revenue in the near term, and, even if they do, any revenue increases may not offset the expenses we incur to promote our brand. Our failure to establish and promote our brand and any damage to our reputation will hinder our growth. In addition, our reputation may be undermined as a result of the negative publicity about our Company or our industry in general.

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Our sales may be affected by the level of medical insurance reimbursement patients receive.

Our ability to sell our services which grant customers access to use the System may be affected by the then available medical insurance coverage in China. The relevant governmental insurance coverage or reimbursement level in China varies from region to region, as local government approvals for such coverage must be obtained in each geographic region in China. In line with market practice, we make our System available for cognitive impairment patients to use primarily in hospitals. The prices we charge is largely dependent on the amount charged by hospitals, which is in turn determined by the price level set by the local provincial health insurance reimbursement lists. In addition, the PRC government may change, reduce or eliminate the governmental insurance coverage then available for DTx. As of the Latest Practicable Date, our System had entered the health insurance reimbursement lists of 30 provinces in China. We cannot assure you that we can expand the number of provinces in China where our System or other products or product candidates enter the provincial health insurance reimbursement lists. To the extent that our products are not included in the medical insurance reimbursement list or if any such insurance schemes are changed or cancelled which result in any removal of our products from the medical insurance reimbursement list, patients may choose, and hospitals may recommend, alternative options.

In the absence of sufficient medical insurance coverage, market demand for DTx may drop, which could in turn materially and adversely affect our business, financial condition and results of operations. Moreover, we may need to lower the prices of our products to have the use of our products included in the then available medical insurance reimbursement list, and such price cut and reimbursement may not necessarily lead to any increase in our sales and our results of operations may be adversely affected.

Guidelines, recommendations and studies published by various organizations could disfavor our product candidates.

Influential recommendations, guidelines and quality metrics issued by various organizations and government authorities may significantly affect customers’ willingness to purchase our products and services. For example, we have been deeply involved in the publications of the first four expert consensus in the field of cognitive impairment DTx in China. In particular, in March 2023, we co-authored the “Chinese expert consensus on digital therapeutics for cognitive impairment (2023 edition)” (《認知數字療法中國專家共識(2023)》) which for the first time in China systematically defined cognitive impairment DTx, according to Frost & Sullivan. In addition, three expert consensus and one guideline published from 2021 to 2023 have referenced our article published on “Alzheimer’s & Dementia” (the “**A&D Journal**”) in 2019. If any such recommendations, guidelines and quality metrics that are currently favorable to us are later updated, overturned or modified, or otherwise interpreted in a manner unfavorable to us, our results of operations and prospects may be adversely affected.

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Our commercialization efforts to date have focused primarily on China. Our ability to enter other foreign markets will depend, among other things, on our ability to navigate various regulatory regimes with which we do not have experience, which could delay or prevent the growth of our operations outside of China.

To date, our commercialization efforts have focused primarily on China. Expanding our business to attract customers in other countries and regions is an element of our long-term business strategy. Our ability to continue to expand our business and to attract talented employees and customers in various international markets will require considerable management attention and resources and is subject to the particular challenges of supporting a rapidly growing business in an environment of multiple languages, cultures, customs, legal systems, alternative dispute resolution systems, regulatory systems and commercial infrastructures. Entering new international markets will be expensive, our ability to successfully gain market acceptance in any particular market is uncertain and the distraction of our senior management team could harm our business, financial condition and results of operation.

Sales of our products outside of China are subject to foreign regulatory requirements that vary widely from country to country. In addition, while the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the marketing authorization of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or marketing authorizations, can be expensive and time-consuming, and we may not receive regulatory authorizations, clearances or approvals in each country in which we may plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or marketing authorizations, if required by other countries, may be longer than that required for NMPA clearance, authorization, or approval, and requirements for such registrations and marketing authorizations may significantly differ from NMPA requirements. If we modify our products, we may need to apply for additional regulatory authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we may no longer be able to sell the applicable product in that country. A failure or delay in obtaining registration or marketing authorization in one country may have a negative effect on the regulatory process in others.

Doing business internationally also involves a number of additional risks, including data security risks, intellectual property protection, financial risks, and other force majeure factors. These risks and uncertainties may impact our ability to enter foreign markets, which could delay or prevent the growth of our operations overseas, and have a material adverse effect on our business, prospects, results of operations and financial condition.

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The actual market size of our products and product candidates may be smaller than we anticipate, which could render them ultimately unprofitable even if commercialized.

Our spending on our cognitive impairment DTx product portfolio may not yield any additional commercially viable products, since the actual market size for them may be smaller than we anticipate. For example, the DTx market in China is emerging and our products and product candidates are considered as relatively novel. In addition, there may be other available treatment methods for our target market, and other players developing similar DTx treatment methods in the target markets that may be more competitive than us, which may further limit the market opportunities of our products. As such, the target markets for our products and product candidates may not consist of as many market opportunities as we expect, which could have a material adverse effect on the profitability of our product candidates even if commercialized.

Risks Relating to Extensive Government Regulation

All material aspects of the research, development and commercialization of our products are heavily regulated.

All jurisdictions in which we conduct our research, development and commercialization activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of China, the EU and the United States. These jurisdictions all have strict regulations on medical devices, and in doing so they employ broadly similar regulatory strategies, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, there are differences in the regulatory regimes in different jurisdictions, which makes regulatory compliance more complex and costly for companies like ours that plan to commercialize our products in each of these jurisdictions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require substantial time and financial resources. The NMPA, EMA, FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a product candidate with an indication that is not desirable for the successful commercialization of that candidate. Legislative and regulatory proposals may also, from time to time, be made to expand existing requirements.

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The regulatory approval processes of the NMPA, its local counterparts and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. The denial or delay of any such approval would delay development and commercialization of our System and other product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

The process to develop and obtain regulatory approval for and commercialize medical device product candidates is long, complex and costly in China and overseas.

In China, before obtaining regulatory approvals for the commercial sale of our products for a specific indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, to the satisfaction of the NMPA or its local counterparts, that the product is safe and effective for use for that indication. We are also required to report any serious or potentially serious incidents involving our products to the NMPA or its local counterparts. We cannot be certain that any submissions will be accepted for filing and review by the NMPA or its local counterparts, and the review timeline may be subject to uncertainty.

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

- failure to begin or complete clinical trials due to various factors, including disagreements with regulatory authorities;
- failure to demonstrate that a product candidate is safe and effective;
- failure to deliver clinical trial results that meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- regulatory authority's disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analysis, reports, data, nonclinical studies and clinical trials, or questions regarding our interpretation of data and results and the emergence of new information regarding our product candidates;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and/or
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

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Comparably, regulatory authorities outside of China also have requirements for approval of medical devices for commercial sale with which we must comply prior to marketing in those jurisdictions. However, regulatory requirements can vary widely from jurisdiction to jurisdiction. Obtaining regulatory approval in one jurisdiction does not mean that the regulatory approval will be obtained in any other jurisdiction. Approval processes vary among jurisdictions and can involve additional product testing and validation, and additional administrative review periods. Seeking foreign regulatory approval may include all of the risks associated with obtaining NMPA approval (and its local counterparts), and could require additional nonclinical studies or clinical trials. For these reasons, we may incur substantial time and financial resources to bring our products to overseas markets in compliance with different regulatory processes. The introduction of our product candidates in these markets could be delayed or prevented, as we may not obtain relevant regulatory approvals on a timely basis, or at all.

In addition, changes in regulatory requirements and guidance may also occur. We may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may impact the costs, timing or successful completion of a clinical trial.

Even if our product candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be provided to users, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following an approval for commercial sale of our product candidates, certain changes, such as changes in design, may be required by the NMPA and/or comparable regulatory authorities. Regulatory approvals for any of our product candidates may also be withdrawn.

If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to generate sufficient revenue and cash flows or obtain sufficient funding to continue the development of any other product candidates in the future.

Our product as applied under existing and expanded indications will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we experience unanticipated problems with our future approved systems.

Our products and any additional product candidates that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to advertising, promotion, sampling, record-keeping, post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China, the EU, the United States, and/or other jurisdictions where we may market or sell our products. We are and will be subject to continual review and inspections by the regulators to assess our compliance with applicable laws, requirements, and adherence to commitments we made in any application materials with the NMPA or other comparable regulatory authorities. Accordingly, we must continue to devote time, money and effort to all areas of regulatory compliance.

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If problems occur after our products reach the market, the NMPA or other comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval. Later discovery of previously unknown problems with our products or product candidates may result in requirements to conduct post-market studies or clinical studies to assess new safety risks or the imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or commercialization of our products, withdrawal of the products from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending indications or applications or supplements to approved indications or applications filed by us or suspension or reduce the scope of previously issued medical device registration certificate;
- product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or
- injunctions or the imposition of civil, administrative or criminal penalties.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in all relevant jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

The regulatory framework for DTx products is constantly evolving. Increasingly stringent regulatory requirements could create barriers to our development and introduction of new products. Conversely, in the event that regulatory requirements are lowered, competitors could potentially enter the DTx market and compete against us more easily.

Our DTx products are novel and represent a new category of therapeutics for which the regulatory framework continues to evolve. Our ability to expand indications for existing products or to seek renewal of existing market authorizations will depend, in part, on our ability to comply with these complex requirements, which include regulations related to product design and development, clinical trials, pre-market clearance, authorization, approval, and marketing, sales and distribution. Maintaining compliance under such evolving framework is highly technical and complex, and may consume significant management and financial resources. Increasing regulatory requirements could lead to higher spending and development barrier in our efforts to introduce new products to market, which could materially adversely affect our business, results of operations and financial condition. If, however, the regulatory framework for DTx products simplifies and the requirements that we and others are required to comply with are lowered, it could result in the increased competition

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and the introduction by competitors of products that are or claim to be superior to our products. For example, if the DTx regulation in China no longer grants Class II or Class III medical device classification to DTx products, and the accompanying clinical validation of DTx safety and efficacy is no longer required for such regulatory approval, it may significantly lower our competitive advantages and entry barriers for potential players to launch products that may compete with ours.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize new product candidates or existing ones under expanded indications and affect the prices we may be able to charge.

In China, the EU, the United States, and some other jurisdictions, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain regulatory approval. In recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies, including measures that may result in more rigorous coverage criteria and downward pressure on the price we receive for any approved product. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to commercialize our products, generate revenue, or attain profitability.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for medical devices. We cannot be sure whether additional legislative changes will be enacted, or whether NMPA, EMA, FDA or other comparable regulatory agency’s regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. For example, according to the Regulations on the Supervision and Administration of Medical Devices (2021 Revision) (《醫療器械監督管理條例(2021修訂)》) effective on June 1, 2021, medical device companies are required to establish a quality management system and monitor and evaluate post-approval risks and adverse events caused by the products. In addition, laws and regulations in China, including those regulating DTx products and medical devices, may be amended from time to time. Changes in these areas could impose more stringent requirements on us and increase our compliance and other operating costs, and we may not be able to achieve or sustain profitability.

Privacy and data protection laws and regulations could have an implication on our reputation and customer preference.

In recent years, privacy and data protection has become an increasing regulatory focus of government authorities across the world. In China, where we operate substantially all our businesses, the PRC government has enacted a series of laws and regulations on the protection of personal data in the past few years. For example, regulatory authorities in China are

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considering a number of legislative and regulatory proposals concerning data protection. The PRC Data Security Law (《中華人民共和國數據安全法》), or the Data Security Law, which was promulgated by the Standing Committee of the National People’s Congress on June 10, 2021 and came into effect on September 1, 2021, outlines the regulatory framework of data security protection. The Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》), which were issued by the General Office of the State Council on July 6, 2021, require to speed up the revision of legislation on strengthening the confidentiality and archives coordination between regulators related to overseas issuance and listing of securities, and improvement to the legislation on data security, cross-border data flow, and management of confidential information.

When conducting our business, we may have access to certain patient data. The personal information of patients or participants for our clinical trials and other clinical and business activities is highly sensitive and we are subject to strict requirements under the applicable data privacy and protection regulations. Accordingly, we have adopted various security policies and measures to ensure legal compliance regarding privacy and data protection. Our Directors are of the view that, during the Track Record Period and up to the Latest Practicable Date, we were in compliance with all applicable PRC laws and regulations with respect to privacy and personal data protection in all material respects. For details, see “Business—Data Privacy and Protection.” While we have adopted these measures to protect our proprietary data and patients’ privacy, privacy leakage incidents might not be avoided due to human error, employee misconduct or system breakdown. In addition, we cooperate with third parties, including principal investigators, hospitals, CROs, and other related parties, for our clinical trials. Any leakage or abuse of patient and customer data by our third-party partners may be perceived by the patients and customer as a result of our failure. Furthermore, we may be required by business partners from time to time to upgrade our products to help them comply with such laws and regulations.

The laws and regulations regarding privacy and data protection in China as well as other jurisdictions are generally complex and evolving, with uncertainty as to the interpretation and application thereof. Maintaining compliance under such complex and evolving framework is crucial to maintaining our reputation and business customers’ preference for our products. However, maintaining such compliance is highly technical and complex, and may consume significant management and financial resources.

We may be restricted from transferring our scientific data abroad.

We may in the future conduct clinical trials, registration and post-market surveillance of our products and product candidates in different jurisdictions, which involve the collection and storage of personal health information for scientific purposes, and it may require cross-border transfer of personal or scientific data, which subjects us to relevant laws and regulations. Our transfer of data may be limited or even restricted if the information is considered of national security interest in certain jurisdictions in which case, our business may be adversely affected as a result.

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On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. To the extent our R&D of our DTx product candidates are subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, if we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of product candidates may be hindered, which may materially and adversely affect our business, operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities. Moreover, Cyberspace Administration of China issued the Measures on Security Assessment of the Cross-border Transfer of Personal Information (Draft for Comment) (《個人信息出境安全評估辦法(徵求意見稿)》) in June 2019, pursuant to which, any cross-border transfer of information that may endanger national security, damage public interest, or fail to offer effective protection of personal information security, as assessed by relevant regulatory bodies, will be prohibited. It is unclear if and the extent to which our clinical data will be considered as an endangerment to national or personal information security, if the regulation becomes effective. On July 7, 2022, the CAC published the Measures for the Security Assessment of Outbound Data Transmission (《數據出境安全評估辦法》) which took effect on September 1, 2022. It specifies the circumstances in which data processors providing data outbound shall apply for outbound data transfer security assessment with the Cyberspace Administration, including, among others, the exit data contains important data. There remain uncertainties whether we would be subject to the outbound data transfer security assessment.

Cross-border data transfer from other jurisdictions may also be limited. For example, cross-border data transfer from the EU to abroad is governed by the General Data Protection Regulation. Also, cross-border transfer of personal data by its nature is subject to general data privacy regulations in various jurisdictions, and may lead to a restriction of transferring our data across different jurisdictions.

The permit, filing or other requirements of the CSRC or other PRC government authorities in relation to our proposed [REDACTED] or further capital raising activities may be required under PRC laws.

On July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the Opinions on Strictly Cracking Down on Illegal Securities Activities (《關於依法從嚴打擊證券違法活動的意見》), which emphasized the need to strengthen the administration over illegal securities activities,

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and the supervision over overseas listings by domestic companies. Stringent measures aimed at establishing a robust regulatory system are expected to be taken to deal with the risks associated with overseas listed companies based in or having significant operations in China, and to tackle any related cybersecurity and data security, cross-border data transmission, and confidential information management, among other matters.

Further, on February 17, 2023, the CSRC released the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) and five ancillary interpretive guidelines (collectively, the “Overseas Listing Trial Measures”), which apply to overseas offerings and listing by domestic companies of equity shares, depository receipts, corporate bonds convertible to equity shares, and other equity securities, and will come into effect on March 31, 2023. According to the Overseas Listing Trial Measures, overseas offering and listing by domestic companies shall be made in strict compliance with relevant laws, administrative regulations and rules concerning national security in spheres of foreign investment, cybersecurity, data security and etc., and duly fulfill their obligations to protect national security, and the domestic companies may be required to rectify, make certain commitment, divest business or assets, or take any other measures as per the competent authorities’ requirements, so as to eliminate or avert any impact of national security resulting from such overseas offering and listing. No overseas offering and listing shall be made under any of the following circumstances: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law, among other scenarios. The Overseas Listing Trial Measures provide that if an issuer meets both of the following conditions, the overseas securities offering and listing conducted by such issuer will be determined as an indirect overseas offering and listing subject to the filing procedure set forth under the Overseas Listing Trial Measures: (i) 50% or more of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements over the same period for the most recent accounting year is accounted for by domestic companies; and (ii) the main parts of the issuer’s business activities are conducted in the Chinese Mainland, or its main places of business are located in the Chinese Mainland, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in the Chinese Mainland. For an initial public offering and listing in an overseas market, the issuer shall designate a major domestic operating entity to file with the CSRC within 3 working days after the relevant application is submitted overseas. Based on the foregoing, we will be required to complete the filing procedures with the CSRC in connection with the proposed [REDACTED] pursuant to the Overseas Listing Trial Measures.

We cannot assure you that we could meet such requirements, obtain such permit from the relevant government authorities, or complete such filing in a timely manner or at all. Any failure may restrict our ability to complete the proposed [REDACTED] or any future capital raising activities, which would have a material adverse effect on our business and financial positions.

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Risks Relating to Our Intellectual Property Rights

If we and our current or future collaboration partners are unable to protect our intellectual property rights throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us and our ability to successfully commercialize our products and product candidates may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technology, products and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights and trade secrets. We seek to protect the technology, products and product candidates that we consider commercially important by filing patent applications in China, the U.S., the EU and other jurisdictions, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories through intellectual property protection.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty or inventiveness of the underlying invention or technology. We may also fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements or include such provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, advisors, hospitals, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. Patent applications in China and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Under the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the Standing Committee of the National People’s Congress (the “NPC”) of the PRC, as amended, patent applications are generally maintained in confidence until their publication at the end of 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and the date on which patent applications were filed. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions.

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Furthermore, the PRC has adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. The United States also moved to this "first-to-file" system in early 2013 through the America Invents Act that was enacted in 2011. Under the first-to-file system, even after reasonable investigation we may be unable to determine with certainty whether any of our products, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual property rights of others, because such third party may have filed a patent application without our knowledge while we are still developing that product, and the term of patent protection starts from the date the patent was filed, instead of the date it was issued. Therefore, the validity of issued patents, patentability of pending patent applications and applicability of any of them to our product development programs may be lower in priority than third-party patents issued on a later date if the application for such patents was filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. In addition, we may be involved in claims and disputes of intellectual property infringement in other jurisdictions (for example, in the United States). In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the China National Intellectual Property Administration (the "CNIPA") for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently, or we may own or license in the future, are to be issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, the United States and other jurisdictions. We may be subject to a third-party preissuance submission of prior art to the CNIPA, the United States Patent and Trademark Office (the "USPTO") or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation, invalidation and re-examination, or inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us without payment to us, or result in our inability to develop or commercialize products and product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in

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interference proceedings declared by the USPTO or other related intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such as invalidation in the CNIPA or oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientific, technical and management personnel, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, though various extensions may be available, the life of a patent and the protection it affords is limited. We may face competition for any approved product candidates even if we successfully obtain patent protection once the patent life has expired for the product. The issued patents and pending patent applications, if issued, for our products and product candidates are expected to expire on various dates as described in “Business—Intellectual Property Rights.” Upon the expiration of our issued patents or patents that may be issued from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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Claims that our System or the sale or use of our future products infringes, misappropriates or otherwise violates the patent or other intellectual rights of third parties could result in costly litigation with an uncertain outcome, or could have material adverse effects on our reputation and result in additional expense and distraction of our personnel, even if litigation is avoided.

Our commercial success depends in part on our avoiding infringement upon, misappropriating, or otherwise violating the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our product candidates.

We may also be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. There are a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the medical device industry generally. As the medical device industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us. If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our product candidates or expanding the indication coverage of our products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would substantially divert attention of our scientific, technical and management personnel and consume other resources. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, such as treble damages, and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Any such license might not be available on reasonable terms, or at all. If we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We may also elect to enter into license agreements to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

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In particular, we in-license the speech recognition technology to support our virtual human technology. See “Business—Our Technologies—Virtual Human” for more details. If the in-licensed technology infringes upon, or receives allegation that it infringes upon, the intellectual property rights of others, or leads to violation of data privacy and protection laws and regulations, we may be involved in litigation, government investigations and/or other legal proceedings, and be found liable for such infringements and/or violations. Even if the licensor is ultimately responsible, we may be nevertheless responsible to pay fines, damages, incur substantial legal costs, and have to divert significant managerial resources during the process, and may not be able to ultimately seek and obtain full indemnification from the licensor.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or [REDACTED] perceive these results to be negative, this could have a substantial adverse effect on the [REDACTED] of our Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Our Directors confirm that during the Track Record Period and up to the Latest Practicable Date, we were not involved in any proceedings in respect of intellectual property right infringement claims against us or initiated by us. However, there can be no assurance that we would not be involved in such proceedings in the future. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Patent terms are limited and thus may be inadequate to protect our competitive position on our products and product candidates for an adequate amount of time.

In most jurisdictions in which we plan to file applications for patents, the term of a granted patent is generally 10 to 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable jurisdictions. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if patents covering our services and products are obtained, we may be open to competition from other companies once our patent rights expire.

As of the Latest Practicable Date, we had been granted 36 patents. Our granted patents have expiration dates ranging from 2032 to 2044. We also had 70 pending patent applications in China and nine pending patent applications overseas as of the Latest Practicable Date. If patents are granted based on these pending patent applications, the resulting patents will be expected to expire ranging from 2041 to 2043, excluding any potential patent term extension or adjustment. Upon expiration of our issued patent or patents that may issue from our pending patent application, and without patent term extensions, we will not be able to assert such patent rights against potential competitors and our business and results of operation may be adversely affected.

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Changes in patent law may reduce the value of patents in general, thereby impairing our ability to protect our products candidates.

Depending on decisions by the NPC and the CNIPA, the laws and regulations governing patents could change in a way that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

Our intellectual property may be subject to further priority or ownership disputes and similar proceedings. Should we be unsuccessful in any of these proceedings, we might be required to obtain licenses from third parties, in terms not necessarily commercially reasonable to us, or to cease the development and commercialization of one or more of our product candidates under different indications, which could have a material adverse impact on our business.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. If we or our potential future licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our potential future licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or potential licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development and commercialization of one or more of our product candidates or cease indication expansion of our products. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar DTx products.

Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

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If we are unable to protect the confidentiality of our trade secrets, or if third parties assert that our employees, consultants, collaborators or partners have wrongfully used or disclosed confidential information or misappropriated trade secrets, our business and competitive position would be materially adversely affected.

In addition to our granted patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our products and product candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, hospitals, consultants, advisors and other third parties. We also enter into employment agreements or consulting agreements with our employees and consultants that includes undertakings regarding assignment of inventions and discoveries. However, nondisclosure agreements with employees, consultants, hospitals and other parties may not adequately prevent disclosures of our trade secrets and other proprietary information. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our management team, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and third parties involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our scientific, technical and management personnel.

RISK FACTORS

Some of our products utilize third-party open-source data and software, and any failure to comply with the terms of one or more of these open-source software licenses could have a material adverse effect on our business, prospects, results of operations and financial condition, subject us to litigation, or create potential liability.

We have chosen, and we may choose in the future, to use open-source software in our products. We use various software composition tools which are designed to monitor risks related to licenses and vulnerabilities related to open-source software. Use and distribution of open-source software may entail greater risks than use of third-party commercial software, as open-source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open-source licenses may contain requirements that we make available source code for modifications or derivative works we create based upon the type of open-source software we use. If we combine our proprietary software with open-source software in a certain manner, we could, under certain open-source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of business opportunities.

Although we intend to monitor any use of open-source software to avoid subjecting our products to conditions we do not intend, the terms of many open-source licenses may impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, there is no assurance that our processes for controlling our use of open-source software in our products will be effective. If we are held to have breached the terms of an open-source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could materially and adversely affect our business, operating results and financial condition.

We may co-own patents or other intellectual property rights with our collaboration partners, which may limit our ability to effectively capitalize on these intellectual property rights.

We may co-own patents or other intellectual property rights with our collaboration partners. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

RISK FACTORS

We may enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant or any future revenue.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances to develop new indications for existing DTx products, develop new DTx products and to expand into new markets. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, and strategic alliances may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

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

We currently hold registered trademarks and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could

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materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in any conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful. Our patent rights relating to our product and product candidates could be found invalid or unenforceable if being challenged in courts or before the CNIPA, the courts or related intellectual property agencies in other jurisdictions.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating our intellectual property rights. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

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Defendant counterclaims alleging invalidity or unenforceability are commonplace, a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China, the United States, the EU or other jurisdictions, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiner could be unaware of invalidating prior art during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Conversely, we may choose to challenge the patentability of claims in a third party's patents. For example, with respect to a third party's U.S. patent, we may request that the USPTO review the patent claims in re-examination, post-grant review, inter partes review, interference proceedings and derivation proceedings. In the EU and other jurisdictions, we may choose to challenge, third party patents in patent opposition proceedings in the European Patent Office (the "EPO") or other foreign patent offices. However, even if successful, such proceedings may produce substantial costs, and may consume our time or other resources. If we fail to obtain favorable results at the USPTO, EPO or other foreign patent offices, we may be exposed to litigation by third parties alleging that our products or product candidates infringed their patents.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as we expect. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees on any issued patent are due to be paid to the CNIPA, the USPTO and other patent agencies in several stages over the lifetime of the patent. The CNIPA, the USPTO and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss

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of patent rights in the relevant jurisdiction. Non-compliance events could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to independently develop similar or alternative technologies or designs that are similar to our services and products but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive services and products for commercialization in our major markets;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing additional products or applications in more indications of our existing products.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

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Risks Relating to Our Reliance on Third Parties

We may be unable to develop our product candidates or expand indication coverage of existing products as anticipated if the third parties with which we cooperate for clinical trials do not perform in an acceptable manner or if these third parties do not successfully carry out their duties or meet expected deadlines.

We cooperate with third parties, primarily hospitals, to assist us in designing, implementing and monitoring our preclinical research and conducting clinical trials. As of the Latest Practicable Date, we had helped more than 120 hospitals establish cognitive centers in China. If any of these parties terminates their cooperation with us, the development of indication expansion of our System and of our other product candidates could be substantially delayed. In addition, these third parties may not successfully carry out their responsibilities under the cooperation, meet expected deadlines or follow regulatory requirements, including clinical and laboratory guidelines. Our reliance on these third parties may result in delays in completing, or in failing to complete, these studies if they fail to perform in accordance with the contractual arrangements. Furthermore, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA and/or other comparable regulatory authorities may not accept the data generated by those studies, which would increase the cost of and the development time for the relevant product candidate. If any of the preclinical studies or clinical trials of our product candidates is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

We may engage CROs and other third-party partners in our research and development process. Our research and development timeline may be delayed if these third parties do not successfully carry out their contractual duties or meet expected deadlines in accordance with regulatory requirements; if there are disagreements between us and such parties; or if such parties are unable to expand capacities. These third parties may also be affected by natural disasters, such as floods or fire, health epidemics, including the ongoing COVID-19 pandemic, or geopolitical developments. These third parties could face production issues, such as contamination or regulatory concerns following a regulatory inspection of their facilities. In such instances, we may need to locate an appropriate replacement third-party facility and establish a contractual relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense and may have a material adverse effect on our business.

In addition, we may collaborate with CROs and other third parties to monitor and manage data for some of our clinical programs and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities.

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The clinical development, marketing and sale of our products require us to maintain close relationships with physicians upon whom we rely on to provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, and as public speakers. If we fail to develop, maintain our relationships with them or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

We engage third party providers for cloud-based infrastructure. Any disruption in the operations of these third-party providers, limitations on capacity or interference with our use could have a material adverse effect on our business, prospects, results of operations and financial condition.

Our technological infrastructure is implemented using third-party hosting services. We have no control over any of these third parties, and we cannot guarantee that such third-party providers will not experience system interruptions, outages or delays, or deterioration in their performance. We need to be able to access our computational platform at any time, without interruption or degradation of performance. Our hosted platform depends on protecting the virtual cloud infrastructure hosted by third-party hosting services by maintaining our configuration, architecture, features, and interconnection specifications, as well as protecting the information stored in these virtual data centers, which is transmitted by third-party Internet service providers. We may experience interruptions, delays and outages in service and availability from time to time due to a variety of factors, including infrastructure changes, human or software errors, hosting disruptions and capacity constraints. Any limitation on the capacity of our third-party hosting services could adversely affect our business, financial condition, and results of operations. In addition, any incident affecting our third-party hosting services' infrastructure, which may be caused by cyberattacks, natural disasters, fire, flood, severe storm, earthquake, power loss, telecommunications failures, terrorist or other attacks, and other disruptive events beyond our control, could negatively affect our cloud-based solutions. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise harm our business. We may also incur significant costs for using alternative equipment or taking other actions in preparation for, or in reaction to, events that damage the third-party hosting services we use.

In the event that our service agreements with our third-party hosting services are terminated, or there is a lapse of service, elimination of services or features that we utilize, interruption of Internet service provider connectivity, or damage to such facilities, we could experience interruptions in access to our infrastructure as well as significant delays and additional expense in arranging or creating new facilities and services and/or re-architecting our hosted software solutions for deployment on a different cloud infrastructure service provider, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

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We rely on providers of marketing and promotional services and operational service provider to promote and market our products and product candidates. If any of them fail to perform their contractual obligations to us in a timely manner, or encounter any operational difficulties, we may be unable to commercialize our products and product candidates as anticipated.

We rely on both our in-house marketing team and third-party provider of marketing and promotional services to market and promote our products. We incurred selling and distribution expenses of RMB10.8 million, RMB11.9 million, RMB38.4 million, RMB17.0 million and RMB25.4 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. We also cooperate with an operational service provider which led to business opportunities with certain hospitals. See “Business—Sales and Marketing—Our Marketing Model—Collaboration with Top Hospitals and Research Institutions” for more details on this arrangement. The success of our marketing activities in part depends on our ability to maintain and enhance our relationships with qualified service providers and our ability to attract, motivate and retain qualified and professional employees in our marketing and sales teams. However, we have limited control over these service providers. If any of these service providers fail to adequately perform their obligations to market and promote our products and product candidates, either due to breaches of their duties or due to their insolvency or other operational difficulties, we may not be able to timely find replacement service providers, and the promotion and commercialization efforts of our products and product candidates may be hindered, and our business operations, results of operations, and financial condition could be materially adversely affected.

A limited number of customers accounted for a substantial portion of our revenue during the Track Record Period, and any decreases in our future sales to them could adversely affect our financial condition and results of operations.

In 2021, 2022, 2023, and the six months ended June 30, 2024, the aggregate sales to our five largest customers were RMB1.6 million, RMB8.3 million, RMB50.8 million, and RMB28.9 million, respectively, representing approximately 70.1%, 73.1%, 75.6%, and 55.6% of our revenue during the same periods, respectively. In 2021, 2022, 2023, and the six months ended June 30, 2024, the aggregate sales to our largest customer were RMB0.8 million, RMB4.4 million, RMB26.8 million, and RMB14.5 million, respectively, representing approximately 35.5%, 39.1%, 39.9%, and 28.0% of our revenue during the same periods, respectively. The percentage of revenue from single largest and five largest customers both presented an increasing trend from 2021 to 2023, and we cannot assure you that we can reverse such trends in future years or periods. It is likely that we will continue to be dependent upon a limited number of customers for a significant portion of our revenue for the foreseeable future. The loss of one or more major customers or a reduction in purchase from any major customer may reduce our revenue.

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RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have been in a net loss position since our inception and may continue to incur net losses for the foreseeable future, and you may lose substantially all your [REDACTED] in us given the high risks and uncertainties associated with our business operations and the cognitive impairment DTx industry.

Cognitive impairment DTx industry is relatively new with limited track record of profitability. Investment in the development of DTx is highly speculative. It entails substantial upfront capital expenditures and significant risks that a product candidate may fail to complete clinical trials, gain regulatory approval or become commercially viable. We incurred significant expenses related to our product and product candidates and our ongoing operations. As a result, we incurred loss and total comprehensive expense of RMB697.8 million, RMB502.5 million, RMB359.1 million, RMB234.6 million and RMB114.4 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs, selling and distribution, as well as administrative expenses associated with our operations.

We may continue to incur losses in the foreseeable future, and the losses may increase as we expand our development of, and seek regulatory approvals for, our product candidates, and commercialize our products. We will also incur costs in support of our growth. The size of our future net losses will depend, in part, on the number and scope of our product development programs and the associated costs of those programs, the cost of commercializing any approved products and our ability to generate revenue. We are unable to predict when, or whether, we will be able to achieve or maintain profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown situations, all of which may result in our failure in some or all of our development efforts. For example, if the clinical trial results of our System for expanded indications or other products or product candidates are not satisfactory, we may be unable to successfully expand our System to additional indications, or to launch our other product candidates as expected. High and increasing labor costs could also affect our profitability, and may result from, among other things, labor shortages that require us to increase salaries in order to attract employees, higher employee health insurance costs, and labor disruptions by our employees. Even if we do succeed in all of the above activities, we may not be able to generate revenue that are significant or sufficient enough to achieve profitability. In addition, we will start incurring costs associated with being a [REDACTED] in Hong Kong after the [REDACTED]. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable may impact [REDACTED] perception of the potential value of our Group and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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The amount of our future losses or potential profits is uncertain, and our annual operating results may fluctuate significantly or fall below the expectations of [REDACTED] or securities analysts, each of which may cause our [REDACTED] to fluctuate or decline.

Our results of operations may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for the System and our other products and product candidates or competing product candidates, or any other change in the competitive landscape of our industry;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing authorization for our product candidates and the timing and scope of any such marketing authorizations we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our System and other products and product candidates, which may change from time to time;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for the System and our other products and product candidates should such product candidates receive marketing authorizations, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to the System and our other products and product candidates, if granted marketing authorization, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile Chinese and global economic environments including global inflationary pressures; and
- future accounting pronouncements or changes in our accounting policies.

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We had net operating cash outflows throughout the Track Record Period. We will need substantial additional financing to fund our operations, and if we are unable to raise capital when needed or on terms favorable to us, our business, financial condition and results of operations could be materially and adversely affected.

We need to devote significant financial resources on clinical development, regulatory registration and approvals, marketing and commercialization, among other investments, before we can generate revenue from expanded indications of our System or from other products and product candidates. Our net cash used in operating activities amounted to RMB49.2 million, RMB100.7 million, RMB136.9 million, RMB66.0 million and RMB75.5 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. Sales of our System have contributed to a portion of our cash flow during the Track Record Period. However, we cannot assure that we will be able to leverage other revenue-generating sources to generate positive cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure that we will generate sufficient cash flows from other sources to fund our operations. If we continue to have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

We expect to continue to spend substantial amounts on research and development, advancing the clinical development of our product candidates, commercializing our products and launching and commercializing any product candidates for which we receive regulatory approval, including building our own commercial organization to address China and other markets. Our existing cash and cash equivalents may not be sufficient to enable us to complete all global development or commercially launch all our current product candidates for the anticipated indications and to invest in additional programs. Accordingly, we will require further funding through public or private offerings, debt financing, among other methods of financing. We cannot assure you that our financial resources will be adequate to support our operations. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on favorable or reasonable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As we are investing heavily in our research and development efforts, our profitability and operating cash flows in the short term may continue to be impacted and we may not generate the results we expect to achieve.

Our technological capabilities and infrastructure are critical to our success. We have been investing heavily in our research and development efforts. We incurred research and development expenses of RMB32.8 million, RMB67.6 million, RMB90.7 million, RMB34.4 million and RMB64.2 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. The industry in which we operate is evolving rapidly in terms of technological innovation. We need to invest significant resources, including financial resources, in research and development to lead technological advances in order to make our products innovative and competitive in the market. As a result, we expect that our research and development expenses will continue to increase. Furthermore, development activities are inherently uncertain, and we might encounter practical difficulties in

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commercializing our development results. Our significant expenditures on research and development may not generate corresponding benefits. Given the fast pace at which technologies have been and will continue to be developed, we may not be able to timely upgrade our technologies in an efficient and cost-effective manner, or at all. New technologies in our industries could render our technologies, our technological infrastructure or products that we are developing or expect to develop in the future obsolete or unattractive, thereby limiting our ability to recover related product development costs, which could result in a decline in our revenue, profitability and market share.

Our results of operations, financial condition, and prospects may be adversely affected by fair value changes in our financial liabilities at FVTPL, which could be uncertain due to the use of unobservable inputs.

During the Track Record Period, we issued redeemable preferred shares which are designated as financial liabilities at fair value through profit or loss. As of December 31, 2021, 2022, 2023, and the six months ended June 30, 2024, our financial liabilities at FVTPL was RMB726.7 million, RMB1,162.6 million, RMB315.5 million and RMB315.8 million, respectively. In 2021, 2022, 2023, and the six months ended June 30, 2023, we recorded fair value loss of financial liabilities at FVTPL of RMB623.8 million, RMB385.9 million, RMB165.2 million, RMB163.5 million and fair value gain of financial liabilities at FVTPL of RMB0.2 million in the six months ended June 30, 2024, respectively, which were primarily driven by fair value changes of the redeemable preferred shares we issued, which could be subject to uncertainty due to use unobservable inputs. Such changes may continue to affect our financial performance until the [REDACTED]. The automatic conversion of redeemable preferred shares into ordinary shares upon the [REDACTED] is expected to ameliorate our net liabilities position. Moreover, we do not expect to recognize any further loss or gain on fair value changes from the redeemable preferred shares in the future. If we continue to incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

The preferred shares we issued are redeemable preferred shares designated as financial liabilities at FVTPL. For details, please see Note 27 to the Accountants’ Report in Appendix I to this Document. The fair value measurement of our preferred shares involves estimates and assumptions that are subject to significant uncertainties and risks. Valuation techniques are certified by an independent qualified professional valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. Valuation models established by the valuer make the maximum use of market inputs and rely as little as possible on our specific data. However, some significant unobservable inputs, such as fair value of our ordinary shares, possibilities under different scenarios such as initial public offering, liquidation and redemption, and discount for lack of marketability, require management estimates. Management estimates and assumptions are reviewed periodically and are adjusted when necessary. Should any of the estimates and assumptions change, it may lead to changes in the fair value of financial liabilities at FVTPL. In addition, the valuation methodologies may involve a significant degree of management judgment and are inherently uncertain, which may result in material adjustment to the carrying amounts of certain liabilities and in turn may materially and adversely affect our results of operations.

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Our results of operations are exposed to the impact of fair value changes for financial assets at FVTPL.

Financial assets at FVTPL primarily consist of short-term Level II structured deposits and wealth management products we purchased from reputable commercial banks in China. We recorded nil, RMB228.8 million, nil, and nil in financial assets at FVTPL as of December 31, 2021, 2022, 2023, and the six months ended June 30, 2024, respectively. Our financial assets at FVTPL are measured at fair value with any fair value gains or losses recognized under “other gains and losses, net” of our results of operations. We recorded fair value gains on financial assets at FVTPL of nil, RMB3.2 million, RMB2.7 million, RMB2.7 million and nil in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. However, we cannot assure you that we will continue to record such gains on financial assets at FVTPL in the future. If we have any financial assets at FVTPL in the future, and their fair value decreases in future periods after impairment assessment under ECL, we may need to record fair value losses on financial asset at FVTPL, which could materially and adversely affect our results of operations and financial condition.

We had net liabilities position and net current liabilities in the past and may not be able to achieve or maintain net assets and net current assets position in the future.

As of December 31, 2021, 2022, 2023 and June 30, 2024, we had net liabilities of RMB681.3 million, RMB1,094.2 million, RMB332.2 million and RMB411.3 million, respectively. We also had net current liabilities of RMB90.1 million as of December 31, 2023. Although the financial liabilities at FVTPL will cease to be classified as liability, and will be reclassified as equity upon the completion of the [REDACTED], there is no assurance that we will not record net liabilities and/or net current liabilities in the future. Having significant net liabilities or net current liabilities could constrain our operational flexibility and adversely affect our ability to expand our business. If we do not generate sufficient cash flow from our operations to meet our present and future liquidity needs, we may need to rely on additional external borrowings for funding. If adequate funds are not available, whether on satisfactory terms or at all, we may be forced to delay or abandon our growth plans, and our business, financial condition and results of operations may be materially and adversely affected.

We are exposed to credit risk when collecting trade receivables from our customers. If we experience delays in collecting payments from our customers with regards to trade receivables, and from other parties with regards to other receivables, our cash flows and operations could be adversely affected.

Our business and financial results are dependent on the timely payments and credit worthiness of our customers. We typically grant customers credit terms that range from 30 to 180 days. As of December 31, 2021, 2022, 2023 and June 30, 2024, our trade receivables were RMB1.1 million, RMB8.4 million, RMB50.7 million and RMB78.8 million, respectively. The average turnover days of our trade receivables was 114.6 days, 153.3 days, 160.7 days, and 227.2 days in 2021, 2022, 2023, and the six months ended June 30, 2024, respectively. If our customers’ cash flows, working capital, financial condition or operations deteriorate, they may

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be unable, or they may otherwise be unwilling, to make payments owed to us promptly or at all. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with customers in a manner that will impair the effective distribution of our products or provision of services. In addition, we may be unable to enforce our contractual rights and collect outstanding payments due to complexities of the procedures in different jurisdictions where we operate. If one or more customers default on their payment obligations to us, and the scale of such defaults is significant, our business, financial condition and results of operations may be materially and adversely affected.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or products.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [REDACTED] of our Shares to decline.

In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Share-based compensation could result in dilution of existing shareholders' equity and have a material adverse effect on our financial performance.

We may issue options, shares or other share-based compensation for the benefit of our employees (including directors) as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. Our share-based compensation was RMB19.4 million, nil, RMB44.9 million, nil and RMB35.3 million in 2021, 2022, 2023, and the six months ended June 30, 2023 and 2024, respectively. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred by our Company with respect to such share-based payment may also reduce the earnings of our Company, resulting in the dilution of our Company's earnings-per-share and therefore have a material and adverse effect on our reported profit.

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We rely on assumptions, estimates, internally developed software and data from third parties to deliver timely and accurate information in order to accurately report our financial results in the timeframe and manner required by law.

We need to receive timely, accurate, and complete information from our internal company data that has not been independently verified utilizing internally developed software and third party software in order to accurately report our financial results on a timely basis. If the information that we receive is not accurate, our consolidated financial statements may be materially incorrect and may require restatement. While these numbers are based on what we believe to be reasonable calculations for the applicable period of measurement, there are inherent challenges in measuring such information. In addition, our measurement of certain metrics may differ from estimates published by third parties or from similarly-titled metrics of our competitors due to differences in methodology and as a result our results may not be comparable to our competitors. As a result, we may have difficulty completing accurate and timely financial disclosures, which could have an adverse effect on our business.

RISKS RELATING TO OUR GENERAL OPERATIONS

Our historical rapid growth may not be indicative of our future growth and, if we continue to grow rapidly, we may not be able to manage our growth effectively.

If we are not successful in managing our growth or executing our strategies effectively, our business, operations, financial condition and future growth may be adversely affected. For example, as part of our growth strategies, we plan to continue our research and development in expanding the indication coverage of our System, as well as in other products and product candidates. As certain jurisdictions we operate or plan to enter, such as China, are large and diverse market, industry trends and clinical demands may vary significantly by regions. Our experience in collaborations with certain partners in major cities may not be applicable in other cities or local regions. As a result, we may not be able to leverage our experience to expand into local or regional markets. Any failure to effectively manage our growth or execute our strategies may have an adverse impact on our business and prospects.

As our development and commercialization plans and strategies evolve, we need to recruit a significant number of additional managerial, operational, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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Our future financial performance and our ability to commercialize our products will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and collaborating partners as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current and future products and services and, accordingly, may not achieve our research, development and commercialization goals.

Our competitors may develop or commercialize competing products before or more successfully than we do, or respond and adapt to the market changes more quickly and effectively.

The development and commercialization of new medical devices is highly competitive. We face competition from other major companies focusing on the development of DTx products worldwide. Our business opportunities could be reduced or eliminated if our competitors develop and commercialize products that have higher accuracy rates, are less expensive or are more convenient than any products that we commercialize or are developing. Our competitors in the global market may also apply for regulatory approvals in China or other countries for products with the same intended use as our products and product candidates. The capacity of the relevant authorities, such as the NMPA, to concurrently review multiple commercialization applications for the same type of medical device may be limited, therefore such authorities' schedule to review our product candidates may be delayed when our product candidates are under the authorities' concurrent review with our competitors' products, and the registration process of our product may be prolonged. Moreover, our competitors may obtain approvals from the NMPA or its local counterparts and other comparable regulatory authorities more rapidly than we do, which may allow our competitors to establish a strong market position before we are able to enter the market.

Many of our competitors have significantly greater financial resources and expertise and experience in research and development, conducting preclinical studies and clinical trials, obtaining regulatory approvals and marketing than we do, and are more capable than us to respond and adapt to the market changes in a timely and effective manner. Our inability to adequately respond to market changes could have a material adverse effect on our market position, and our reputation may be materially and adversely affected, which could adversely affect our relationships with physicians and hospitals and our long-term ability to effectively market and sell our products or conduct clinical trials for our new products. In this regard, our business, financial condition and results of operation may be materially and adversely affected.

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Mergers and acquisitions in the medical device industries may result in even more resources being concentrated among a small number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and marketing personnel, establishing clinical trial sites and trial participant registration for clinical trials, as well as acquiring technologies complementary to, or necessary for, our product development programs. Our inability to compete effectively could reduce our revenue and current market share, impair our ability to achieve our targeted market share in future periods, cause a decline in our growth rates, and harm our position in the DTx industry, and our business, financial condition, results of operation and return on capital expenditures may be materially and adversely affected.

Our future success depends on our ability to retain key executives and key personnel in our R&D team, sale and marketing team, and our ability to attract, train, retain and motivate qualified and highly skilled personnel especially R&D, clinical related, sales and marketing staff.

Our business and growth depend on the continued service of our senior management and personnel in our R&D team to develop product candidates, as well as our sales and marketing team to promote our products and services. Although we have formal employment agreements with each of our employees, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development and commercialization objectives.

To retain valuable employees, in addition to salary and cash incentives, we have provided share awards to our employees. The value to employees of these equity grants may be significantly affected by movements in the Share [REDACTED] that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and impact our ability to successfully implement our business strategy.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products or services. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous medical device companies for similar personnel.

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We also experience competition for the recruiting of R&D (including but not limited to talents in the fields of AI and algorithms) and clinical personnel from universities and research institutions. Our consultants and advisors may be engaged by our competitors and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy may be impacted.

If we fail to effectively expand our overseas clinical development and initiate international commercialization, our business prospects may be adversely affected.

We have proprietary rights in respect of our products and product candidates in China and other selected overseas jurisdictions through patent registration and protection over proprietary technologies. To grow our business, we intend to expand our business operations internationally.

We plan to broaden our sales and expand our presence globally, especially in the United States and the EU. However, our limited experience in overseas markets may expose us to risks and uncertainties. Our success in expanding our business and providing services internationally, and competing in international markets is subject to our ability to manage various risks and difficulties, including, but not limited to:

- our ability to effectively manage and coordinate our employees across different geographic locations;
- our ability to develop and maintain relationships with customers, suppliers and other local stakeholders;
- the ability to provide sufficient levels of technical support in different locations;
- obtaining the necessary approvals for registering and selling our products in additional countries;
- reliance on overseas partners for the development, commercialization or marketing of our products, which may incur additional costs;
- commercializing our products in new markets where we have limited experience and no sales and marketing infrastructure;
- product and professional liability litigation and regulatory scrutiny arising from the marketing and sale of products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities;

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- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;
- variations and changes in laws applicable to our operations in different jurisdictions, including enforceability of intellectual property and contractual rights;
- our ability to obtain and renew licenses that may be needed in overseas locations to support operations;
- trade restrictions, political changes, disruptions in financial markets, and deterioration of economic conditions, particularly the relations between China and the United States;
- foreign investment restrictions;
- changes in tariffs, taxes and foreign currency exchange rates, which could result in increased operating expenses and reduced revenue;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- economic weakness and inflation;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

Our profitability and ability to implement our business strategies, maintain our market share and compete successfully in international markets may be compromised if we are unable to manage the foregoing risks and other international risks successfully.

Our business significantly depends on our reputation and customer perception of us, and any negative publicity on us or failure to maintain and enhance our recognition and reputation may materially adversely affect our business, financial condition and results of operations.

Our reputation and customer perception of our brand are critical to our business. Maintaining and enhancing our reputation and recognition depend primarily on the quality and consistency of our products, as well as continued promotion efforts. Because our products and product candidates are considered relatively new and novel therapeutic approaches, our success will depend upon physicians who specialize in the treatment of cognitive impairment targeted by our products and product candidates and may choose to prescribe potential treatments that

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involve the use of our products and product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Access will also depend on consumer acceptance and adoption of products that are commercialized. Our promotion efforts may be expensive and ineffective. In addition, our reputation and customer perception of us could suffer in events that:

- our products fail to gain acceptance by hospitals, physicians and patients;
- our products are defective or malfunction;
- lawsuits or regulatory investigations are instituted against us or relating to our products or industry;
- we provide poor or ineffective customer service; or
- we are subject to product liability claims.

Negative publicity concerning our products or the DTx market as a whole, could limit market acceptance of our products and product candidates. If patients and healthcare providers have a negative perception of DTx, then a market for our products and product candidates may not develop at all, or it may develop more slowly than we expect. Our success will depend to a substantial extent on the willingness of healthcare providers to prescribe our products, the extent to which coverage and adequate reimbursement for these products and product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations and our ability to demonstrate the value of our products and product candidates to existing and potential patients and physicians. Similarly, negative publicity regarding patient confidentiality and privacy in the context of technology-enabled healthcare or concerns experienced by our competitors could limit market acceptance of DTx.

If we are unable to maintain and further enhance our reputation and recognition, our ability to attract and retain customers may be impeded and our business prospects may be materially adversely affected. Any negative incident or negative publicity concerning us, our products, our management and our employees, regardless of its veracity, could harm our image and diminish the trust from our customers and the market, which could in turn result in decreased sales of our products and materially and adversely affect our business. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

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Any failure to offer high quality patient support may adversely affect our relationships with our existing and prospective patients, and in turn our business, results of operations and financial condition.

Our patients will depend on our patient support to properly use and upgrade our DTx products resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for patient support. Increased patient demand for support could increase costs and adversely affect our results of operations and financial condition. Any failure to maintain high-quality patient support, or the market perception that we do not maintain high quality patient support, could adversely affect patient satisfaction and their willingness to continue to use our products or the willingness of physicians to prescribe our products, which in turn could harm our business, results of operations and financial condition.

If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operations and reputation could be materially and adversely affected.

We will become a [REDACTED] upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our [REDACTED] reporting obligations are expected to place a strain on our managerial, operational and financial resources and systems in the foreseeable future. To address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. The violation of or deviation from these internal controls and procedures by any of our employees could adversely affect our reputation, financial position and current and future business relationships. If one or more of our employees or former employees were to engage in misconduct or were to be accused of such misconduct, our businesses and our reputation could be adversely affected.

In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

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Our technology infrastructure may experience unexpected system failure, interruption, inadequacy, security breaches or cyberattacks.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

Our internal computer systems store a wide variety of business-critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenue. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information to gain access to our data and/or systems. Like other companies, we may experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyberattacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as

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technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

Security breaches, ransomware attacks, loss of data and other disruptions could compromise sensitive information related to our patients or business or prevent us from accessing critical information and expose us to liability, which could have a material adverse effect on our reputation, business, prospects, results of operations and financial condition.

We depend on our information technology for a significant portion of our operations. Our information technology systems store and process a variety of sensitive data, including but not limited to, legally protected personal health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We also manage and maintain our applications and data utilizing on-site and cloud-based systems. These applications and data encompass a wide variety of business-critical information including R&D information, commercial information and business and financial information. Thus, it is essential that our information technology infrastructure remains secure and is perceived by hospitals, patients and our research partners to be secure. We seek to preserve the security of our information technology infrastructure by maintaining physical security of our premises and physical and electronic security of our information technology systems by measures such as installing antivirus software, establishing firewalls, backing up data on a stand-alone workstation with password protection, and saving physical copy of data when appropriate. Despite our security measures, our information and other technology systems are vulnerable to damage from a variety of sources, such as telecommunications or network failures, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Our servers are also vulnerable to physical break-ins, employee errors and similar disruptive problems.

We cannot assure that it would not happen in the future. Failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from serving patients and physicians, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, deploying our products and services and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, reputation, and expose us to significant financial liabilities. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

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We do not own any real estate with respect to our current principal place of operation and may be exposed to risks associated with leased properties. For example, we may be subject to fines due to the lack of registration of our leases.

We do not own any real property for our operations. As of the Latest Practicable Date, we leased an aggregate GFA of approximately 11,000 square meters in China. Some of our lessors were not able to provide property ownership certificates, while the right of certain other lessors to lease out properties had already expired when leasing the properties to us. This has led to uncertainties in our abilities to maintain the relevant leasehold relationships. We also used certain of our leased properties for purpose inconsistent with those set forth in the relevant lease agreements. If we fail to maintain such leases or otherwise continue to use any of our leased property as a result of the above, we may need to seek an alternative location and incur expenses related to such relocation, and our operation and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

As advised by our PRC Legal Advisor, our right to use the mortgaged properties are subordinate to the rights of mortgages relating to the relevant properties, which may affect our use of leased properties. In case such properties we leased are transferred due to the enforcement of mortgages, which had been set before the properties were leased to us, we may be required to relocate. As of the Latest Practicable Date, we had not been aware of any enforcement of the mortgages of the above-mentioned properties. We cannot assure that in the future, we may not encounter such challenges. In addition, in the event of relocation, we may incur additional costs, which could adversely affect our daily operation and cause an impact on our financial condition.

As of the Latest Practicable Date, the lease agreements with respect to the 16 properties we leased in the PRC for our business operations had not been registered and filed with the relevant PRC government authorities. As advised by our PRC Legal Advisor, failure to register such lease agreements with the relevant PRC government authorities does not affect the validity and enforceability of the relevant lease agreements but the relevant PRC government authorities may order us or the lessors to, within a prescribed time limit, register the lease agreements. Failure to do so with the time limit may subject us to a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease. During the Track Record Period and as of the Latest Practicable Date, we had not received any such request or suffered any such fine from the relevant PRC government authorities. For details, see “Business—Our Properties.”

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Our relationships with customers will be subject to applicable anti-bribery, anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Anti-bribery laws, anti-kickback, false claims laws, doctors' payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations could expose us to sanctions, penalties, contractual damages or reputational damages that would have a material adverse effect on our business, financial conditions and operations.

We are subject to the anti-bribery laws of various jurisdictions. As our business expands, the applicability of the applicable anti-bribery laws to our operations has increased. Our procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or agents. If we fail to comply with the applicable anti-bribery laws due to either our own deliberate or inadvertent acts or those of others, our reputation could be damaged and we could incur criminal or civil penalties, other sanctions and/or expenses, which would have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

In addition, healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions where we operate. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to personal privacy regulation. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the governments of the jurisdictions where we operate, which will result in diminished profits and future earnings. Furthermore, there are ambiguities as to what is required to comply with certain requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties. If any of the doctors or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

Physicians and other healthcare service providers play a primary role in the recommendation and use of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback laws, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, including, without limitation, Criminal Law of the PRC, Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Administrative Measures for the Registration and Record Filing of Medical Devices (《醫療器械註冊與備案管理辦法》). Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

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Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We help hospitals build cognitive centers to establish relationships with hospitals and market our products. We also sponsor academic conferences to promote the awareness of our products among the medical community. However, we, our employees or our collaborating partners may be subject to allegations that the above activities constitute or relate to corruption and bribery. Such allegations and any related investigations, litigations and other legal proceedings could harm our reputation, and the costs of defending against such allegations could be substantial and could divert our resources and harm our results of operations.

We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us, which could adversely affect our business, financial conditions, results of operations and reputation.

We face an inherent risk of product and professional liability as a result of the commercialization of our products, the provision of our services, and any future commercialization of our product candidates in China and globally. For example, we may be sued if our products or product candidates cause or are perceived to cause injury, or fail to deliver favorable results in improving patients' cognitive functions as intended. Any such product and professional liability claims may include allegations of defects in design, a failure to warn of dangers inherent in the DTx product, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection acts. During the Track Record Period, we had not been subject to any product or professional liability claim. Responding to such claims could significantly divert our management's attention from our general business operations. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product and professional liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and product candidates and provision of our services. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;

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- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or subjects, product recalls, withdrawals, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and/or
- a decline in our Share [REDACTED].

If we are unable to obtain sufficient product and professional liability insurance at an acceptable cost, potential product and professional liability claims could prevent or inhibit the commercialization of our products and product candidates. Our insurance policies may also have various exclusions, and we may be subject to a product and professional liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our insurance coverage may not completely cover the risks related to our business and operations, which could expose us to significant costs and business interruptions.

Our operations are subject to hazards and risks associated with our research and development, as well as other aspects of our operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies, including social insurance for all of our employees and personal accident insurance. For details, see "Business—Insurance." However, there is no assurance that our insurance policies will be adequate to cover all losses incurred. Losses incurred and associated liabilities may have a material adverse effect on our results of operation if such losses or liabilities are not covered by our insurance policies.

RISK FACTORS

If we engage in acquisitions, joint ventures or strategic alliances, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, may have a material adverse effect on our ability to manage our business and may not result in the development of commercially viable products or the generation of significant or any future revenue.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, ongoing or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and product candidates and regulatory approvals; and/or
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

If we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. In addition, we may not be able to integrate any future acquisition targets to achieve the expected synergies with our existing operations and to fulfill the contemplated purposes of these acquisitions. We may not achieve the operational or economic synergies expected from such acquisitions. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our acquisitions may be offset by costs incurred in the acquisition, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

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Furthermore, our future acquisition targets may not provide us with the intellectual property rights, technology, R&D capability, production capacity or sales and marketing infrastructure we had anticipated, or they may be subject to unforeseen liabilities. We may be unable to successfully increase the efficiencies of the acquired businesses in the manner we contemplated or devote more resources and management attention than desirable to the integration and management of the acquired businesses. Hence, there can be no guarantee that we will be able to enhance our post-acquisition performance or grow our business through our recent or future acquisitions.

We face risks related to natural disasters, health epidemics, civil and social disruption and other outbreaks, which could significantly disrupt our operations.

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand across China and globally. In March 2020, the World Health Organization characterized the COVID-19 outbreak as a global pandemic. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. In May 2023, the WHO declared that COVID-19 is now an established and ongoing health issue which no longer constitutes a public health emergency of international concern.

The COVID-19 outbreak has caused and may continue to cause a long-term adverse impact on the economy and social conditions in the PRC and other affected countries, which may have an indirect impact on our industry and have a material adverse effect on our business, financial condition and operations.

In addition, any future occurrence of force majeure events, natural disasters or outbreaks of other epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus or the Ebola virus disease, may materially and adversely affect our business, financial condition and operations. Any future occurrence of severe natural disasters in the PRC or other overseas jurisdictions may materially and adversely affect their economy and our business.

Damage or extended periods of interruption to our corporate, development and research and development facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to delay or cease development or commercialization of some or all of our product candidates. Our insurance might not cover all losses under such circumstances and our business may be impacted by delays and interruptions. We cannot assure that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken by the governments of the jurisdictions where we operate or plan to enter in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and operations.

RISK FACTORS

Changes in the political and economic policies may materially and adversely affect our business, financial condition, results of operations and prospects.

Due to our extensive business operations in the PRC, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. Our growth prospect is in part affected by the overall economic growth in China, which is in turn influenced by the governmental regulations and policies in relation to resource allocation, monetary policies, regulations of financial services and institutions, preferential treatment to particular industries or companies and others. Any of the foregoing would affect our business, financial condition, results of operations and prospects.

Failure to pay the social insurance and housing provident funds on behalf of our employees in accordance with the Labor Contract Law or comply with other PRC regulations may have an adverse impact on our financial conditions and results of operation.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) implemented on December 29, 2018 and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to make timely and adequate contribution of social insurance premium for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium within a specified period of time, and the competent authority may further impose fines or penalties.

In the future, we may not apply for social insurance registrations and housing provident fund payment and deposit registrations in a timely manner, and we may not be able to make full contribution to the social insurance and housing provident funds for our employees in the future in accordance with the relevant PRC laws and regulations. As a result, we may be required by competent authorities to pay the outstanding amount and could be subject to late payment penalties or enforcement application made to the court. As of the Latest Practicable Date, no competent government authorities had imposed administrative action, fine or penalty to us with respect to any non-compliance incident nor had any competent government authorities required us to settle any outstanding amount of social insurance payments and housing provident fund contributions. We will continue to make full contributions or pay any historical shortfall within a prescribed time period if demanded by the relevant government authorities. Our Directors, having consulted our PRC Legal Advisor, are of the opinion that such non-compliance will not have a material adverse effect on our business.

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We, including but not limited to our HK subsidiary, may be deemed to be a PRC tax resident enterprise under the EIT Law, which could result in unfavorable tax consequences to us, and may materially and adversely affect our profitability and the value of your [REDACTED].

We are a company incorporated under the laws of the Cayman Islands. Pursuant to the EIT Law and its implementation rules, if an enterprise incorporated outside the PRC has its "de facto management bodies" within the PRC, such enterprise would generally be deemed a "PRC resident enterprise" for tax purposes and be subject to an EIT rate of 25% on its global income. "De facto management bodies" is defined as the body that has actual overall management and control over the business, personnel, accounts and properties of an enterprise. In April 2009, July 2011 and January 2014, the SAT issued several circulars, as amended from time to time, to clarify certain criteria for the determination of the "de facto management bodies" for foreign enterprises controlled by the PRC enterprises. However, there have been no official implementation rules regarding the determination of the "de facto management bodies" for foreign enterprises not controlled by PRC enterprises (including companies like ourselves). We are currently not regarded as a PRC tax resident enterprise. Nevertheless, if we are regarded as a PRC tax resident enterprise by the PRC tax authorities, we would have to pay PRC EIT at a rate of 25% for our entire global income, which may materially and adversely affect our profits and hence our retained profit available for distribution to our Shareholders.

You may be subject to PRC withholding tax on dividends from us and PRC income tax on any gain realized on the transfer of our Shares.

Under the EIT law and its implementation rules, PRC withholding tax at a rate of 10% is normally applicable to dividends from a PRC source paid to investors that are "non-resident enterprises," which do not have an establishment or place of business in the PRC, or which have such an establishment or place of business but whose relevant income is not effectively connected with the establishment or place of business. Any gain realized on the transfer of shares by such non-resident enterprise investors is generally subject to a 10% PRC income tax if such gain is regarded as income derived from sources within the PRC.

Under the PRC EIT Law and its implementation rules, dividends from sources within the PRC paid to foreign individual investors who are not PRC residents are generally subject to a PRC withholding tax at a rate of 20% and gains from PRC sources realized by such investors on the transfer of shares are generally subject to PRC income tax at a rate of 20% for individuals.

Any PRC tax may be reduced or exempted under applicable tax treaties or similar arrangements. However, it is unclear whether non-PRC resident investors would in practice be able to obtain the benefits of any tax treaties between their country of tax residence and the PRC in the event that a company incorporated outside the PRC is deemed to be a PRC resident enterprise.

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If we are treated as a PRC resident enterprise, dividends we pay with respect to our Shares, or the gain realized from the transfer of our Shares, may be treated as income derived from sources within the PRC and as a result be subject to the PRC income taxes described above. If PRC income tax is imposed on gains realized through the transfer of our Shares or on dividends paid to our non-resident [REDACTED], the value of your [REDACTED] in our Shares may be materially and adversely affected.

Our use of [REDACTED] from business operations may be subject to currency exchange laws and regulations.

The conversion of RMB into foreign currencies and, in certain cases, the remittance of currency out of China, are subject to PRC regulations and approvals. A substantial portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, we and our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, we may not obtain such approvals. Since our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Changes in international trade policies may affect our business operations.

Any unfavorable government policies on international trade, such as capital controls or tariffs, may adversely affect our business, financial condition, results of operations, cash flows and prospects. The current and former United States administrations have called for substantial changes to U.S. foreign trade policy with respect to China and other countries, including the possibility of imposing greater restrictions on international trade and significant increases in tariffs on goods imported into the United States. China has responded by imposing, and proposing to impose additional, new, or higher tariffs on certain products imported from the United States. Following mutual retaliatory actions for months, on January 15, 2020, the United States and China entered into the Economic and Trade Agreement as a phase one trade deal, effective on February 14, 2020. It remains unclear what additional actions, if any, will be taken by the United States or other governments with respect to international trade, tax policy related to international commerce, or other trade matters. If any new tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition and results of operations.

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Any failure by the Shareholders or beneficial owners of our shares to comply with PRC foreign exchange or other regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The Circular on Relevant Issues concerning Foreign Exchange Administration of Overseas Investment and Financing and Return Investments Conducted by Domestic Residents through Overseas Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (“SAFE Circular 37”), which was promulgated by SAFE and became effective on July 4, 2014, requires PRC residents to register with banks designated by local branches of SAFE in connection with their Direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents’ legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a “special purpose vehicle.”

If the shareholders of an offshore holding company who are PRC residents fail to fulfill their required registration with the local SAFE branches, the PRC subsidiaries of the offshore holding company may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its PRC subsidiaries. Furthermore, failure to comply with the SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls.

We have requested 41 persons, being the PRC residents who we know hold interest in us to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. We may not be fully informed of the identities of all our shareholders or beneficial owners who are PRC residents to ensure their compliance with SAFE Circular 37 or other related rules. In addition, we cannot provide any assurance that all of our shareholders and beneficial owners who are PRC residents will comply with our request to make, obtain or update any applicable registrations or comply with other requirements required by SAFE Circular 37 or other related rules in a timely manner. Even if our shareholders and beneficial owners who are PRC residents comply with such request, we cannot provide any assurance that they will successfully obtain or update any registration required by Circular 37 or other related rules in a timely manner due to many factors, including those beyond our and their control. Any failure by our PRC residents shareholders or beneficial owners to register with SAFE or update their SAFE registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of our future shareholders or beneficial owners who are PRC residents to comply with the registration requirements set forth in SAFE Circular 37 and subsequent implementation rules may result in penalties and limit our PRC subsidiaries’ ability to make distributions, pay dividends or other payments to us or affect our ownership structure and restrict our cross-border investment activities, which could adversely affect our business, financial condition and results of operations.

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PRC laws and regulations impose significant regulatory approvals and scrutiny requirements that may make it more difficult for us to grow through acquisitions in China.

PRC laws and regulations, such as the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者並購境內企業的規定》) (the “M&A Rules”) which came into effect on September 8, 2006 and was amended on June 22, 2009, established procedures and requirements that are expected to make merger and acquisition activities in China by foreign investors subject to requirements in some instances that MOFCOM be notified in advance of any change of control transaction in which a foreign investor takes control of a PRC domestic enterprise, or that the approval from MOFCOM be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies. PRC laws and regulations also require certain merger and acquisition transactions to be subject to merger control review or security review.

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially reduce the value of your [REDACTED].

Our revenue and expenses are substantially denominated in Renminbi. A portion of the revenue must be converted into other currencies in order to meet our foreign currency obligations. For example, we will need to obtain foreign currency to make payments of declared dividends, if any, on our Shares. In addition, our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. The change in the value of currencies may fluctuate and is affected by, among other things, changes of the relevant political and economic conditions and foreign exchange policies. Any significant change in the related exchange rates may adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

Any failure to comply with PRC regulations regarding the registration requirements for employee stock incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly-Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “SAFE Circular 7”), replacing the previous rules issued by SAFE in March 2007. Under the SAFE Circular 7 and other relevant rules and regulations, PRC residents who participate in a stock incentive plan in an overseas publicly-listed company are required to register with SAFE or its local branches and complete certain other procedures. Participants of a stock incentive plan who are PRC residents must retain a qualified PRC agent, which could be a PRC subsidiary of the overseas publicly listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the stock incentive plan on behalf of its participants. The participants must also retain an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests

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and fund transfers. In addition, the PRC agent is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes. Also, SAFE Circular 37 stipulates that PRC residents who participate in a share incentive plan of an overseas non-publicly-listed special purpose company may register with SAFE or its local branches before they exercise the share options. We and our PRC employees who have been granted share options will be subject to these regulations upon the completion of this [REDACTED]. Failure of our PRC share option holders to complete their SAFE registrations may subject these PRC residents to fines of up to RMB300,000 for entities and up to RMB50,000 for individuals, and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limit our PRC subsidiaries' ability to distribute dividends to us, or otherwise materially and adversely affect our business.

The STA has also issued relevant rules and regulations concerning employee share incentives. Under these rules and regulations, our employees working in the PRC will be subject to PRC individual income tax upon exercise of the share options. Our PRC subsidiaries have obligations to file documents with respect to the granted share options or restricted shares with relevant tax authorities and to withhold individual income taxes for their employees upon exercise of the share options or grant of the restricted shares. If our employees fail to pay or we fail to withhold their individual income taxes according to relevant rules and regulations, we may face sanctions imposed by the competent governmental authorities.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our Shares, and an active [REDACTED] market for our Shares may not develop and the [REDACTED] for our Shares may decline or become volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the Joint Sponsors, and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED] or that the [REDACTED] of the Shares will rise following the [REDACTED].

The [REDACTED] and [REDACTED] of our Shares may be volatile, which could lead to substantial losses to [REDACTED].

The [REDACTED] and [REDACTED] of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [REDACTED] of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our

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product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting our industry, business model, or corporate structure, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors or ourselves. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and our Shares may be subject to changes in [REDACTED] not directly related to our performance.

Future sales or perceived sales of a substantial number of our Shares in the [REDACTED] following the [REDACTED] could materially and adversely affect the [REDACTED] of our Shares and our ability to raise additional capital in the future and may result in dilution of your shareholding.

Prior to the [REDACTED], there has not been a public market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the [REDACTED] market or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] of our Shares and our ability to raise equity capital in the future.

In addition, our Shareholders would experience dilution in their shareholdings upon [REDACTED] or sale of additional share capital or share capital-linked securities by our Company in future offerings. If additional funds are raised through our issuance of new share capital or share capital-linked securities other than on a *pro rata* basis to existing Shareholders, the shareholdings of such Shareholders may be reduced and such new securities may confer rights and privileges that take priority over those conferred by the [REDACTED].

As the [REDACTED] of our [REDACTED] is higher than our net tangible book value per share, [REDACTED] of our Shares in the [REDACTED] may experience immediate dilution upon such purchases. [REDACTED] of Shares may also experience further dilution in shareholdings if we issue additional Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, [REDACTED] of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value, and our existing Shareholders will receive an increase in the [REDACTED] adjusted consolidated net tangible assets per Share of their Shares. In order to expand our business, we may consider offering and issuing additional Shares in the future. [REDACTED] of the [REDACTED] may also experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price that is lower than the net tangible asset value per Share at that time.

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Our Controlling Shareholders may have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Immediately following the completion of the [REDACTED], our Controlling Shareholders will hold in aggregate approximately [REDACTED]% of the voting power at general meetings of our Company, assuming the [REDACTED] is not exercised. Our Controlling Shareholders will, through their voting power at the Shareholders meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling Shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the [REDACTED] of our Shares.

We cannot assure you that we will declare and distribute any amount of dividends in the future.

We intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the commercialization of our products, the research and development activities of our product candidates and to expand our product portfolio. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board declares and pays dividends, the timing, amount and form of future dividends, if any, will depend on our future operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the [REDACTED] at which you [REDACTED] the Shares. You may not realize a [REDACTED] on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways with which you may or may not agree or which do not yield a favorable return to our shareholders. See “Future Plans and Use of [REDACTED]—Use of [REDACTED].”

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However, our management has complete discretion as to the actual application of our net [REDACTED]. You are entrusting your [REDACTED] to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

We cannot guarantee that our Shares will remain [REDACTED] on the [REDACTED].

Although we currently intend to retain the [REDACTED] of our Shares on the Stock Exchange, there is no guarantee of the continued [REDACTED] of the Shares. Among other factors, our Shares may also fail to satisfy the [REDACTED] requirements of the Stock Exchange. Accordingly, Shareholders will not be able to [REDACTED] their Shares through [REDACTED] on the [REDACTED] if the Shares are no longer [REDACTED] on the [REDACTED].

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

On April 30, 2018, the Stock Exchange adopted new rules under Chapter 18A of the Listing Rules. Under the new rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this Document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A of the Listing Rules. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

The industry facts, statistics and forecasts in the document obtained from various government publications and the industry report have not been independently verified.

Facts, forecasts and statistics in this Document relating to the DTx industry are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Joint Sponsors, [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the industry statistics in this Document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this Document, we disclaim responsibility for them. Accordingly, prospective [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this Document only and should not rely on any other information.

You should rely solely upon the information contained in this Document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in our [REDACTED]. By applying to [REDACTED] our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this Document and the [REDACTED].