Potential [**REDACTED**] *should read and consider carefully all the information set out in this document, and, in particular, should evaluate the following risks and uncertainties before deciding to make any* [**REDACTED**] *in our H Shares. You should pay particular attention to the fact that we conduct our operations in China, the legal and regulatory environment of which in some respects may differ from that in Hong Kong. Any of the risks and uncertainties listed below could have a material adverse effect on our business, results of operations, financial condition or on the* [**REDACTED**] *of our H Shares, and could cause you to lose all or part of your* [**REDACTED**]. *The risks and uncertainties identified below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business and results of operations.*

You should only rely on the information included in this document and the documents issued by our Company to make your [**REDACTED**] *decision and should not rely on any other information, including any forward-looking information published by our Controlling Shareholders.*

Our business is subject to numerous risks and uncertainties, including (1) risks relating to our business and industry, which primarily includes risks relating to commercialization and distribution, research and development, manufacture and supply, extensive government regulations, our intellectual properties and our operations, (2) risks relating to doing business in China, and (3) risks relating to the [**REDACTED**].

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to Commercialization and Distribution

Downward changes in the pricing of our products may have a material adverse effect on our business, results of operations and financial condition.

We generally price our products and product candidates upon commercialization by taking into consideration a variety of factors, including pricing guidance set by the government authorities, bargaining power and preferences of hospitals, prices of similar products offered by our competitors, our operating costs and the continuous upgrades of existing products, some of which are beyond our control.

If the PRC government issues pricing guidance for our products and/or product candidates upon commercialization, it may negatively affect the price at which we can sell our products and therefore have a material adverse effect on our business, results of operations and financial condition. In addition, the PRC government has adopted a centralized procurement regime in an effort to regulate the prices of certain medical devices, which may exert downward pressure on the said pricing of medical devices that are included under such regime. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Reform Plan on

High-Value Medical Consumables." Although none of our medical devices was included under the centralized procurement regime in China during the Track Record Period and up to the Latest Practicable Date, we cannot assure you that any of our products or product candidates upon commercialization will not be included under the regime in the future. We may also face downward changes in pricing if additional products of ours are included in the medical insurance reimbursement list, even if we expect such inclusion to increase the sales volume of our products. See "Business — Sales, Distribution and Marketing — Pricing" and "— Our sales depend to a certain extent on the level of insurance reimbursement patients receive for treatments using our products, especially, whether our products are covered in the medical insurance scheme." Also, when setting the prices for our products, hospitals may gain more bargaining power depending on the availability of alternative products, demands of patients and the preferences of physicians. If hospitals seek to lower retail prices of our products and therefore reduce the profitability of our distributors, our distributors may have less incentive to purchase and promote our products, and we may need to lower the order price we set for our distributors. Furthermore, along with our increasing efforts to promote our product candidates, as well as the continuous development of competing product candidates, awareness of these products is expected to increase. More competing products may become available, which will offer alternatives for hospitals and patients to choose.

In addition, with the development of technologies and increasing competition in the industry, we may experience reduced pricing from our existing products, particularly along with the launch of new products that can replace or further improve the safety and efficacy profile of our existing products, while the manufacturing and material costs may remain constant or increase. If we are unable to successfully introduce more advanced and/or more profitable products to the market, or if we fail to effectively control our operating and manufacturing costs, our business, financial condition and results of operations could be materially and adversely affected.

Failure to achieve broad market acceptance could have a material adverse impact on our business and results of operations.

The commercial success of our products depends upon the degree of market acceptance each of such products achieves, particularly among physicians, patients and hospitals. As a treatment recently developed and introduced to the market, interventional therapies involving our occluder products and product candidates and heart valve product candidates may fail to receive broad acceptance from patients or physicians as anticipated. As an alternative, open-chest surgeries may have certain advantages over interventional therapies, given its established market acceptance, comparatively lower price and coverage by governmental and private medical insurance. In addition, physicians could face a learning process to become proficient in the use of our products, which may take longer than expected and therefore affect our ability to market our products.

If any of our products or product candidates upon commercialization fails to gain sufficient market acceptance by physicians, patients, hospitals, third-party payors or others in the industry, the sales of our products will be adversely affected. For example, currently commercialized interventional medical devices, such as the occluder products and heart valve products developed by some of our competitors are well established in the China and overseas markets, and physicians may continue to rely on these treatments to the exclusion of our products and product candidates. In addition, physicians, patients, hospitals, and third-party payors may prefer other novel products to ours. If our products and product candidates upon commercialization do not achieve an adequate level of acceptance, we may not be able to generate significant product sales revenue and to improve profitability. The degree of market acceptance of our products and product candidates (if approved for commercial sale) will depend on a number of factors, including, among others:

- the clinical indications for which our products and product candidates are approved;
- physicians, patients and hospitals considering our products and product candidates upon commercialization as a safe and effective treatment;
- the potential and perceived advantages and disadvantages of our products, product candidates upon commercialization and relevant treatments compared to alternative products and treatments;
- the prevalence and severity of any side effect, adverse event or complication;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our products and product candidates upon commercialization as well as competing products;
- the cost of treatment in relation to alternative treatments;
- pricing and the availability of adequate coverage and reimbursement 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; and/or
- the effectiveness of our sales and marketing efforts.

If any product that we commercialize fails to achieve market acceptance among physicians, patients, hospitals, or others in the industry or if we fail to maintain good relationships with them, 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 received and more cost effective than our products.

We may face intense competition in the interventional medical device market targeting structural heart diseases, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The interventional medical device market targeting structural heart diseases is intensely competitive and rapidly changing. We face competition from major interventional medical device providers for structural heart diseases worldwide. There are several multi-national and domestic companies having products at or near commercial stage, or pursuing the development and undergoing clinical trials of product candidates targeting the structural heart diseases as our products and product candidates do. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacture and commercialization on interventional medical devices for structural heart diseases.

Our commercialized products may face competition based on factors including, among others, their safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer severe adverse events, or are less expensive than any products that we commercialize or may develop. As a result, we may become obsolete overtime and lose our market share. In terms of product candidates, our competitors may be applying for marketing approvals in China or other countries for medical device products with the same intended use as our product candidates. The ability of the relevant authorities to concurrently review multiple marketing applications for the same type of innovative medical device may be limited. For example, when our product candidates and their competing products are subject to the NMPA's concurrent review, we cannot guarantee that the NMPA's schedule would not be affected, and the registration process of our product candidates may be prolonged. Moreover, our competitors may obtain approval from the NMPA or other comparable regulatory authorities for their products more quickly than we obtain approval for ours, which could result in our competitors establishing a strong market position or gaining acceptance in the same markets that we are targeting before we are able to enter the market. As a result, we may be unable to maintain or enhance our market share or achieve our targeted market share in the industry.

Moreover, some of our competitors, including certain first-movers and multi-national companies, may have greater commercial infrastructure, better financial, technical and personnel resources than we have. 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 and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development. Our business and results of operations will suffer if we fail to compete effectively.

Disruptive technologies and medical breakthroughs may also render our products obsolete or non-competitive. Without the timely introduction of new and improved products, our products could become technologically obsolete or more susceptible to competition and our revenue and operating results would suffer. We may have to make significant investments in new products and advanced technologies to face such competitions. However, technical innovations often require substantial time and investment before we can determine their commercial viability, which could have a material adverse impact on our financial condition. Furthermore, should the new generation of our products succeed in obtaining an approval, it may capture a significant share of our previous generation products and thereby reduce the sales of our previous generation products.

We depend on distributors for a substantial portion of our revenue and our revenue growth. We may fail to maintain or renew relationships with distributors, or further expand our network of distributors.

We rely on third-party distributors to distribute our products. As of June 30, 2022, we had 288 distributors covering all provinces, municipalities and autonomous regions in China. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we generated 91.8%, 92.6%, 93.9%, 94.8% and 97.0% of our total revenue through sales to distributors, respectively. We expect we will continue to rely on distributors for our revenue growth. Our ability to maintain and expand our business depends on our ability to maintain effective distributor networks that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. We rely on our distribution agreements to manage our distributors. However, all of our distributors, except for the Retained Lepu Medical Group, are independent third parties over whom we have limited control. Moreover, in line with industry practice, we generally do not enter into long-term distribution agreements, and our standard distribution agreement has a term of one year, which may be automatically renewed for three months. In order to maintain our network of distributors, we need to continually renew distribution agreements. However, we cannot guarantee that we will be able to renew such agreements with our preferred distributors on terms favorable to us or at all. If our distributors elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, including in the event that PRC pricing regulations or other factors limit the margins our distributors can obtain through the resale of our products to hospitals, many of which are beyond of control, our business, results of operations and financial condition could be materially and adversely affected.

Sales to our five largest customers in each year/period of the Track Record Period amounted to RMB32.2 million, RMB56.0 million, RMB47.2 million and RMB18.9 million, respectively, representing 27.6%, 37.8%, 21.2% and 15.1% of our total revenue for the same periods, respectively. Sales to the largest customer in each year/period of the Track Record Period amounted to RMB10.2 million, RMB31.0 million, RMB16.0 million and RMB4.4 million, respectively, representing 8.8%, 20.9%, 7.2% and 3.5% of our total revenue for the same periods, respectively. Substantially all of our five largest customers during the Track Record Period were our distributors. If any of our major distributors was to substantially

reduce the size or amount of the orders they place with us or were to terminate their business relationship with us entirely, we may not be able to obtain orders from other customers to replace any such lost sales on comparable terms or at all. As a result, our sales volume and business prospects could be materially and adversely affected.

In addition, competition for distributors in the medical device market is intense. We compete for desired distributors with other leading medical device manufacturers and importers that may have greater visibility, brand recognition and financial resources, and a broader product portfolio than we do. Our competitors may enter into exclusive distribution agreements that restrict their distributors from selling our products. Consequently, maintaining relationships with existing distributors and replacing distributors may be difficult and time consuming. Further, the implementation of the "two-invoice system" limits the distribution to a single level of distributors from manufacturers to public hospitals or similar systems in the medical device industry. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Two-Invoice System." Related changes may have a negative impact on us, as there would be a smaller pool of distributors, which may increase the bargaining power of distributors. As the implementation of the "two-invoice system" is still at an early stage, and the interpretation and enforcement of such system in the medical device industry are evolving and subject to uncertainty, we cannot predict how the implementation and enforcement will evolve in different provinces in China, or whether and how that will affect our business and results of operations in the future. If we engage more than one layer of distributors in the provinces or municipal cities that have implemented the two-invoice system, we could risk violating the relevant local regulations and may be subject to regulatory measures imposed by the relevant local government authorities. Any disruption of our distributor network, including our failure to renew our existing distribution agreements with our preferred distributors, could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, results of operations and financial condition.

If our distributors fail to expand or maintain their sales network, or if we fail to educate or manage our distributors effectively, our sales may decline.

We have limited control over the operations and actions of our distributors. We rely on the distribution agreements and the policies and measures we have in place to manage our distributors, including their compliance with laws, rules, regulations and our policies. See "Business — Sales, Distribution and Marketing — Sales to Distributors." We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach our agreements and policies. Our distributors could take actions, including one or more of the following, which could have a material adverse effect on our business, prospects and reputation:

- failing to meet the sales targets for our products in accordance with relevant agreements;

- selling products that compete with our products;

- selling our products outside their designated territories;
- procuring sub-distributors in connection with the sales of our products;
- failing to adequately promote our products;
- failing to maintain the requisite license or otherwise failing to comply with applicable regulatory requirements when selling our products;
- failing to provide proper training and after-sales services to our end-customers; or
- violating anti-corruption, anti-bribery, sanctions, competition or other laws and regulations of China or other jurisdictions.

During the Track Record Period and up to the Latest Practicable Date, we entered into written distribution agreement with each distributor we directly worked with, which would set forth various terms and restrictions, such as designated hospitals and authorized product type. However, we historically sold our products overseas through the Retained Lepu Medical Group, who then distributed our products to sub-distributors in overseas markets. See "Business — Sales, Distribution and Marketing — Sales Arrangements." We did not require the Retained Lepu Medical Group to seek our approval before engaging such sub-distributors. We did not engage these sub-distributors directly or maintain contractual relationships with them, and instead, mainly relied on the Retained Lepu Medical Group to manage and control such sub-distributors in accordance with regulatory requirements and our policies and measures that the Retained Lepu Medical Group agree to comply with. As a result, we had a more limited control over these sub-distributors. We cannot assure you that the sub-distributors had complied with the distribution requirements under our distribution agreements and policies. Furthermore, as there was no contractual relationship between us and these sub-distributors, we had no direct legal recourse against them if their activities caused harm to our business or reputation. As of September 30, 2021, we had terminated our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas and entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "Business — Sales, Distribution and Marketing — Sales Arrangements." We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution. We cannot assure you, however, that we will be successful in executing this new model in the future. Overseas distribution network is substantially different from our domestic distribution network in many ways. For instance, overseas distributors are primarily importer-distributors who have both the expertise in foreign trade and established distribution and marketing capabilities in local markets. They need to import products from us, and independently conduct promotional and sales activities tailored for the local markets. Therefore, the overseas distribution chain can be longer and more complex as compared to domestic distribution, which could lead to additional uncertainties and adversely affect our business, financial condition and results of operations. Moreover, we also face uncertainties in

managing our distribution networks across geographical locations and in an environment of multiple languages, cultures, customs, and legal and regulatory systems, which could adversely affect distribution efficiency, which in turn could adversely affect our business, financial condition and results of operations.

Any violation or alleged violation by our distributors and sub-distributors of the distribution agreements, our policies or any applicable laws and regulations could result in the erosion of our goodwill, a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects.

Our sales may fail to accurately reflect the actual demand of end-customers as a result of our distribution sales model.

We typically set a sales target with our distributors, which is subject to review and amendment upon renewal of distribution agreements. The sales target serves as annual sales goals instead of strict purchase requirements. As a result, there is a risk that the products are not reaching end-customers but remain in our distributor network. We have implemented policies and measures, including close monitoring of our distributors' sales performance and inventory levels and strict product return and exchange policy, to prevent channel-stuffing of our products. However, as our control over distributors is limited, if sales to distributors were higher than actual market demand, certain distributors may decrease their order volume or cease to order additional products from us until they eventually sell the stocked products to end-customers, and as a result, our business and results of operations may be adversely affected.

Failure to effectively expand our sales and marketing capabilities could harm our ability to increase the sales of our products and achieve broader market acceptance.

In addition to the sales through our distributors, we sell our products directly to hospitals. We rely on our sales and marketing team to promote our products and communicate with hospitals and physicians. They also work closely with our research and development team to improve our existing products and introduce new products or enhancements by providing first-hand market trend and customer feedback. The success of our sales and marketing efforts depends on our ability to attract, motivate and retain qualified employees in our sales and marketing team who have, among other things, education background and work experience in the medical device industry. Furthermore, since we expect to commercialize our heart valve product candidates and launch new occluder product candidates, we expect to hire additional employees with relevant experience and knowledge to support our sales and marketing efforts. If we are unable to recruit, develop and retain qualified sales and marketing personnel, or if our new sales and marketing personnel are unable to achieve desired performance levels in a reasonable period of time, we may not be able to increase the sales of our products and achieve broader market acceptance, and our business and results of operations may be negatively affected.

Moreover, we promote our products through academic marketing, by establishing research and clinical collaboration and training relationships with hospitals, physicians and KOLs. We cannot assure you that we will be able to maintain or strengthen our relationships with these industry participants, or that our efforts to maintain or strengthen such relationships will yield increased sales. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. In addition, we cannot assure you that our academic promotion and marketing strategy will continue to serve as an effective marketing strategy. Industry participants may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield larger hospital coverage or increased sales commensurate to our efforts spent. In addition, the hospitals, physicians and KOLs that we focus on may not continue to have a significant demand for our products or product candidates. If we are unable to develop new products or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

Further, we historically collaborated together with the Retained Lepu Medical Group to explore sales and marketing opportunities in overseas markets. As of September 30, 2021, we had terminated our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas and entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "Business — Sales, Distribution and Marketing — Sales Arrangements" for details. We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution. We also intend to continue integrating our domestic and overseas sales and marketing efforts. However, such integration process may take longer than expected to achieve the full effect, and our overseas sales could decline if we fail to integrate overseas sales and marketing activities in an effective and efficient manner.

We cannot guarantee that we will succeed in expanding our sales network to cover new hospitals.

We plan to expand our sales network to cover more hospitals to increase our market share and penetration in the China market to drive future growth. We may seek to expand our sales network to cover additional hospitals which have limited experience in interventional therapies involving our occluder products and heart valve product candidates and hospitals in emerging markets with relatively limited resources. This marketing strategy could require us to strengthen our sales and marketing efforts, and we may not be able to do so. If we are unable to expand our sales network effectively, our sales volumes and business prospects could be materially and adversely affected.

We derived a majority of our revenue from the sale of CHD occluder products and occluder related procedural accessories during the Track Record Period, and we expect to continue to do so in the near future. If we are unable to manufacture or sell newly launched products or successfully commercialize our various product candidates, or if demand for these products is reduced, our revenue would significantly decline.

During the Track Record Period, we generated a majority of our revenue from the sale of CHD occluder products and occluder related procedural accessories. Our occluder related procedural accessories primarily include delivery systems and snares mainly related to CHD occluder products. Revenue generated from the sale of CHD occluder products was RMB86.7 million, RMB106.6 million, RMB132.5 million, RMB64.1 million and RMB90.7 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 74.5%, 71.9%, 59.5%, 57.8% and 72.7% of our total revenue for the same periods, respectively. Revenue generated from sales of occluder related procedural accessories was RMB28.9 million, RMB32.0 million, RMB41.6 million, RMB18.4 million and RMB27.1 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 24.8%, 21.6%, 18.7%, 16.6% and 21.7% of our revenue in the same periods, respectively. Among our CHD occluder products, revenue generated from the sale of ASD occluder products was RMB56.1 million, RMB69.7 million, RMB99.8 million, RMB47.8 million and RMB71.3 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, representing 48.1%, 47.0%, 44.8%, 43.1% and 57.1% of our revenue for the same periods, respectively. See "Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Revenue — Major Product." While we are dedicated to diversifying our product portfolio, prior to the broad acceptance of our newly launched products and successful commercialization of our various product candidates, we expect to continue to derive a majority of our revenue from the sale of our occluder products and occluder related procedural accessories in the near future. Continued market acceptance and demand for these products are critical to our revenue. If we are unable to manufacture or sell these products due to commercial, regulatory, intellectual property or any other reasons, or if demand for these products is reduced due to the ever-increasing competition or advances in alternative treatments or products, our revenue would significantly decline.

We are exposed to credit risk in relation to our trade and other receivables.

Our trade receivables consisted of amounts due from our third-party customers or our related-party customers. Our customers include distributors who on-sell our products to hospitals and, to a lesser extent, hospitals. We generally do not grant a credit period to our distributors, including the Retained Lepu Medical Group. Under limited circumstances, we may grant distributors who have a good track record with us a temporary credit period. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had trade receivables of RMB45.3 million, RMB38.3 million, RMB23.9 million and RMB32.9 million, respectively. In 2019, 2020, 2021 and the six months ended June 30, 2022, trade receivables turnover days were 144 days, 122 days, 64 days and 56 days, respectively. See "Financial Information — Discussion

of Major Balance Sheet Items — Trade Receivables." We had also recorded other receivables – net of RMB8.6 million, RMB10.7 million, RMB1.8 million and RMB18.9 million, respectively, as of December 31, 2019, 2020 and 2021 and June 30, 2022, representing other receivables due from third parties and related parties. See "Financial Information — Discussion of Major Balance Sheet Items — Prepayments and Other Receivables."

We are exposed to the risks that our customers or other business partners may delay or even be unable to pay us in accordance with the payment terms included in our agreements in a timely manner, or at all. Although we closely monitor our outstanding trade and other receivables, we cannot assure you that we will be able to fully recover the outstanding amounts in a timely manner, or at all. In addition, as our business continues to scale up, our trade and other receivables may continue to grow, which may increase our credit risk. Any substantial delay in or default of payments from our customers and other business partners could materially and adversely affect our cash flows. Moreover, we could be required to terminate our relationship with distributors in a manner that will impair the effective distribution of our products. Any of the foregoing could materially and adversely affect our business, results of operations and financial condition.

Our failure to honor our obligations in respect of our contract liabilities may lead to our refund obligation, customer dissatisfaction, or even customer disputes with us, which may adversely affect our reputation, business, results of operations and financial condition.

Our contract liabilities consisted primarily of customers' rights to claim for additional units, volume rebates to customers, and nonrefundable prepayment from customers. We had contract liabilities of RMB12.2 million, RMB15.3 million, RMB14.8 million and RMB14.4 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. The volume rebates are offered to our distributors who outperformed the pre-determined sales levels. The considerations for products that are used as settlement for our unsatisfied performance obligations with respect to the aforementioned claims for additional units and volume rebates have been deferred and accounted for as our contract liabilities. See Note 32 to the Accountant's Report in Appendix I to this document. If we fail to honor such obligations, we may not be able to recognize the related revenue in a timely manner, if at all, which may adversely affect our business, results of operations and financial condition. The prepayments from customers are generally not refundable. However, if we fail to honor our obligations in respect of our contract liabilities, customers may request to cancel their agreements with us or request a partial or full refund, which may lead to our refund obligation, customer dissatisfaction or even customer disputes with us. In the event that we are required to refund some or all of the prepayments from our customers pursuant to the contract provisions, we may not have the cash or other available resources to fulfill the refund obligation. Even if we are able to fulfill the refund obligation from available resources (including potentially a portion of the net [**REDACTED**] of this [**REDACTED**]), we may need to seek additional sources of capital to fund our operations, which funding may not be available when needed or on acceptable terms, if at all. If any of the foregoing circumstances occurs, our business, results of operations, financial condition and reputation may be materially and adversely affected. Furthermore, in the future, customers may elect not to prepay us for our products, in which case

we would have to find other sources of funding for our operations, capital expenditures and expansion plans, which would be costly as compared to the aforementioned cost-free customer prepayment funding and may not be available when needed or on acceptable terms, if at all.

The growth and success of our business depends on the performance of us and our distributors in tender processes.

Our future growth and success significantly depend on our ability to successfully market our products to hospitals. We participate in public tender processes organized by procurement platforms managed by the government agencies at provincial or municipal level to secure the right to sell our products to the hospitals in such provinces or municipalities. Our distributors do not participate in such public tender processes at the provincial or municipal level. In addition, hospitals may organize public tenders either by themselves or through local governments. The procedures of public tenders organized by hospitals vary from hospital to hospital and from region to region, and there could be uncertainties with respect to the timing of such hospital-organized public tenders. As a result, we primarily depend on experienced local distributors to assist us during such procedures. However, we may not always be able to locate a sufficient number of experienced local distributors to sell our products to hospitals.

Furthermore, even if we could locate a sufficient number of experienced distributors, our bids during the public tender process may not be successful and our products may not be chosen for a number of reasons, including where:

- our prices are not competitive;
- our products fail to meet the technical or quality requirements imposed by the hospitals or are less clinically effective than competing products;
- our reputation is adversely affected by unforeseeable events; or
- our service quality or any other aspect of our operation fails to meet the relevant requirements.

If we fail in the tender process, we may face difficulties in maintaining the existing level of sales of our products, and we may find it difficult to sell our product candidates upon commercialization and our revenue may decline, materially adversely affecting our results of operations and financial condition.

Our sales depend to a certain extent on the level of insurance reimbursement patients receive for treatments using our products, especially, whether our products are covered in the medical insurance scheme.

Our ability to sell our products depends to a certain extent on the availability of governmental and private health insurance in China and overseas covering treatments using our products. Practice varied among provinces in the PRC for the reimbursement of interventional therapies involving our occluder products and heart valve product candidates. As the national medical insurance reimbursement system in China covers the treatment of CHD, all the occluder products and the related procedural accessories for the treatment of CHD are eligible for the medical insurance reimbursement. Accordingly, as of the Latest Practicable Date, our MemoPart® ASD Occluder I, MemoPart® VSD Occluder I, MemoPart® PDA Occluder I, MemoPart® interventional delivery system I, MemoPart® Snare I and interventional delivery system II were eligible for medical insurance reimbursement in all the provinces, autonomous regions and municipal cities in China. As of the same date, our MemoCarna® ASD Occluder III, MemoCarna® PDA Occluder III, MemoLefort® LAA Closure Occluder I, MemoCarna® VSD Occluder III, integrated interventional delivery system for Plug III, delivery system and interventional delivery system (biodegradable) were subject to medical insurance reimbursement in certain provinces in China. China has a complex medical insurance system which is currently undergoing reform. Governmental insurance coverage or the reimbursement rates in China for treatments using new medical devices such as our products and product candidates are subject to uncertainty and vary from region to region, as local government approvals for such coverage must be obtained in each geographic region. In addition, the PRC government may change, reduce or eliminate the governmental insurance coverage currently available for treatments using our products. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — National Medical Insurance Program."

We cannot assure you that reimbursement will be available for our products and product candidates upon commercialization and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the prices of our products. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with newly introduced technologies and medical devices. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize the product candidates that we successfully develop.

In the absence of sufficient medical insurance coverage for the use of our products, patients may choose alternative treatment methods, such as open-chest surgeries and drug treatment, and hospitals may recommend such alternative treatments, which would reduce demand for our products and in turn materially and adversely affect our business, results of operations and financial condition. Moreover, we may need to lower the prices of our products in order to have them included in the medical insurance reimbursement list, and such price cut and reimbursement may not necessarily lead to increase in our sales and our results of operations may be adversely affected.

Lack of sufficient sophisticated physicians that can perform interventional therapies involving our occluder products and heart valve product candidates may adversely affect our business.

Sophisticated physicians that can perform interventional therapies involving our occluder products and heart valve product candidates play a significant role in our business. We involve physicians in our product development stage and solicit their feedback, proposals and suggestions based on their clinical experience. We also rely on influential physicians to endorse the quality of our products and promote their use among hospitals. Additionally, sales volume of our products is largely determined by the number of interventional therapies involving our occluder products and heart valve product candidates performed, and physicians' performance is key to ensuring the proper implantation and function of our products in human bodies. However, interventional therapies are at a relatively early stage of implementation in China, with qualified physicians primarily employed by Class III hospitals. If the market acceptance of related procedures and the number of qualified physicians fail to grow as expected, our research and development efforts and sales of our products could be adversely affected.

Risks Relating to Research and Development

Our future growth depends substantially on the success of our product candidates.

Our ability to generate revenue from our product candidates and improve profitability in the future substantially depends on our ability to complete the development of our product candidates, obtain the requisite regulatory approvals and successfully commercialize our approved products in a timely manner. As of the Latest Practicable Date, we had 30 major product candidates at various development stages, including our biodegradable occluders and heart valve product candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing product candidates. For 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our research and development expenses were RMB25.8 million, RMB39.0 million, RMB41.4 million, RMB16.4 million and RMB19.6 million, respectively. See "Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Research and Development Expenses." We expect to continue to incur substantial and increasing expenses in developing, registering and commercializing our product candidates. Whether we can generate profit from our research and development activities depends on the successful commercialization of our product candidates, which in turn depends on a variety of facts, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;

- establishment of commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with suppliers;
- ability of our CROs to conduct or assist in conducting our clinical trials safely and efficiently and in accordance with our specified trial protocols;
- performance by any other third party we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- receipt and maintenance of patent, trade secret and other intellectual property protection and regulatory exclusivity;
- prevention of infringement, misappropriation or other violation of the patent, trade secret or other intellectual property rights of third parties;
- required marketing authorizations and commercial sales launch in China and other targeted markets, if and when approved;
- favorable governmental and private medical reimbursement for our products, if and when approved;
- appropriate pricing of our product candidates and timely collection of payments;
- competition with other occluder products and heart valve products; and
- continued acceptable safety profile following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to obtain approval for our product candidates, and/or to successfully commercialize our approved products, which would materially harm our business and we may not be able to generate sufficient revenue and cash flows to continue our operations.

Clinical development involves lengthy and expensive process with uncertain outcomes.

All of our products and product candidates are classified as Class III medical devices pursuant to a catalogue issued by the NMPA, which involve the highest degree of associated risks and therefore are subject to the largest extent of regulatory control to ensure safety and effectiveness. To obtain product registrations for medical devices of Class III in China, we may need to conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate the safety and efficacy of our products.

Clinical testing is expensive and can take several years to finish, and its outcome is inherently uncertain. Failures can occur at any stage of the clinical trial process, and clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. We cannot assure you that these trials or procedures can be completed in a timely or cost-effective manner or result in commercially viable products. We may experience numerous unexpected events before and during the clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including but not limited to:

- regulators, institutional review boards or ethics committees may not authorize us or our clinical trial site investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- clinical trials of our product candidates may have undesirable side effects, produce negative or inconclusive results, or other unexpected characteristics, and we may decide, or regulators may require us, to conduct additional clinical trials, or even suspend or terminate the product development programs;

- the initial or interim results of clinical trials may not be predictive of the final clinical trial results and may be subject to adjustments;

- the number of patients required for clinical trials of our product candidates may be larger than anticipated;

- we may not be able to reach agreements on acceptable terms with prospective CROs, which can be subject to extensive negotiation and may vary significantly among different CROs;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to delay, suspend or terminate clinical trials of our product candidates for various reasons, many of which are beyond our control, including a finding of lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks such as the outbreak of COVID-19;

- regulators or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;

- the cost of clinical trials of our product candidates may be greater than we anticipate; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or the quality may be inadequate.

In addition, changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Any delay in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenue for that candidate. Any of these occurrences may materially and adversely affect our business, results of operations, financial condition and prospects.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in a timely manner or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The results of preclinical studies and feasibility clinical trial of our product candidates may not be predictive of the results of confirmatory clinical trial. Product candidates in confirmatory clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and/or feasibility clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in the protocols, and differences in physical conditions of the patient population. We cannot assure that future clinical trial results of our product candidates can lead to favorable results. Even if our future clinical trial results show favorable efficacy, there is a possibility that certain of our product candidates may not suit the conditions of certain patients, and severe adverse events and complications may occur for some patients after the procedure.

If we are required by competent government authorities, such as the NMPA, to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be subject to substantial liabilities;
- be delayed in obtaining regulatory approval for our product candidates, or not be able to obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended, with additional pre-requisites;
- have the product removed from the market after obtaining regulatory approval;

- be subject to additional post-market study and testing requirements;
- be subject to restrictions on how the product is distributed or used;
- be unable to obtain reimbursement for use of the product; or
- be inferior to products of competitors when being selected by physicians and hospitals.

Any of such events could materially and adversely affect our ability to commercialize the subject product candidates.

We rely on the Entrustment Arrangements to exercise control over the Entrusted Products. Ineffective implementation of the Entrustment Arrangements due to factors beyond our control may adversely affect our business and results of operations.

As part of the Reorganization, we entered into an asset transfer agreement with Lepu Medical in January 2021 whereby the interventional heart valve business of Lepu Medical was injected into our Group to solidify our position as the sole platform under Lepu Medical Group focusing on interventional medical devices primarily targeting structural heart diseases. Among the product candidates under the injected interventional heart valve business, the key research and development work including type inspections and animal tests of certain heart valve product candidates (i.e., the Entrusted Products) had been conducted under the name of Lepu Medical prior to the business injection. Taking into account the Entrusted Products Regulatory Restrictions and for the purpose of maintaining a clear business delineation between our Group and the Retained Lepu Medical Group in interventional heart valve business subsequent to the business injection, we have entered into the Entrustment Arrangements with Lepu Medical as detailed in "Business — Our Products — Heart Valve Product Candidates — Entrusted Products."

The Entrustment Arrangements were devised for us to gain control of the Entrusted Products to the greatest extent possible under the prevailing regulatory framework and restrictions. On March 11, 2022, the NMPA amended the Catalogue of Medical Device Prohibited from Entrusted Production (《禁止委託生產醫療器械目錄》) (the "Prohibited Catalogue"). According to the Prohibited Catalogue, which became executive on May 1, 2022, Lepu Medical as the medical device registrant would be prohibited from authorizing us to manufacture TAVR system and TMVCRS and they would conduct the manufacturing of such products pursuant to the Entrustment Arrangements. Nevertheless, as Lepu Medical has irrevocably and exclusively authorized us to carry out commercialization and sales activities for each of the Entrusted Products, our interests under the Entrustment Arrangements would not be materially and adversely affected as a result of the Prohibited Catalogue. However, the interpretation and implementation of the prevailing laws and regulations are subject to discretion of government authorities and involve uncertainties which may not be favorable to

us, and we cannot assure you that there will not be any unfavorable regulations promulgated in the future which may lead to stricter or additional regulatory restrictions applicable to the Entrusted Products as compared to the currently prevailing Entrusted Products Regulatory Restrictions. As a result, we may have to renegotiate with Lepu Medical or we may be prevented from exerting effective control over the Entrusted Products. Furthermore, Lepu Medical, being one of our Controlling Shareholders, has substantial influence over us and conflicts of interest may arise between Lepu Medical and us as further elaborated in "— Risks Relating to Our Operations — Our Controlling Shareholders may have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders." There can be no assurance that we will be able to maintain a cooperative relationship with Lepu Medical in effecting the Entrustment Arrangements pursuant to the terms of the asset transfer agreement in the future. Any such ineffective implementation of the Entrustment Arrangements due to factors beyond our control could result in additional costs and diversion of our management's attention and resources, thereby adversely affecting our business and results of operations.

We rely on third parties to conduct certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to successfully register our product candidates and our business could be substantially harmed.

As a common practice in our industry, we have engaged and plan to continue to engage third parties, including leading academic institutions, hospitals, clinics, experienced physicians, and/or CROs, to assist us in designing, implementing and monitoring our pre-clinical research and conducting clinical trials. If we are unable to maintain or enter into agreements with these third parties on favorable terms to us, or if any such engagement with us is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate, and the development of our product candidates covered by such agreements could be substantially delayed.

In addition, our reliance on third parties would cause us to have less control over the quality, timing and cost of our pre-clinical research and clinical trials than if we conducted these procedures entirely by ourselves. We cannot guarantee that these third parties would devote adequate time and resources to our studies or perform as required under their contractual obligations, adhere to our protocols, act in accordance with regulatory requirements, meet expected deadlines, or timely transfer to us any regulatory information. If such third parties with which we contract for pre-clinical research and clinical trials perform in a sub-standard manner or in a manner that compromises the quality and/or accuracy of their activities and/or the data they obtain, the pre-clinical research and clinical trials of our product candidates may be extended, delayed or terminated, our data generated from such studies may be rejected by applicable regulatory authorities, and the costs in developing relevant product candidates may be increased. As a result, we may be unable to develop and successfully commercialize our product candidates as anticipated, which would have a material adverse effect on our business and prospects.

If we encounter difficulties or delays in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in line with their respective protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population, the patient eligibility criteria defined in the protocols, the size of the study population required for analysis of the trial's primary endpoints, the accessibility of trial sites for the patients, the design of the trial, our ability to recruit clinical trial site investigators with competence and relevant experience, the patients' perceptions as to the potential advantages and side effects of the product candidates being studied in relation to other available products, product candidates or therapies, and the risk that patients enrolled in clinical trials may drop out or fail to return for post-treatment follow-ups at a higher rate than anticipated.

Our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. 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 patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may 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 and timely commercialization of our product candidates. If we experience delays in the completion of, or even termination of, any clinical trial of our product candidates, our ability to obtain requisite regulatory approvals and then commercialize our products will be delayed. In addition, any delay in completing our clinical trials will increase our costs, slow down our development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may have a material adverse effect our business, results of operations, financial condition and prospects.

We may not be able to develop new products that are competitive in the market, or in a timely manner or at all.

The interventional medical device market targeting structural heart diseases is competitive in China. Our success depends on our ability to anticipate industry trends and continuously identify, develop and market in a timely manner new and advanced products that meet the demand of our customers. We expect the markets for occluder products and heart valve products to evolve towards newer and more advanced products, some of which we do not currently produce. Developing new products in a timely manner can be difficult, particularly because product designs can change with market conditions and hospitals' and physicians' preferences. Our research and development efforts may not lead to new products that will be

commercially successful. We may also experience delays or be unsuccessful in any stage of product development, manufacturing, clinical trials, product registration, marketing or pricing. Even if we are able to launch new products, it takes time for the new products to gain market acceptance. We may not be able to successfully market our new products or our end customers may not be receptive to our new products.

The success of any of our new product offerings will depend on several factors, including our ability to:

- properly identify and anticipate industry trends and market demand;
- complete product development process successfully in a timely manner;
- optimize our manufacturing and procurement processes to predict and control costs;
- manufacture and deliver new products in a timely manner;
- minimize the time and costs required to obtain required regulatory approvals;
- anticipate and compete effectively with other medical device developers, manufacturers and marketers;
- price our new products at both competitive and commercially justifiable levels; and
- increase end-customer awareness and acceptance of our new products.

If we are not successful in producing or selling our new products to meet market demand, or if there is insufficient demand for our new products once they are introduced to the market, our business, results of operations, financial condition and prospects could be materially and adversely affected.

We may not be successful in developing, enhancing or adapting to new technologies and methodologies.

We must keep pace with new technologies and methodologies to maintain our competitive position. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in research, development and manufacturing, which are capital- and time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so could harm our business and prospects.

Risks Relating to Manufacture and Supply

The manufacturing of our products is highly complex and subject to strict quality controls. Our business could be materially and adversely affected if our products and product candidates are not produced in compliance with all the applicable quality standards.

The manufacturing of our products is highly complex and subject to strict quality controls. In addition, quality is extremely important in our industry due to the serious and costly consequences of a product failure. We have established a comprehensive set quality control and assurance procedures in order to prevent quality issues with respect to our products and operation process. See "Business — Quality Control." Despite our quality control procedures, we cannot eliminate the risk of product defects or failures. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, defects or other issues in raw materials, or human errors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, damages to customer relationship, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Furthermore, if contaminants are discovered in our supply of our products or product candidates or in the production facilities, such production facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Stability failures and other issues relating to the manufacturing of our products or product candidates could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. In addition, as we expand into new markets, we may face unanticipated surges in demands for our products which could strain our production capacity.

If any of the foregoing arises or if we otherwise fail to meet our internal quality standards or those of the NMPA or other applicable regulatory bodies, which include detailed record-keeping requirements, we could become subject to safety alerts, product recalls, license revocation, regulatory fines, product liability claims or other negative effects, which could materially and adversely affect our reputation, business and results of operations.

We primarily rely on our production facilities in Shanghai to manufacture our products and product candidates. Any disruption to the operation of our production facilities could materially adversely affect our business, results of operations and financial condition.

We manufacture our products and product candidates primarily at our production facilities located in Shanghai. Our facilities may be harmed or rendered inoperable by physical damage from fires, floods, earthquakes, typhoons, power outages, mechanical breakdowns, telecommunications failures, loss of licenses, certifications and permits, changes in governmental planning for the land underlying the facility, and regulatory changes, many of which are beyond our control. Any substantial interruption in manufacturing operations at our production facilities could result in our inability to satisfy the demands of sales and distribution as to our products and of our clinical trials as to our product candidates, or even lead to our failure to fulfill contractual obligations, which could in turn materially and adversely affected our business, results of operations and financial condition.

Advances in manufacturing techniques may render our facility and equipment inadequate or obsolete, and therefore we may also need to develop advanced manufacturing techniques and process controls in order to fully utilize our facilities. If we are unable to do so, if the process to do so is delayed, or if the cost of this scale-up is not economically feasible for us, we may not be able to supply our products in a sufficient quantity to meet future demand, which would limit our development and commercialization activities and our opportunities for growth.

We rely on a limited number of suppliers, and may not be able to secure a stable supply of qualified raw materials at all times or at all.

Principal raw materials for our products are nitinol materials, animal source materials, polymer materials, and sheathes and other metal components. We only procure raw materials from select suppliers that can satisfy our technical specifications and regulatory compliance requirements to ensure the consistently high quality and performance of our products. In order to acquire raw materials in high quality, we currently rely on a limited number of select third-party suppliers to supply raw materials used in our research, development and manufacturing. Although we believe that we have stable and long-term relationship with our existing suppliers and we have maintained a list of qualified suppliers, we cannot assure you that we will be able to secure a stable supply of qualified raw materials at all times going forward. Further, the custom clearance procedures for importing raw materials could be lengthy and thus could adversely affect the timely supply of such raw materials. If any of these suppliers loses its qualification or eligibility for a variety of reasons including its failure to comply with regulatory requirements, or if we encounter lengthy custom clearance procedures to import certain of our raw materials, we may experience delays in the supply of our raw materials and interruption in our manufacturing process.

General economic conditions could also adversely affect the financial viability of our suppliers, resulting in their inability to provide raw materials used in our manufacturing process. In addition, some of our suppliers are located outside China, and therefore trade or regulatory embargoes imposed by foreign countries or China, especially in light of recent international trade disputes between China and the United States, could result in delays or shortages of our raw materials sourced overseas. See "— Risks Relating to Our Operations — Changes in international trade policies and trade barriers, or the escalation of trade tensions, may have an adverse effect on our business." If we are unable to identify alternative suppliers or raw materials and secure approval for their use in a timely manner, our business could be materially and adversely affected.

An increase in the market price of our raw materials and components may adversely affect our profitability.

Our production process requires substantial amounts of raw materials and components. We are exposed to risks associated with fluctuations in prices and availability of raw materials. Significant fluctuations in raw material and component prices and availability could disrupt our operations and have a negative impact on our gross margin. During the Track Record Period, the supply of principal raw materials used in our product activities was generally available and sufficient for our demand, and their prices from our suppliers were generally stable. However, we cannot assure you that this will continue to be the case in the future. The prices of raw materials may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, duties and tariffs, natural disasters, disease outbreaks and general economic conditions. A significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins and, more generally, our business, results of operation, financial conditions and prospects.

Failure to manage our inventory effectively would materially and adversely affect our results of operations, financial condition and cash flows.

Our inventory consists of raw materials, and work-in-progress and finished goods. To operate our business successfully and meet our customers' demands and expectations, we must manage our inventory effectively to ensure immediate delivery when required. We regularly monitor our inventory to ensure timely supply and reduce the risk of overstocking. We maintain our inventory levels based on our internal forecasts which are inherently uncertain. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had inventories of RMB11.1 million, RMB23.3 million, RMB33.4 million and RMB40.3 million, respectively. In 2019, 2020, 2021 and the six months ended June 30, 2022, our inventory turnover days were 277 days, 414 days, 413 days and 435 days, respectively. See "Financial Information — Discussion of Major Balance Sheet Items — Inventories." We may be exposed to increased inventory risks due to accumulated excess inventory of our products or raw materials, some of which are subject to expiration. Excess inventory levels may increase our inventory holding costs, obsolescence risks or potential impairment loss. On the other hand, if our forecasted demand is lower than actual level, we may not be able to maintain an adequate inventory level of our products or manufacture our products in a timely manner, and may lose sales and market share to our competitors.

Furthermore, as we will not be able to recoup our cash paid for raw materials during the production process until the finished products are sold to customers and the purchase price is settled, our business is subject to significant working capital requirements given the high inventory level and inventory turnover days. If our inventory level increases substantially in the future, our financial condition and cash flows could be materially and adversely affected.

If we fail to implement our expansion plan as planned, or our expansion plan fails to achieve expected benefits, our business and prospects could be materially and adversely affected.

We plan to enhance the production capacity for our marketed products. We also intend to install several new product lines, including production lines for biodegradable occluder product and product candidates and heart valve product candidates. See "Business — Growth Strategies — Expand our production capabilities to support future growth." However, we cannot assure you that our expansion plan will be successfully implemented without delays or at all. Our ability to successfully implement our expansion plan is subject to a number of factors. New manufacturing facilities may require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. This review may be costly and time-consuming and could delay or halt the launch of our products. The new facilities will also be subject to pre-approval inspection. In addition, we have to demonstrate that the products made at the new facilities are equivalent to or not worse than the products made at the former facilities by verification methods, which are costly and time consuming. Regulatory authorities may also require clinical testing as a way to prove equivalency, which would result in additional costs and delays. In addition, we may not be able to timely recruit sufficient qualified staff to support the increase in production capacity.

Any failure or delay in implementing any part of our expansion plan may result in a lack of production capacity to support our growth and market expansion, which in turn could adversely affect our business, results of operations and financial condition. Moreover, our plans to increase our production capacity require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could materially and adversely affect the realization of expected return on our expenditures. In addition, if we fail to fully utilize the additional production capacity due to any adverse change to the market environment, technologies, relevant policies during the implementation of projects, our business, results of operations and financial condition could be materially and adversely affected.

Risks Relating to Extensive Government Regulations

The research, development and commercialization of our products are heavily regulated in all material aspects.

All jurisdictions in which we conduct our research, development and commercialization activities regulate these activities in great depth and details. We intend to focus our activities in the major markets of China, the European Union and the United States. These geopolitical areas all have comprehensive regulation 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 regions, which make regulatory compliance more complex and costly for companies like us that plan to operate in each of these regions.

The process of obtaining regulatory approvals under and compliance with appropriate laws and regulations require substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical holds, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties, all of which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be unable to obtain, maintain or renew the regulatory filings and registration certificates required to commercialize our products in a timely manner, or at all.

We are required to complete regulatory filings or obtain registration certificates for our products from the NMPA or its local regulatory branches or from the competent regulatory authorities in other jurisdictions where we sell our products. In China, medical devices are classified into Class I, Class II and Class III depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. All of our products and product candidates are or are designed to be Class III medical devices, which are subject to the most strict registration requirements among all classes. According to applicable regulations, Class III medical devices shall be examined by the NMPA, which will issue registration certificates upon approval. In order to obtain such registration certificates, Class III medical devices are required to undergo clinical trials, unless they are exempted from clinical trials under the Catalogues of Medical Device Exempted from Clinical Trials promulgated by the NMPA from time to time. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Registration and Fillings of Medical Device Products." For risks relating to clinical trials, see "— Risks Relating to Research and Development — Clinical development involves lengthy and expensive process with uncertain outcomes." The registration process can be lengthy, costly and unpredictable. Our product candidates could fail to obtain regulatory approval for numerous reasons, including:

- failure to begin or complete clinical trials;
- failure to demonstrate that a product candidate is safe and effective;
- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- encountering of data integrity issues related to our clinical trials;
- disagreement by any regulatory authority with our interpretation of data from pre-clinical studies or clinical trials;
- finding of deficiencies related to the manufacturing processes or facilities from regulatory authorities;
- changes in approval policies or regulations that render our pre-clinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results; and
- emergence of new information regarding our product candidates.

In addition, the time required to obtain approval from the regulatory authorities is unpredictable but typically takes years following the commencement of pre-clinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. As of the Latest Practicable Date, two of our product candidates were undergoing regulatory approval process in China. It is possible that none of our existing product candidates or any product candidate we may discover, in-license or acquire and seek to develop in the future will ever obtain such approval.

Furthermore, 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 areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products and product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. The foreign regulatory approval process may include all of the risks associated with obtaining NMPA approval. For these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

Moreover, registration certificates for medical devices in China are valid for five years and must be renewed by filing renewal applications with the NMPA or its local branches six months prior to the expiration date. In addition, CE Marks are also generally valid for five years and must be renewed by filing renewal applications with relevant CE notified bodies for conformity assessment. As of the Latest Practicable Date, we had obtained a total of 14 NMPA registration certificates for Class III medical devices and valid CE Marks for nine of our products. The renewal process with the NMPA normally takes two to five months, while the CE Mark renewal process generally takes one to two years. When deciding whether or not to grant renewal, the NMPA or its local branches usually focuses on, among other things, whether the product conforms to latest applicable standards or quality requirements. If the NMPA or its local branches decide not to grant the renewal of our registration certificates, we will not be able to continue to manufacture and sell the relevant products, which would have a material and adverse effect on our business, financial condition and results of operations. Furthermore, our existing CE Marks were granted in April 2021 pursuant to the Medical Device Directive of the European Union (the "MDD") and valid through May 2024 in accordance with the transition period permitted under the new Medical Device Regulation of the European Union (the "MDR"). We plan to make MDR applications going forward to renew existing, or apply for new, CE Marks. Compared with the MDD, the MDR has elevated the standards on quality and safety measures and imposed additional continuous compliance requirements on medical device providers. If we fail to renew or obtain CE Marks under the new MDR standards, our overseas product sales would be materially and adversely affected.

We may not be able to obtain, maintain or renew all the permits, licenses and certificates required for our business and operations.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products in China or export our products outside of China, including but not limited to the Medical Device Registration Certificate (醫療器械註冊證), the Medical Device Production Permit (醫療器械生產許可證), the Medical Device Operation Permit (醫療器械經營許可證) and the Medical Device Export Certificate (醫療器械產品出口銷售證明). We are also required to obtain requisite licenses, approvals and certificates to sell our products in relevant overseas jurisdictions. For details, see "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices" and "Business — Licenses, Permits and Approvals."

Such permits, licenses and certificates are subject to periodic reviews and renewals by the relevant government authorities, and the standards of such reviews and renewals may change from time to time. We cannot assure you that the relevant authorities will approve our renewal applications in the future. Any failure by us to obtain the necessary permits, licenses and certificates, or procure such renewals and otherwise maintain all the licenses, permits and certificates required for our business at any time could disrupt our business, which could have a material adverse effect on our business, results of operations and financial condition. In addition, the regulatory framework for the medical device industry in China has undergone significant changes, including, with respect to quality control, supply, pricing and tender process for medical devices. We cannot predict the likelihood, nature or extent of regulatory

changes that may arise from existing or future legislation in China. If, as a result of any change in the interpretation of existing laws and regulations or the promulgation and implementation of new laws and regulations, we are required to obtain additional permits, licenses or certificates for our operations involving our products and product candidates, we cannot assure you that we will be successful in obtaining these permits, licenses or certificates in a timely manner, or at all. Such changes may also result in increased compliance costs, prevent our successful development, manufacture or commercialization of products in China, or adversely affect our ability to export our products overseas which would adversely affect our business, financial condition and results of operations.

We may not be able to comply with ongoing regulatory obligations which may result in withdrawal of approvals for our products.

Our products and any additional product candidate that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging storage, 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 and other applicable jurisdictions where the products are approved. For example, manufacturers and manufacturers' facilities are required to comply with extensive regulatory requirements from the NMPA and/or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other authorities. Further, the regulatory approvals for our products and any approval that we expect to receive for our product candidates are and may be subject to limitations on the indicated uses for which our product may be marketed. Products may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The approvals we obtain may also be subject to other conditions which may require potentially costly post-market testing and surveillance to monitor the safety and efficacy of our products or product candidates upon commercialization. Such limitations and conditions could adversely affect the commercial potential of our products and product candidates.

The NMPA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if we fail to maintain compliance with these ongoing regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products or product candidates including adverse events of unanticipated severity or frequency, or with our manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling or requirements to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the relevant products from the market, or voluntary or mandatory product recalls;

- fines, warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, suspension or revocation of license approvals or withdrawal of approvals;
- 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 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 China or overseas, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained, which could materially and adversely affect our business and prospects.

We may be subject, directly or indirectly, to 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 and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Hospitals and physicians play a primary role in the recommendation and prescription of any product 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, the Criminal Law of the PRC, the Regulations 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 Filing of Medical Devices (《醫療器械註冊與備案管理辦法》). These laws may impact, among other things, our proposed sales and marketing programs. 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.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. 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 action is 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 business and our results of operations. In addition, we are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

If any of the physicians 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.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, results of operations and financial condition. We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, results of operations and financial condition. We are subject to the anti-bribery laws of various jurisdictions, particularly in China, that generally prohibits companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, such as related onboard and on-going training sessions, we cannot assure you that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities we acquire. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, results of operations, financial condition and liquidity. We could also be adversely affected by any allegation that we violate such laws.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instance of fraud, bribery, and other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instance in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks relating to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the patients enrolled in our clinical trials and post-commercialization clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement actions against us, fines, imprisonment of company officers, public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, results of operations, financial condition or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled patients and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the patients' private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. While we have adopted security policies and measures to protect our proprietary data and patients' privacy, privacy leakage incidents might not be avoided due to hacking, human error, employee misconduct or negligence or system breakdown. We also cooperate with third parties including hospitals, CROs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. In particular, certain industry-specific laws and regulations may affect the collection and transfer of personal data in China, including the Interim Measures for the

Administration of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) and the implementation guidelines issued by the Ministry of Science and Technology and Ministry of Health. For details, see "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Sampling and Collecting Human Genetic Resources Filing." It is possible that these laws and regulations may be interpreted and applied in a manner inconsistent with our clinical trial practices, potentially resulting in confiscation of human genetic resource samples and associated data as well as administrative fines. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security and transfer may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damages. Any of the foregoing could have a material adverse effect on our competitive position, business, results of operations, financial conditions and prospects.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or manufacturing activities. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Relating to Our Intellectual Properties

If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends, in large part, on our ability to protect our proprietary technologies, products and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technologies, products and product candidates that we consider commercially important by filing patent applications in China and other countries, 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, prosecute or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our product candidates, or otherwise provide us with any competitive advantage. As a result, we may not be able to prevent competitors from developing and commercializing competing products in all such fields and territories.

A patent may be invalidated or found unenforceable, and a patent application 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 inventive step of the underlying invention or technology that is claimed in the patent application. We may also fail to identify patentable aspects of our research and development output in time to obtain patent protection. Moreover, the patent position of medical devices companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we have filed may not be granted in the end. As such, we do not know the degree of future protection that we will have on our products and technologies, if any, and a failure to obtain adequate intellectual property protection with respect to our technologies, products and product candidates could have a material adverse impact on our business.

Although we enter into non-disclosure 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 and third parties involved in our research and development activities, 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.

The issuance of a patent is not conclusive as to its inventor, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in China and other countries. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA or other patent offices, or become involved in post-grant proceedings such as opposition, derivation, revocation 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 technologies, products or product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products and product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the CNIPA or other patent offices to determine priority of invention or in post-grant challenge proceedings, such as 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 found unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies, products and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and senior management, 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, although 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 term 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 "Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group" to this document. Upon the expiration of our issued patents or patents that may issue 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, a limited number 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, without accounting to us, their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, results of operations, financial conditions and prospects.

We may not be able to protect our intellectual property rights.

Filing, prosecuting, maintaining and defending patents on products and product candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength from those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing medical products made using our patented technologies or inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other countries. These products may compete with our products and product candidates, and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing with us.

As of the Latest Practicable Date, we owned 232 registered patents and had 51 pending patent applications in China. To facilitate our strategy to enter overseas market, we also had 14 pending patent applications in the United States and the European Union. The research and development of substantially all of the patents that we owned or applied for relied on our internal efforts. The 232 registered patents in China will expire in accordance with the stipulations in the patent registrations. See "Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group." Following the expiration, we may lose the statutory protection and cannot prevent third parties from exploiting such technology and developing and commercializing competing medical devices embodying such technology in the relevant fields or territories. In addition, as of the Latest Practicable Date, we also owned 41 trademarks in China and four trademarks in Hong Kong. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could 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, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in countries such as China. The legal system in these countries could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights in these countries. Proceedings to enforce our intellectual property and proprietary rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 products and product candidates could be found invalid or unenforceable if being challenged.

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. Third parties may also raise similar claims before administrative bodies in China or abroad, 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon 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, found 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.

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any intellectual property disputes or infringement claims which had, or were likely to have any material adverse impact on our Group. However, we may be subject to intellectual property disputes and infringement claims in the ordinary course of business. 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 or commercializing one or more of our product candidates or products in additional jurisdictions. Defense of these claims, regardless of their merit, would incur substantial litigation expenses

and would substantially divert resources from our business. 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, 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 development or allow commercialization of our product candidates or products in additional jurisdictions. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop or commercialize one or more of our product candidates or products in additional jurisdictions, which could harm our business significantly. We may also elect to enter into license agreements in order 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.

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 our Shareholders perceive these results to be negative, this could have a substantial adverse effect on the [**REDACTED**] of our H 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. 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.

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 and other patent agencies in several stages over the lifetime of the patent. The CNIPA and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other requirements or duties 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 of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to office actions or examination reports within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. We are not aware of any material non-compliance events during the Track Record Period and up to the Latest Practicable Date. We cannot assume you that any such event will not occur in the future, in which case, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may face intellectual property disputes with our business partners.

We may face intellectual property disputes with our business partners. We may from time to time establish or seek strategic alliances that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop and we will seek to enjoy the intellectual property rights through intellectual property delegation, join intellectual property application or in-licensing arrangements. As of the Latest Practicable Date, we had collaborated with several hospitals and research institutions in China, such as Fuwai Yunnan Cardiovascular Hospital (雲南省阜外心血管病醫院) and the National Engineering Research Center for Biomaterials (國家生物醫學材料工程技術研究中心). We cannot assure that we will not be subject to intellectual property claims brought by our business partners or any third party. We may be subject to injunctions, damages or other reliefs if such claims are successful, which could prevent us from developing and commercializing related product candidates.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technologies 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 confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, and third parties involved in our research and development activities. We are not aware of any breach or unauthorized disclosure by such parties that had a material adverse effect on our business during the Track Record Period and up to the Latest Practicable Date. However, 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. Proving or 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 our trade secrets to compete with us and our competitive position would be compromised. Furthermore, many of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees, including one of our senior management, are subject to proprietary rights, non-disclosure and non-competition obligations in connection with such previous employment. Although we try to ensure that our employees do not use or disclose 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 senior management, but in the future litigation may be necessary to defend against such claims. If we fail to defend 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 distract our management's attention.

In addition, while we have detailed protocols governing our employees' service inventions and typically require third-party collaborators involved in the development of intellectual property to execute agreements assigning such intellectual property to us at the project proposal and approval stage, we may be unsuccessful in executing such an agreement with each party which 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 distract the attention of our management and scientific personnel.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws, implementing rules and regulations, or their interpretation in China or other countries may diminish our ability to protect our inventions and to obtain, maintain, defend and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing or may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors. The claim scope in a patent application can be significantly reduced before the patent application issues into a patent, and the claim scope can still be reinterpreted after patent issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. 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 subject to uncertainties, and any result unfavorable to us could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Relating to Our Operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate other qualified and highly skilled personnel, and we may experience labor shortages or increases in labor costs.

Our success and future growth depend largely upon the continued services of key executives and other key employees, such as qualified and highly skilled research and development, manufacturing and production, and sales and marketing personnel. We cannot assure you that these key personnel will not voluntarily terminate employment with us. If one or more of our key personnel are unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all and may incur additional expenses to recruit and train new personnel. Experienced personnel in the interventional medical device market targeting structural heart diseases is in high demand, and competition for relevant talents is intense. Many of the companies with which we compete for experienced personnel have greater resources than we have. We cannot assure you that we will be able to maintain an adequate skilled labor force necessary for us to execute our business, nor can we guarantee that we will not incur significant expense as a result of our continued efforts to attract and retain talent in a labor market with a shortage in the supply of skilled personnel. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth could be adversely affected. In particular, our research and development team for heart valve product candidates was injected into our Group along with the injection of the interventional heart valve business of Lepu Medical, and we did not have such a team prior to the business injection. See "History, Reorganization and Corporate Structure — Our Corporate Development — Business Injection." We will continue to utilize our established sales force and sales network for occluder business to promote our heart valve business. The viability of our heart valve business is highly relied upon the contribution of our heart valve research and development personnel, especially Ms. Zhang Yuxin, our executive Director, deputy general manager and chief technology officer, and the efforts by our sales and marketing team upon commercialization. The loss of services of any of these personnel could impede the achievement of our research, development and commercialization objectives for heart valve product candidates.

In addition, if any of our executive officers or key employees joins a competitor or forms a competing company, we may face the risks of losing know-how, trade secrets, suppliers, customers and other business partners. We enter into standard confidentiality agreements with all of our full-time employees, which also contain non-compete provisions. Although non-compete agreements are generally enforceable under PRC laws, PRC legal practice regarding the enforceability of such agreements is not as well developed as in countries such as the United States. As a result, we cannot assure you that a PRC court would enforce the non-compete agreements. Moreover, to retain valuable employees, in addition to offering competitive compensation packages, we provide them with well-structured training resources and learning opportunities. These and other measures we have adopted or may adopt in the

future may lead to increased labor costs and operating and other expenses, and may not be sufficient to counteract more lucrative offers from our competitors. In line with industry practice, we do not maintain key man life insurance for any of our executives, including Ms. Zhang Yuxin, which is not mandatory under PRC laws. If any of them leaves us for any reason, our business and prospects may be materially and adversely affected. We may experience labor shortages, and our business and competitive position would be harmed, which could have a material adverse effect on our results of operations and prospects.

If our products or product candidates cause, or are perceived to cause, severe adverse events, our reputation, revenue and profitability could be materially and adversely affected.

Some of our products and product candidates are considered as emerging and relatively novel therapeutics, and may cause unintended or undesirable severe adverse events as a result of a number of factors, many of which are beyond our control. These factors include potential complications not revealed in clinical trials, side effects in isolated cases, defective products not detected by our quality control measures or misuse of our products. Our products and product candidates may also be perceived to cause adverse events when a conclusive determination as to the cause of the adverse events is not obtained or is unobtainable. In addition, our products and product candidates may be perceived to cause severe adverse events if one or more regulators, determine that other companies' products containing the same or similar key parts or using the same delivery technologies as our products or product candidates cause or are perceived to have caused severe adverse events.

If our products cause, or are perceived to cause, severe adverse events, we may face a number of consequences, including:

- injury or death of patients;
- a severe decrease in the demand for, and sales of, the relevant products;
- the recall or withdrawal of the relevant products;
- revocation of regulatory approvals for the relevant products or the relevant production facility;
- damage to the brand name of our products and our reputation;
- failure to include our products into the relevant medical insurance coverage; and/or
- exposure to lawsuits, regulatory investigation or government enforcement actions relating to the relevant products that result in liabilities, fines or penalties.

Moreover, if our product candidates cause, or are perceived to cause, severe adverse events, it could cause us or regulatory authorities to interrupt, delay or halt clinical trials, affect patient recruitment or the ability of enrolled patients to complete the trial, adversely impact our ability to obtain regulatory approval in China and other jurisdictions where we may seek to commercialize our products, and/or subject us to product liability claims as well as substantial liabilities. Any of the foregoing could materially and adversely affect our reputation and business operations and prospects.

We may be exposed to potential product liability claims and product recalls, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur.

We face an inherent risk of product liability as a result of the commercialization of our products and the clinical testing and any future commercialization of our product candidates. For example, we may be sued if our products or product candidates cause or are perceived to cause injuries or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Such product liability claims may include allegations of defects in manufacturing, defects in design, failure to warn of dangers inherent in the medical device product, negligence, strict liability or breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our business partners for product liability claims, we may be subject to substantial liabilities or be required to limit commercialization of our products and product candidates. Even successful defense would require significant financial and management's resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products and loss of revenue;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend against the related claims;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- diversion of management's time and our resources;
- exhaustion of any available insurance and capital resources; and/or
- inability to commercialize any product candidate.

Under PRC laws and regulations, if we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products or product candidates are found to be defective. In addition, we may be required to recall the relevant products or product candidates, suspend or cease sales and distribution activities. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

Our business and operations have been and may continue to be materially and adversely affected by the COVID-19 outbreak.

An outbreak of respiratory illness caused by COVID-19 has and is continuing to spread rapidly throughout the world. On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the outbreak a "Public Health Emergency of International Concern (PHEIC)." Government efforts to contain the spread of COVID-19 through city lockdowns or "stay-at-home" orders, widespread business closures, restrictions on travel and emergency quarantines, among others, have caused significant and unprecedented disruptions to the global economy and normal business operations across sectors and countries. To date, the spread of COVID-19 continues to affect China, where we conduct most of our business and engage in pre-clinical studies and clinical trials, as well as certain other countries and regions where we sell our products and where our business partners reside.

Our business, including our production plan and pre-clinical studies and clinical trials, as well as our ability to continue to manage our operations effectively, could be impacted by the current pandemic or future continuance or reoccurrence of COVID-19 in numerous ways, including but not limited to: (1) requirements for us to quarantine certain of our employees or facilities or take extra security precautions for our operations, which may result in higher costs; (2) delay in patient enrollment for our clinical trials; (3) diversion of medical resources required for our clinical trials for the treatment of patients with COVID-19; (4) lowered demand by hospitals for our products, as many patients rescheduled their visits to hospitals to avoid cross-infections and most of the hospitals devoted their resources to dealing with COVID-19 in the first half of 2020 and, therefore, reduced the number of unrelated operations; (5) delay in logistics for suppliers of raw materials resulting from temporary restrictions or bans on traveling by local governments to contain the spread of the outbreak; and (6) temporary closure or flexible working hours of competent regulatory authorities, such as administration and registration authorities, which may delay regulatory submissions and required approvals of our product candidates, and could cause us to incur additional costs and affect our ability to execute our operations as planned. We have also experienced extended payment cycles and delayed collection of accounts receivables in the first half of 2020 as a result of the COVID-19 outbreak. In addition, our business and results of operations could also be adversely affected to the extent the COVID-19 outbreak harms the business of our customers, suppliers, distributors and other business partners. See "Financial Information — COVID-19 Outbreak and Effects on Our Business."

While our Director confirmed that, up to the Latest Practicable Date, the COVID-19 outbreak did not have a material adverse effect on our results of operations and financial condition, the effects of the current COVID-19 pandemic or future outbreaks on our business or our industry will depend on a number of factors outside our control, including the extent to which the current pandemic continues to spread, particularly in China and other countries and regions where we sell our products and where our business partners reside, and such effects could be material. The Chinese and global economy is subject to the risk of a general slowdown, which would have a material adverse effect on our results of operations and financial condition in the near term. Moreover, if the outbreak persists or escalates, we may be subject to further negative impact on our business, results of operations and financial condition.

If we fail to effectively expand our overseas business, our business prospects may be adversely affected.

We plan to seek product registrations and intellectual property applications in the European Union and the United States. We also plan to expand our sales and increase our brand recognition in global markets, and specifically, to accelerate the commercialization of our future biodegradable occluder products and heart valve products in overseas markets such as the European Union, Southeast Asia and the United States. See "Business — Growth Strategies — Expand our global footprint by increasing product development and commercialization and broadening overseas sales channels." However, our limited experience in overseas markets may expose us to risks and uncertainties, including the risks associated with the following:

- 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;
- substantial time which may be required for us to obtain approval for registering and selling our products in additional countries, especially in developed countries;
- commercializing our products in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- reliance on overseas partners or distributors for the distribution, commercialization and marketing of our products;
- product 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;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness and inflation;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, sanctions, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We could be adversely affected as a result of any sales we make to certain countries that are, or become subject to, sanctions administered by the United States, the European Union, the United Nations, Australia and other relevant sanctions authorities.

The United States and other jurisdictions or organizations, including the European Union, the United Nations and Australia, have, through executive order, passing of legislation or other governmental means, implemented measures that impose economic sanctions against such countries or against targeted industry sectors, groups of companies or persons, and/or organizations within such countries.

During the Track Record Period, we had sold our non-U.S. origin interventional medical devices to the Retained Lepu Medical Group which on-sold such products to customer/distributors in Iran, a Comprehensively Sanctioned Country. Revenue generated from such transactions with the Retained Lepu Medical Group was minimal compared with our total revenue during the Track Record Period and did not involve any U.S. nexus, and no U.S. dollar payments were received by us for such sales. As advised by our International Sanctions Legal Advisors, we are not subject to sanctions risk that could have a material adverse risk on our business from our past indirect sales of products in Iran on the bases that (1) the transaction value was minimal compared with our total revenue during the Track Record Period, (2) the nature of the sales involved medical products, and (3) we had ceased all such indirect sales to Iran as of June 18, 2021.

The United States also has enacted secondary sanctions targeting non-U.S. persons who have engaged in certain sanctionable activities related to certain Comprehensively Sanctioned Countries or Sanctioned Persons, including Iran. As advised by our International Sanctions Legal Advisors, given that (1) Section 1244 of the Iran Freedom and Counter-Proliferation Act of 2012 ("IFCA") contains a humanitarian exception under secondary sanctions for sale of medicine and medical devices to Iran; (2) during the Track Record Period, the counterparties in our sales had not been identified as SDNs; and (3) the nature of the our sales did not involve certain Iranian industries or products targeted by U.S. secondary sanctions, our sales of medical products to Iran do not trigger exposure to U.S. secondary sanctions.

As further advised by our International Sanctions Legal Advisors, (1) our indirect business dealings in Iran will not be considered as unlawful under the restrictive measures adopted by the European Union, the United Nations and Australia; and (2) we did not violate relevant sanctions as a result of Primary Sanctioned Activity or Secondary Sanctionable Activity during the Track Record Period.

As of the Latest Practicable Date, our Directors confirmed that we had not been notified that any International Sanctions penalties would be imposed on us for our historical sales to the Comprehensively Sanctioned Countries. We have no present intention to undertake any future business with persons on the SDN Lists, or any other business that may expose us to sanctions risks including further sales directly or indirectly to Iran. In addition, we have implemented enhanced internal control and risk management measures which we believe enable us to monitor and evaluate our business to address economic sanction risks. See "Business — Risk Management and Internal Control — Internal Control." Given the scope of the [**REDACTED**] and the expected [**REDACTED**] as set out in this document, our International Sanctions Legal Advisors are of the view that the involvement by parties in the [**REDACTED**] will not implicate any applicable International Sanctions on such parties, including our Company and our subsidiaries, the respective directors and employees of our Company and our subsidiaries, our Company's or our subsidiaries' investors, shareholders as well as the Stock Exchange and its related group companies.

However, we are unable to predict the interpretation or implementation of the International Sanctions with respect to any past activities by us. If any government agencies or organizations were to determine that we were deemed to be engaged in prohibited or sanctionable activities targeted by the International Sanctions, we could be subject to certain sanctions or penalties and our reputation and future business prospects could be adversely affected. In addition, because economic sanctions programs are constantly evolving, new requirements or restrictions could come into effect, or relevant regulatory authorities may interpret current sanctions in such a manner that might increase scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions or being sanctionable. Our internal control and risk management measures may not be able to react timely or comprehensively to such changes. There is no assurance that our activities in any particular country or region will be in compliance with evolving applicable rules and regulations or that they will not result in negative media attention or reputational damage.

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

Our Controlling Shareholders have substantial influence over our business, including matters relating to our management, policies and decisions regarding mergers, expansion plans, consolidations, sales of all or substantially all of our assets, election of directors and other significant corporate actions. As of the Latest Practicable Date, Lepu Medical, together with its wholly-owned subsidiary Target Medical, held 86.34% equity interest in our Company, with Lepu Medical and Target Medical directly holding 85.48% and 0.86% equity interests in our Company, respectively. Immediately following the completion of the [**REDACTED**] and [**REDACTED**], Lepu Medical and Target Medical will directly hold approximately [**REDACTED**]% and [**REDACTED**]% equity interest in our Company, respectively, assuming the [**REDACTED**] is not exercised. Dr. Pu is the Actual Controller of Lepu Medical. Lepu Medical, Dr. Pu and Target Medical are considered as a group of Controlling Shareholders of our Company. See "Relationship with Our Controlling Shareholders." This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of our Company and might reduce the price of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, our Controlling Shareholders may exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

Lepu Medical, as a public company in China, has published and may continue to publish, from time to time, reports, projections, valuations and other types of information which may concern us, our business and financial condition, and/or our industry. Lepu Medical may publish such information voluntarily or in response to regulatory or stock exchange requirements or inquiries. Specifically, Lepu Medical, as a company listed on the Shenzhen Stock Exchange, has ongoing obligations to publish information in relation to our Company. We have no control over whether or when, if at all, Lepu Medical may publish any such information that concerns us, nor can we assure you that we will be given the opportunity to review or endorse any such information. As such, we cannot guarantee that any such information regarding us will not have any impact on the perception of us and our business by the [**REDACTED**] community, the [**REDACTED**] of our H Shares, or the interest of the [**REDACTED**] Shareholders.

You should only rely on the information included in this document and the documents issued by our Company to make your [REDACTED] decision and should not rely on any particular statements in other published announcements, news reports and/or research analyst reports relating to our Controlling Shareholders, our Group and the [REDACTED].

Prior to the publication of this document, subsequent to the date of this document and after the [**REDACTED**], there have been, and there may continue to be, announcements, press and media coverage and research analyst reports regarding Lepu Medical and its subsidiaries (including our Group) and the [**REDACTED**], which may include certain historical and forward-looking financial information about Lepu Medical, including the business and operations that are operated by our Group.

We are not expected to endorse or participate in the disclosure of any such information. We do not accept any responsibility for any such announcements, press and media coverage or research analyst coverage or the accuracy or completeness of any such information. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. If any such information appearing in publications other than this document or the documents issued by us is inconsistent or conflicts with the information contained in this document, we disclaim it. You should only rely on the information included in this document and the documents issued by our Company in making your [**REDACTED**] decision and should not rely on any other information, including any forward-looking information published by our Controlling Shareholders. See "Relationship with our Controlling Shareholders" for further details.

We have entered into collaboration, and may establish or seek collaborations, strategic alliances or equity [REDACTED] or enter into licensing arrangements in the future, and we may not timely realize the benefits of such arrangements.

We may from time to time establish or seek collaborations, strategic alliances or equity [**REDACTED**] or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. As of the Latest Practicable Date, we had collaborated with several hospitals and research institutions in China. We face significant competition in seeking appropriate strategic partners, and the negotiation process for collaboration, alliances or licensing arrangements can be complex and time-consuming. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a development stage for collaborative efforts, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. Furthermore, if and when we collaborate with a third party for development and commercialization of a product candidate, we may be required by our collaborators through commercial negotiation to relinquish some or all of the control over the future success of that product candidate to them. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing Shareholders, or disrupt our management and business. For any product or product candidate that we may seek to in-license from third parties, we may face significant competition from other medical device companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

Furthermore, collaborations involving our products and product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

- collaborators may not pursue the development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to availability of funding, acquisition of competing products, or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay, suspend or terminate clinical trials, provide insufficient funding for clinical trials, abandon a product candidate, repeat or conduct new clinical trials, or require a new design of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liabilities;

- disputes may arise between us and collaborators that cause delays in or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management's attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the relevant product candidates; and/or

- collaborators may own or co-own intellectual property covering our products and product candidates that results from our collaborations with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic alliances or the license of our third-party products if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such arrangement. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate expected revenue, which would harm our business, results of operations, financial condition and prospects.

If parties on whom we rely on fail to maintain or renew the necessary permits, licenses and certificates required for the development, production, sales and distribution of our products, our ability to conduct our business could be materially impaired.

Third parties, such as CROs, suppliers and distributors on whom we may rely to develop, produce, promote, sell and distribute our products and product candidates, may be required to obtain, maintain and renew various permits, licenses and certificates. Third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and we cannot assure you that the third parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our such third parties' business, and if parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation of existing laws and regulations change, or new regulations are promulgated and come into effect, requiring parties on whom we rely to obtain any additional permit, license or certificate that was previously not required to operate their respective businesses, we cannot assure you that parties on whom we rely will successfully obtain such permits, licenses or certificates in a timely manner or at all, which in turn will adversely affect our ability to conduct our business.

Non-compliance with law on the part of any third parties with which we conduct business could disrupt our business and adversely affect our results of operations and financial condition.

Third parties with which we conduct business, such as physicians, suppliers and customers, may be subject to regulatory penalties or punishments because of their regulatory compliance failures, which may, directly or indirectly, disrupt our business. Although we conduct review of legal formalities and certifications before entering into contractual relationship with third parties, and take measures to reduce the risks that we may be exposed to in case of any non-compliance by third parties, we cannot be certain whether such third parties have violated any regulatory requirements. For example, physicians may involve in malpractice which can cause certain injuries to patients using our products, and we may not be able to identify and supervise all instances of such malpractice. In such events, even though we have related disclaimers, we may be involved in legal proceedings regarding malpractice and may even be held liable and have to pay damages to compensate such patients. Even though we have the contractual right to seek indemnification from the relevant patients, we cannot assure you that we will be able to enforce such right. As a result, our business, results of operations and financial condition could be materially and adversely affected. Similarly, suppliers may also not be in full compliance with applicable laws and regulations, which may have an adverse effect as to our business, results of operations and financial condition.

We expect to incur substantial share-based compensation expense pursuant to certain existing limited partnership agreement, and such expense may affect our financial performance and such compensation may result in a dilution of the shareholdings of the shareholders in our Group.

In February 2021, we established partnerships, Ningbo Jiadu, as a shareholding platform, where our employees, including certain senior management members, and certain of our Directors hold interests as limited partners to such partnership. As provided in the relevant limited partnership agreement, the foregoing persons are restricted from selling, transferring or disposing of their respective partnership interest for the first 12 months from the [**REDACTED**]. On the first [**REDACTED**] after each of the first and second anniversary of the [**REDACTED**], 15% of the interest owned by each of them will be released. On the first [**REDACTED**] after the third anniversary of the [**REDACTED**], the remaining 70% of the interest owned by each of them will be released. See "History, Reorganization and Corporate Structure — Our Corporate Development — Establishment of Ningbo Jiadu and Ningbo Jiacheng as the shareholding platforms." Consequently, we expect to incur substantial expenses associated with share-based compensation as a result of the granting of partnership interest in Ningbo Jiadu to our employees and Directors, which will have an adverse effect on our results of operations and financial condition in the relevant periods between the grant date and release date. In addition, we may also grant share-based awards pursuant to share incentive plans or other equity award plans which we may adopt in the future to help us attract and retain key personnel and employees. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations and financial condition, and such compensation may result in a dilution of the shareholdings of the shareholders in our Group.

We are exposed to risks associated with our investments in wealth management products, including the risks of fair value change and uncertainty in valuation of our investments in wealth management products due to the use of unobservable inputs.

We may invest in wealth management products from time to time in our ordinary course of business. The wealth management products we invested in were usually principal-guaranteed and had a short term ranging from one to three months. We have implemented investment and treasury management policies to ensure proper management and risk assessment.

We are subject to the risks that any of our counterparties, such as the banks that issued wealth management products, may not perform their contractual obligations, such as in the event that any such counterparty declares bankruptcy or becomes insolvent. Any material non-performance of our counterparties with respect to the wealth management products we invested in could materially and adversely affect our financial position and cash flow. Furthermore, our investments in wealth management products are subject to overall market conditions, including the capital markets, which expose us to the risk of valuation uncertainty. We recorded interest income on wealth management products of RMB6.7 million in 2021, which was recognized in other income for the same period. Any volatility in the market or

fluctuations in interest rates may negatively impact the fair value of our wealth management products, which may in turn have a material adverse effect on our financial condition. In addition, we are also exposed to the risks of fair value change and uncertainty in valuation of our investments in wealth management products due to the use of unobservable inputs in relation to the valuation of the level 3 financial assets at fair value through profit or loss. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the level 3 instruments, which may in turn have a material adverse effect on our financial condition. See Note 3.3 to the Accountant's Report in Appendix I to this document.

Impairment of goodwill may materially and adversely affect our results of operations.

Our goodwill remained the same at RMB48.3 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, primarily as a result of the acquisition of Shanghai Shape Memory Alloy, our wholly-owned subsidiary, by Lepu Medical, a Controlling Shareholder, in 2008. The value of goodwill is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant write-off of our goodwill and record a significant impairment loss. Furthermore, our determination on whether goodwill is impaired requires an estimation of the recoverable amount of the CGUs to which the goodwill is allocated, which depends on the expected future cash flows from the CGUs and a suitable discount rate to calculate the present value. If we expected future cash flow to decrease, our goodwill may be impaired. Any significant impairment of goodwill could have a material adverse effect on our business, financial condition and results of operations. For more information, see Note 2.10 and Note 17 to the Accountant's Report in Appendix I to this document.

Impairment of our intangible assets could materially and adversely affect our results of operations.

As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had intangible assets of RMB54.3 million, RMB66.0 million, RMB136.6 million and RMB161.6 million, respectively. Our determination on whether intangible assets are impaired requires an estimation on recoverable amount of the intangible assets, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed its recoverable amount, and our intangible assets may be impaired. As a result, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information, see Note 2.9 and Note 18 to the Accountant's Report in Appendix I to this document.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to deepen the penetration of our products and advance our product candidates, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our development and commercialization plans and strategies evolve, we need to recruit a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant additional responsibilities on members of management. Our 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 third parties; and

- improving our operational, financial and management controls, as well as reporting systems and procedures.

Our future financial performance and our ability to develop and commercialize our products and product candidates and to compete effectively 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 business partners as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our business and reputation may be adversely affected by negative publicity involving us, our Shareholders, Directors, Supervisors, officers, employees, distributors, suppliers or other parties we cooperate with, or by general negative publicity in the industry.

We, our Shareholders, Directors, Supervisors, officers, employees, distributors, suppliers or other parties we cooperate with may be subject to negative media coverage and publicity from time to time in our ordinary course of business, which could threaten the perception of our reputation as a trustworthy interventional medical device provider. In addition, to the extent we, our Shareholders, Directors, Supervisors, officers, employees, distributors, suppliers or other parties we cooperate with were involved in any legal or administrative proceedings or violate or allegedly violate any laws or regulations, our reputation could be

materially and adversely affected, which may, in turn, adversely affect our business and results of operations. Any negative publicity regarding our industry could also affect our reputation and customer confidence in our brand and products.

Any negative publicity or allegations may cause us to spend significant time and incur substantial costs, and we may not be able to diffuse them to the satisfaction of our [**REDACTED**], customers, hospitals and physicians, which could materially and adversely affect our reputation, business, results of operations and financial condition and the [**REDACTED**] of our H Shares.

Use of social media platforms presents new risks.

Social media increasingly is being used to communicate about our products, product candidates and the diseases our therapies are designed to treat. Social media practices in the medical device and pharmaceutical industries are evolving, which creates uncertainty and risk of non-compliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, our products or product candidates. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

Changes in international trade policies and trade barriers, or the escalation of trade tensions, may have an adverse effect on our business.

During the Track Record Period, certain of our raw materials were sourced overseas, and we also distributed our products in foreign countries and regions. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. China's political relationships with those foreign countries and regions may affect the prospects of our relationship with third parties, such as customers, suppliers, distributors and business partners. We cannot assure you that our existing or potential partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tension, political concern, and trade friction between China and the relevant foreign countries or regions may cause a decline in the demand for our products and adversely affect our business, results of operations, financial condition, cash flows and prospects. In the event that China and/or the relevant foreign countries impose import tariffs, trade restrictions or other trade barriers affecting the importation of raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. In addition, any escalation in existing trade tensions or the advent of a trade war, or news and rumors of the escalation of a potential trade war, could affect consumer confidence and have a material adverse effect on our business, results of operations and, ultimately, the [**REDACTED**] of our H Shares.

In particular, recent international trade disputes between China and the United States, and the uncertainties created by such disputes may disrupt the transnational flow of goods and significantly undermine the stability of the global and Chinese economy, thereby harming our business. Political tensions between the United States and China have escalated due to, among other things, the COVID-19 outbreak, the National People's Congress' passage of Hong Kong national security legislation, sanctions imposed by the U.S. Department of Treasury on certain officials of Hong Kong and the central government of the PRC, and the Trump administration executive orders issued in August 2020 and the new executive order issued by the U.S. President in June 2021 which sought or seek to prohibit certain transactions with, or equity investment in, certain Chinese companies and their respective subsidiaries. Rising political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between the two major economies, which would have a material adverse effect on global economic conditions and the stability of global financial markets. Any of these factors could have a material adverse effect on our business, prospects, financial condition and results of operations.

We historically received government grants and subsidies for our research and development and other activities and we may not receive such grants or subsidies in the future.

We historically received government grants in the form of subsidies received from local government intended to support our research and development activities and business operations. For 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we recognized government grants of RMB9.0 million, RMB5.6 million, RMB7.7 million, RMB4.5 million and RMB2.6 million, respectively. For details, see "Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Other Income and Gains/(Losses) – Net." Our eligibility for government grants is dependent on a variety of factors, including assessment of our improvement on existing technologies, relevant government policies, availability of funding at different granting authorities and research and development progress made by other peer companies. In addition, the policies according to which we historically received government grants may be halted by the relevant government entities at their sole discretion. We cannot assure you that we will continue to receive such government grants or receive similar level of government grants, or at all, in the future. Any loss of or reduction in government grants could have an adverse effect on our results of operations, financial condition and business prospects.

The discontinuation of any of the preferential tax treatments currently available to us could reduce our profitability.

Under PRC tax laws and regulations, Shanghai Shape Memory Alloy enjoys certain preferential tax treatments. The EIT Law and its implementation rules generally impose a uniform income tax rate of 25% on all enterprises, but grant preferential treatment to "High and New Technology Enterprises" ("HNTEs") to enjoy a reduced enterprise tax rate of 15%. According to the relevant administrative measures, to qualify as an HNTE, Shanghai Shape

Memory Alloy must meet certain financial and non-financial criteria and complete verification procedures with the administrative authorities. Continued qualification as an HNTE is subject to a three-year review by the relevant government authorities in China, and in practice certain local tax authorities also require annual evaluation of the qualification.

In addition, according to the relevant laws and regulations promulgated by the State Council and the SAT with effect from 2008 onwards, enterprises engaging in research and development activities were entitled to claim 150% of their research and development expenses so incurred as tax deductible expenses when determining their assessable profits for that year ("Super Deduction"). In September 2018, the SAT announced that enterprises engaging in research and development activities would be entitled to claim 175% of their research and development expenses as Super Deduction from January 1, 2018 to December 31, 2020. The Super Deduction ratio has increased to 200% since 2021. During the Track Record Period, Shanghai Shape Memory Alloy enjoyed the preferential tax treatment of Super Deduction.

If the preferential tax treatments are discontinued or not verified by the local tax authorities, and the affected entity fails to obtain preferential tax treatments based on other qualifications, it will become subject to the standard PRC enterprise income tax rate of 25%. We cannot assure you that the tax authorities will not, in the future, discontinue any of our preferential tax treatments, potentially with retroactive effect, which would have a negative impact on our business, results of operations and financial condition.

If we become subject to litigation, legal or contractual disputes, governmental investigations or administrative proceedings, our management's attention may be diverted and we may incur substantial costs and liabilities.

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. As of the Latest Practicable Date, we were not involved in any litigations and legal proceedings that may materially affect our research and development of our product candidates, business and results of operations. On-going or threatened litigation, legal or contractual disputes, governmental investigations or administrative proceedings involving us or our employees may divert our management's attention, and result in damages, liabilities and legal and other costs. Furthermore, any litigation, legal or contractual disputes, governmental investigations or administrative proceedings which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved.

If the outcomes of these proceedings are unfavorable to us, we could be required to pay significant legal costs and monetary damages, assume legal and other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, governmental investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. As a result, our business, results of operations and financial condition may be materially and adversely affected.

Failure to make adequate contributions to social insurance and housing provident fund for our employees as required by the PRC regulations may subject us to penalties.

Pursuant to the relevant PRC laws and regulations, employers are obligated to directly and duly contribute to the social insurance and housing provident fund for their employees. During the Track Record Period, we failed to timely make full social insurance and housing provident fund contributions for certain of our eligible employees. We estimate that the accumulated shortfall of social insurance and housing provident fund contributions as of December 31, 2019, 2020 and 2021 and June 30, 2022 was approximately RMB0.2 million, RMB0.2 million, RMB0.3 million and RMB0.3 million, respectively, which was immaterial and would not have a material adverse effect on our business. As a result, we did not make any provisions in connection with the foregoing non-compliance during the Track Record Period and up to the Latest Practicable Date.

As advised by our PRC Legal Advisors, we may be required to make up the deficiencies and be subject to late fees and fines for our insufficient contributions to the social insurance and housing provident fund. According to the relevant PRC laws and regulations, for outstanding social insurance contributions that we did not fully pay within the prescribed period, the relevant PRC authorities may demand that we pay the outstanding social insurance contribution within a stipulated deadline and we may be liable for a late payment fee equal to 0.05% of the outstanding contribution amount of each day of delay; if we fail to make such payments within a stipulated deadline, we may be liable to a fine of one to three times of the outstanding contribution amount. In addition, for outstanding housing provident fund contributions that we did not fully pay within the prescribed period, the relevant government authorities may demand that we pay the outstanding housing provident fund contributions by a stipulated deadline. If we fail to rectify by that deadline, we may be subject to an order from the relevant PRC courts for compulsory enforcement. We have adjusted the payment basis of the social insurance and housing provident funds for our employees pursuant to the standards stipulated under the applicable PRC laws and regulations. Our Directors believe that these incidents would not have a material adverse effect on our business and results of operations, considering that (1) we have not received any notice from relevant regulatory authorities regarding any claim for inadequate contributions of our current and former employees, nor any notifications from the relevant authorities requiring us to pay the shortfalls; (2) we were not aware of any employee complaints or claims with respect to social insurance and/or housing provident funds; (3) we would make full payment within the stipulated deadline as required by

relevant authorities once we received the notifications from the relevant authorities requiring us to pay the shortfalls; and (4) as advised by our PRC Legal Advisors, based on the above and provided that the relevant regulations and policies issued by PRC governments are still in effect, the likelihood that the relevant social insurance authorities would collectively take initiative to recover the historically unpaid social insurance from us and/or impose the administrative penalties on us due to our failure to make full payment of the social insurance is remote, and the likelihood that the relevant housing provident fund authorities would impose the administrative penalties on us due to our failure to make full payment of the housing provident funds is remote. As a result, we did not make any provisions in connection with the non-compliance during the Track Record Period and up to the Latest Practicable Date. However, we cannot assure that the relevant local government authorities will not require us to pay the outstanding amount within a specific time limit or impose late or additional fees or fines on us, which may adversely affect our financial condition and results of operation.

Failure to comply with PRC property laws and relevant regulations may adversely affect our business, results of operations and financial condition.

Historically, two floors we occupied in the same building with a gross floor area of approximately 3,582.17 square meters where our headquarters are located and where we conduct substantially all of our manufacturing activities were renovated without obtaining the construction commencement permit (施工許可證) and going through the construction completion acceptance procedures (竣工驗收) as required by PRC laws and regulations. According to our PRC Legal Advisors, for construction work carried out without construction commencement permit, we are subject to the risk of being required to adopt remedial measures within a certain time limit and being fined 1% to 2% of the contract price of the construction project. As for construction project that is delivered for use without passing the construction completion acceptance procedures, the construction entity may be ordered to rectify, subject to a fine of not less than 2% but not more than 4% of the contract price of the construction, and may also be required to pay compensation where any damage has been caused. We cannot assure you that we will be able to obtain all the outstanding permit and registration for the building we occupied in a timely manner. The aggregate contract price of the above construction is RMB9.08 million and, accordingly, the maximum penalty under relevant laws and regulations would be a fine of RMB544,800. See "Business — Properties — Owned Properties." While we had not suffered any such fine from the relevant government authorities as of the Latest Practicable Date, we cannot assure you that we will not be subject to penalties or other disciplinary actions in the future.

Under the applicable PRC laws and regulations, parties to a lease agreement are required to register and file the executed lease agreement with the relevant government authorities. As of the Latest Practicable Date, we had not obtained lease registration for 14 properties under six lease agreements we leased in China. As advised by our PRC Legal Advisors, while failure to complete the lease registration will not affect the legal effectiveness of the lease agreements under PRC law, relevant real estate administrative authorities may require parties to the lease agreements to complete registration within a prescribed period of time and failure to do so may

subject the parties to fines ranging from RMB1,000 to RMB10,000 for each non-registered lease. See "Business — Properties — Leased Properties." While we had not received any such request or suffered any such fine from the relevant government authorities as of the Latest Practicable Date, we cannot assure you that we will not be subject to penalties or other disciplinary actions for our past and future non-compliance.

Our internal IT systems may fail or suffer security breaches.

Despite the implementation of security measures, our internal IT 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 disruption of our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, personal information of our employees, and intellectual property and proprietary business information. In addition, we manage and maintain our data utilizing on-site systems and outsourced suppliers. These data encompass 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 suppliers 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. 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 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 data maintained in the information systems and networks of our Company and our suppliers, such as personal information of our employees, and company confidential data. In addition, outside parties may attempt to penetrate our systems or those of our suppliers or fraudulently induce our personnel or the personnel of our suppliers to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. 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 suppliers 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 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.

Our future acquisitions and investments may subject us to risks and uncertainties.

We plan to actively seek opportunities for strategic acquisitions or investments to strengthen our research and development capabilities, expand our product portfolio, and enhance our market position. Such endeavors may involve significant risks and uncertainties, including distraction of management from current operations, the inability to generate sufficient revenue to offset the costs and expenses of acquisitions, and risks relating to market acceptance, loss of key acquired personnel, difficulties in integrating diverse corporate cultures, and increased costs to integrate managerial, operational, financial, and administrative systems. We currently plan to use approximately [**REDACTED**]% of the [**REDACTED**] from the [**REDACTED**], or approximately HK$[**REDACTED**] million, to fund potential strategic investment and acquisitions within the next five years that could complement and expand our product portfolio and technologies. As of the Latest Practicable Date, we had not identified any specific acquisition targets, formed any specific acquisition plans or entered into any agreements with potential targets. See "Business — Growth Strategies" and "Future Plans and [**REDACTED**] — [**REDACTED**]."

We cannot assure you that all the proposed investment and our future investments will be consummated in a timely manner or at all, or that we will realize the economic or commercial benefits from such investment as anticipated. We may be unable to successfully complete an acquisition deal due to reasons including unsuccessful negotiation, even if we identify suitable acquisition targets. In addition, we may be unable to manage an acquired entity profitably or successfully integrate its operations with our own. These factors could harm our ability to achieve anticipated levels of profitability at operations we have acquired or invested in, or realize other anticipated benefits of an acquisition or investment, or even successfully complete an acquisition deal, and could adversely affect our business, results of operations and financial condition. Any acquisition or investment may also cause us to assume liabilities, increase our expenses and working capital requirements, or subject us to litigation, which would reduce our return on invested capital. Failure to manage the acquisitions and investments we make could materially harm our business and results of operations by bringing significant net cash outflows for financing activities, with limited, if any, increase in our revenue.

Future acquisitions of businesses, technologies or know-how could materially and adversely affect our business, financial condition and results of operations if we fail to integrate the acquired businesses or technologies successfully into our existing operations or if we discover previously undisclosed liabilities.

To enhance our growth, we may acquire businesses, technologies or know-how that we believe would benefit us in terms of product development, technology advancement or distribution network. Our ability to grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. Even if we complete acquisitions, as we have limited experience with significant acquisitions, we may experience:

- difficulties in integrating any acquired companies, technologies, or personnel into our existing business, particularly integrating different business operations, financial and risk management, quality control procedures and management, customer service and other business functions;

- delays or failure in realizing the benefits of the acquired company, technologies or know-how;

- diversion of our management's time and attention from other business concerns;

- higher costs of integration than we anticipated;

- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions; or

- difficulties in implementing and enforcing our management and internal control mechanisms as well as quality assurance program that timely and adequately respond to our expanded scope of operations.

If we invest in businesses that operate outside of China, these risks may increase because of our limited experience in operating overseas.

An acquisition could also materially impair our results of operations through use of substantial amounts of cash, potentially dilutive issuances of equity securities, increasing operating expenses and cash requirements, significant depreciation and amortization expenses related to acquired intangible or other assets, impairment losses, deferred compensation charges, adverse tax consequences, significant diversion of management's attention, incurrence of debt on unfavorable terms, assimilation of operations and exposure to potential unknown liabilities of the acquired business. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance and product liabilities in businesses we acquire which we did not uncover prior to such acquisition. Therefore, we may become subject to penalties, lawsuits or other liabilities. Any difficulties in the integration of acquired businesses, technologies or know-how or unexpected penalties, lawsuits or liabilities in connection with such businesses, technologies or know-how could have a material adverse effect on our business, results of operations and financial condition.

Our insurance coverage may not be adequate, which could expose us to significant costs and business disruption.

Our operations are subject to hazards and risks associated with our research and manufacturing operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. For example, we maintain insurance policies that cover losses arising from accidents and natural calamities in respect of our machinery, equipment, inventories and other fixed assets in our research and manufacturing facilities. We also maintain insurance policies covering clinical trial liability and are in the process of securing an insurance policy against product liability claims. For details, see "Business — Insurance." In line with industry practice in China, we have elected not to maintain certain types of insurances such as key man life insurance, which is not mandatory under PRC laws. We cannot assure you that our insurance policies will be adequate to cover all losses incurred. In particular, our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. 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.

We may need additional capital, and we may be unable to obtain such capital in a timely manner or on acceptable terms, or at all.

We may require additional capital beyond those generated by the [**REDACTED**] from time to time to grow our business, to better serve our customers, develop and enhance our products, and improve our operating infrastructure. Accordingly, we may need to sell additional equity or debt securities or obtain a credit facility. Future issuances of equity or equity-linked securities could significantly dilute our existing Shareholders, and any new equity security we issue could have rights, preferences and privileges superior to those of holders of our ordinary shares. The incurrence of debt financing would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations or our ability to pay dividends to our Shareholders.

Our ability to obtain additional capital is subject to a variety of uncertainties, including:

- our market position and competitiveness in the interventional medical device market targeting structural heart diseases;
- our future profitability, overall financial condition, and results of operations;
- general market conditions for capital raising activities by companies in the interventional medical device market targeting structural heart diseases in China, which in turn depends on the prospect of this industry; and
- economic, political and other conditions in China and globally.

We may be unable to obtain additional capital in a timely manner or on acceptable terms, or at all. If we are unable to obtain adequate financing on terms satisfactory to us when we require it, our ability to continue to support our business growth could be significantly impaired, and our business and prospects could be adversely affected.

A severe or prolonged downturn in the global or Chinese economy could materially and adversely affect our business, results of operations, financial condition and prospects.

The global macroeconomic environment is facing challenges, including the end of quantitative easing by the U.S. Federal Reserve, the economic slowdown in the Eurozone since 2014 and uncertainties over the impact of Brexit. The Chinese economy has shown slower growth compared to the previous decade since 2012 and the trend may continue. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world's leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa, which have resulted in market volatility. There have also been concerns over the relationship between China and other countries, including the surrounding Asian countries. Recent international trade disputes, including tariff actions announced by the United States, China and certain other countries, and the uncertainties created by such disputes may cause disruptions in the international flow of goods and services and may adversely affect the Chinese economy as well as global markets and economic conditions. In addition, the recent market panics over the global outbreak of COVID-19 and the drop of oil price materially and negatively affected the global financial markets in March 2020, which may cause slowdown of the world's economy. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policies and the expected or perceived overall economic growth rate in China. Any severe or prolonged slowdown in the global or Chinese economy may materially and adversely affect our business, results of operations, financial condition and prospects.

Any catastrophe, including outbreaks of health pandemics and other extraordinary events, could have a negative impact on our business operations.

We are vulnerable to natural disasters and other calamities. Fire, floods, typhoons, earthquakes, power loss, telecommunications failures, wars, riots, terrorist attacks or similar events may give rise to server interruptions, breakdowns, system failures or Internet failures, which could cause the loss or corruption of customer data, malfunctions of software, hardware and equipment as well as adversely affect our ability to manufacture our products and provide our services.

Our business could also be adversely affected by the effects of COVID-19, Ebola virus diseases, H1N1 flu, H7N9 flu, avian flu, Severe Acute Respiratory Syndrome (SARS), or other epidemics. Our business operation could be disrupted if any of our employees is suspected of having any of the aforementioned epidemics or another contagious disease or condition, since it could require our employees to be quarantined and/or our offices to be disinfected. In addition, our business, results of operations and financial condition could be adversely affected to the extent that any of these epidemics harms the economy of China and other overseas markets in general.

RISKS RELATING TO DOING BUSINESS IN CHINA

The economic, political and social conditions in China could affect our business, results of operations, financial condition and prospects.

We generate a substantial portion of our revenue from our operations in China. Accordingly, our business, financial condition, results of operations and prospects are subject to and influenced by the economic, political and social conditions in China. Economic reforms begun in the late 1970s have resulted in significant economic growth in China. However, any economic reform policies or measures in China may from time to time be modified or revised. China's economy differs from the economies of most developed countries in many respects, including with respect to the degree of government involvement, control of foreign exchange, allocation of resources, as well as the overall level of development. While China's economy has experienced significant growth in the past 30 years, growth has been uneven across different regions and among different economic sectors. In addition, the rate of growth has been slowing since 2012, and the impact of COVID-19 on China's and global economies was severe and may persist in the future.

The PRC government exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our results of operations and financial condition may be adversely affected by government control over capital investments or changes in tax regulations. In addition, in the past, the PRC government has implemented certain measures, including interest rate adjustment, to control the pace of economic growth. These measures may cause decreased economic activities in China, which may adversely affect our business and results of operations. In addition, the increased global focus on social, ethical and environmental issues may lead to China's adoption of more stringent standards in these areas, which may adversely impact the operations of China-based companies including us. We cannot predict future changes in China's economic, political and social conditions and the effect that new government policies would have on our business and prospects. Any actions and policies adopted by the PRC government could adversely affect our business, results of operations, financial condition and competitive position.

Uncertainties with respect to the PRC legal system could have a material adverse effect on our business, results of operations and financial condition.

Our business and operations are primarily conducted in China and are governed by applicable PRC laws, rules and regulations. The PRC legal system is based on written statutes and their interpretation by the Supreme People's Court. Prior court decisions may be cited for reference, but have limited weight as precedents. Since the late 1970s, the Chinese government has significantly enhanced China's legislation and regulations to provide protection to various

forms of foreign investments in China. However, since these laws and regulations are relatively new and the PRC legal system continues to rapidly evolve, the interpretations of many laws, rules and regulations are not always uniform and enforcement of these laws, rules and regulations involves uncertainties, which may limit legal protections available to us.

Even if we endeavor to comply with relevant laws and regulations, we may not always be able to do so due to a lack of detailed implementation rules by relevant government authorities. In addition, some government authorities (including local government authorities) may not consistently apply regulatory requirements issued by themselves or other PRC government authorities, making strict compliance with all regulatory requirements impractical, or in some circumstances, impossible. For example, we may have to resort to administrative and court proceedings to enforce the legal protection that we enjoy either by law or contract. However, since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into with our customers, suppliers, distributors and business partners. In addition, such uncertainties, including the inability to enforce our contracts, together with any development or interpretation of PRC laws adverse to us, could materially and adversely affect our business and operations. Furthermore, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Accordingly, we cannot predict the effect of future developments in the PRC legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. These uncertainties could limit the legal protections available to us and other foreign investors, including you. In addition, any litigation or regulatory enforcement action in China may be protracted and may result in substantial costs and the diversion of resources and management's attention, which in turn could have a material adverse effect on our results of operations and financial condition.

Government control of currency conversion could limit our ability to utilize our revenue effectively, to pay dividends and other obligations, and affect the value of our H Shares.

The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Our revenue and expenses are substantially denominated in Renminbi, and the [**REDACTED**] from the [**REDACTED**] and any dividends we pay on our H Shares will be in Hong Kong dollars. Under China's existing foreign exchange regulations, following the completion of the [**REDACTED**], we will be able to make current account foreign exchange transactions, including paying dividends in foreign currencies without prior approval from the SAFE.

However, in the future, the PRC government may take measures, at its discretion, to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. If such measures are implemented, we may not be able to pay dividends in foreign currencies to holders of our H Shares. Foreign exchange transactions under our capital account are subject to significant foreign exchange controls and require SAFE's approval. These limitations could affect our ability to obtain foreign exchange through offshore financing.

Furthermore, the [**REDACTED**] from the [**REDACTED**] are expected to be deposited in currencies other than Renminbi until we obtain necessary approvals from relevant PRC regulatory authorities to convert these [**REDACTED**] into onshore Renminbi. If the [**REDACTED**] cannot be converted into onshore Renminbi in a timely manner, our ability to deploy these [**REDACTED**] efficiently may be affected as we will not be able to invest these [**REDACTED**] on RMB denominated assets onshore or deploy them in uses onshore where Renminbi is required. All of these factors could materially and adversely affect our business results of operations, financial condition and prospects.

Fluctuations in exchange rates could adversely affect our results of operations and the value of your [REDACTED].

Fluctuations in the exchange rate of Renminbi against Hong Kong dollar, U.S. dollar and other foreign currencies are affected by, among other things, the policies of the PRC Government and changes in China's and international political and economic conditions.

The [**REDACTED**] from the [**REDACTED**] will be denominated in Hong Kong dollars. As a result, any appreciation of Renminbi against U.S. dollar, Hong Kong dollar or any other foreign currencies may result in a decrease in the value of our foreign currency-denominated assets and our [**REDACTED**] from the [**REDACTED**]. Conversely, any depreciation of Renminbi may adversely affect the value of, and any dividends payable on our H Shares in foreign currencies. In 2021, we recorded net foreign exchange gains of RMB5.2 million from retranslation of U.S. dollar-denominated bank balances and redemption liabilities. In the six months ended June 30, 2021 and 2022, we recorded net foreign exchange losses of RMB1.8 million and RMB26.9 million, respectively, from retranslation of redemption liabilities resulted from exchange rate fluctuations. There are limited instruments available for us to reduce our foreign currency risk exposure at reasonable cost in China, and we have not utilized, and may not in the future utilize, any such instrument. All of these factors could materially and adversely affect our business, results of operations, financial condition and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

[REDACTED] of our H Shares may become subject to PRC taxation on dividends received from us and gains from the disposition of our H Shares.

Non-Chinese resident individual holders of H Shares whose names appear on the register of members of H Shares ("Non-Chinese Resident Individual Holders"), are subject to Chinese individual income tax on dividends received from us. Pursuant to the Circular on Questions Concerning the Collection of Individual Income Tax Following the Repeal of Guo Shui Fa [1993] No. 045 (Guo Shui Han [2011] No. 348) (《關於國税發[1993]045號文件廢止後有關個人所得税徵管問題的通知》(國税函[2011]348號)) dated June 28, 2011 and issued by the SAT, the tax rate applicable to dividends paid to Non-Chinese Resident Individual Holders of H Shares varies from 5% to 20% (usually 10%), depending on whether there is any applicable tax treaty between China and the jurisdiction in which the Non-Chinese Resident Individual Holder of H Shares resides, as well as the tax arrangement between China and Hong Kong. Non-Chinese Resident Individual Holders who reside in jurisdictions that have not entered into tax treaties with the PRC are subject to a 20% withholding tax on dividends received from us. See "Appendix VI — Taxation and Foreign Exchange" to this document. In addition, under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得税法》) and its implementation regulations, Non-Chinese Resident Individual Holders of H Shares are subject to individual income tax at a rate of 20% on gains realized upon the sale or other disposition of H Shares. However, pursuant to the Circular Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得税的通知》) issued by the Ministry of Finance and the SAT on March 30, 1998, gains of individuals derived from the transfer of listed shares of enterprises may be exempt from individual income tax. Based on our knowledge, as of the Latest Practicable Date, the Chinese tax authorities have not in practice sought to collect individual income tax on such gains. If such tax is collected in the future, the value of such non-Chinese resident individual holders' [**REDACTED**] in H Shares may be materially and adversely affected.

Under the EIT Law and its implementation regulations, a non-Chinese resident enterprise is generally subject to enterprise income tax at a rate of 10% with respect to its Chinese-sourced income, including dividends received from a Chinese company and gains derived from the disposition of equity interests in a Chinese company. This rate may be reduced under any special arrangement or applicable treaty between the China and the jurisdiction in which the non-Chinese resident enterprise resides. Pursuant to the Circular on Questions Concerning Withholding of Enterprise Income Tax for Dividends Distributed by Resident Enterprises in China to Non-resident Enterprises Holding H-shares of the Enterprises (Guo Shui Han [2008] No. 897) (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得税有關問題的通知》(國税函[2008]897號)) promulgated by the SAT on November 6, 2008, we intend to withhold tax at 10% from dividends payable to non-Chinese resident enterprise holders of H Shares (including [**REDACTED**] Nominees). Non-Chinese resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the Chinese tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be

subject to the Chinese tax authorities' approval. See "Appendix VI — Taxation and Foreign Exchange" to this document. There are uncertainties as to the interpretation and implementation of the EIT Law and its implementation rules by the Chinese tax authorities, including whether and how enterprise income tax on gains derived upon the sale or other disposition of H Shares will be collected from non-Chinese resident enterprise holders of H Shares. If such tax is collected in the future, the value of such non-Chinese resident enterprise holders' [**REDACTED**] in H Shares may be materially and adversely affected.

Payment of dividends is subject to restrictions under PRC law.

Under PRC law, dividends may be paid only out of distributable profits. Distributable profits are defined as our profits after taxes as determined under PRC GAAP less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make. As a result, we may not have sufficient, if any, distributable profits to enable us to make dividend distributions to our Shareholders in the future, including periods for which our financial statements indicate that our operations have been profitable. Any distributable profits not distributed in a given year are retained and available for distribution in subsequent years.

Moreover, because the calculation of distributable profits under PRC GAAP is different from the calculation under IFRS in certain respects, our subsidiaries may not have distributable profits as determined under PRC GAAP, even if they have profits for that year as determined under IFRS. Even though there are no material differences between our distributable profit during the Track Record Period under PRC GAAP and IFRS, we may not receive sufficient distributions from our subsidiaries in the future. Failure by our subsidiaries to pay dividends to us could have a negative impact on our cash flow and our ability to make dividend distributions to our Shareholders in the future, including those periods in which our financial statements indicate that our operations have been profitable.

It may be difficult to effect service of process, enforce foreign judgments or bring original actions against us, our Directors, Supervisors and senior management residing in China.

We are a company incorporated under the laws of China, and a majority of our assets are located in China. In addition, most of our Directors, Supervisors and senior management reside within China, and the assets of our Directors, Supervisors and senior management are likely to be located within China. As a result, it may be difficult or impossible for you to effect service of process within Hong Kong, the United States or elsewhere outside China upon us or these persons, or to bring an action in Hong Kong against us or these individuals. Moreover, China does not have treaties with most of the other jurisdictions that provide for the reciprocal recognition and enforcement of judicial rulings and awards.

On July 14, 2006, the Supreme People's Court of China and Hong Kong entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgements in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the "2006 Arrangement"). Pursuant to such arrangement, a party with a final judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China, and vice versa. However, it is subject to the parties in the dispute agreeing to enter into a choice of court agreement in writing under the 2006 Arrangement.

On January 18, 2019, the Supreme People's Court of China and Hong Kong entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the "2019 Arrangement"), the commencement date of which shall be announced after the Supreme People's Court promulgates judicial interpretations and relevant procedures are completed in Hong Kong. The 2019 Arrangement will supersede the 2006 Arrangement and afford greater clarity and certainty for reciprocal recognition and enforcement of judgments in civil and commercial matters. The 2006 Arrangement will remain applicable to a "choice of court agreement in writing" entered into before the 2019 Arrangement taking effect. However, there remains uncertainties as to the outcome of any applications to recognize and enforce such judgments and arbitral awards in China.

Furthermore, an original action may only be brought in China against us or our Directors, Supervisors and senior management if the actions are not required to be arbitrated by PRC laws and upon satisfaction of the conditions for commencing a cause of action pursuant to the PRC civil procedure law. As a result of the conditions set forth in the PRC civil procedure law and the discretion of the PRC courts to determine whether the conditions are satisfied and whether to accept the action for adjudication, it is uncertain whether [**REDACTED**] will be able to bring an original action in China in this manner.

The custodians or authorized users of our controlling non-tangible assets, including chops and seals, may fail to fulfill their responsibilities, or misappropriate or misuse these assets.

Under the PRC law, legal documents for corporate transactions, including agreements and contracts are executed using the chop or seal of the signing entity or with the signature of a legal representative whose designation is registered and filed with relevant PRC market regulation administrative authorities.

In order to secure the use of our chops and seals, we have established internal control procedures and rules for using these chops and seals. In any event that the chops and seals are intended to be used, the responsible personnel will submit a formal application, which will be verified and approved by authorized employees in accordance with our internal control procedures and rules. In addition, in order to maintain the physical security of our chops, we generally have them stored in secured locations accessible only to authorized employees. Although we monitor such authorized employees, the procedures may not be sufficient to prevent all instances of abuse or negligence. There is a risk that our employees could abuse their authority, for example, by entering into a contract not approved by us or seeking to gain control of one of our subsidiaries or our affiliated entities or their subsidiaries. If any employee obtains, misuses or misappropriates our chops and seals or other controlling non-tangible assets for whatever reason, we could experience disruption to our normal business operations. We may have to take corporate or legal action, which could involve significant time and resources to resolve and divert management from our operations, and we may not be able to recover our loss due to such misuse or misappropriation if the third party relies on the apparent authority of such employees and acts in good faith.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our H Shares, and the [REDACTED] and [REDACTED] of our H Shares may be volatile.

Prior to the [**REDACTED**], there has been no [**REDACTED**] market for our H Shares. The [**REDACTED**] for our H Shares was the result of negotiations between us, the Sole [**REDACTED**] and the [**REDACTED**] on behalf of the [**REDACTED**], and the [**REDACTED**] may differ significantly from the [**REDACTED**] for our H Shares following the [**REDACTED**]. We have applied for [**REDACTED**] of, and permission to [**REDACTED**] in, our H Shares on the Stock Exchange. A [**REDACTED**] on the Stock Exchange, however, does not guarantee that an active and [**REDACTED**] for our H Shares will develop, or if it does develop, that it will be sustained following the [**REDACTED**] or that the [**REDACTED**] of our H Shares will not decline following the [**REDACTED**]. Furthermore, the [**REDACTED**] and [**REDACTED**] of our H Shares may be volatile. The following factors may affect the [**REDACTED**] and [**REDACTED**] of our H Shares:

- actual or anticipated fluctuations in our operating performance and revenue;
- news regarding recruitment or departure of key personnel by us or our competitors;
- announcements of competitive developments, acquisitions or strategic alliances in our industry;
- potential litigation or regulatory investigations;

- general market conditions or other developments affecting us or our industry;
- the operating and stock price performance of other companies in our industry, and other events or factors beyond our control; and
- the release of [**REDACTED**] or other transfer restrictions on our outstanding H Shares or sales or perceived sales of H Shares by us or other Shareholders.

Moreover, the capital market has from time to time experienced significant price and trading volume fluctuations that were unrelated or not directly related to the operating performance of the underlying companies in the market. These broad market and industry fluctuations may have a material and adverse effect on the [**REDACTED**] and [**REDACTED**] of our H Shares.

An active and liquid [REDACTED] market for our H Shares may not develop.

Prior to the [**REDACTED**], our H Shares were not traded on any other market. We cannot assure you that an active and liquid [**REDACTED**] for our H Shares will be developed or be maintained after the [**REDACTED**]. Liquid and active [**REDACTED**] usually result in less price volatility and more efficiency in carrying out [**REDACTED**]' purchase and sale orders. The [**REDACTED**] of our H Shares could vary significantly as a result of a number of factors, some of which are beyond our control. In the event of a drop in the [**REDACTED**] of our H Shares, you could lose a substantial part or all of your [**REDACTED**] in our H Shares.

Any [REDACTED] of Domestic Shares and Unlisted Foreign Shares and subsequent [REDACTED] into H Shares in the future could dilute your shareholding under H Shares, increase the supply of our H Shares in the [REDACTED] and negatively impact the [REDACTED] of our H Shares.

On December 29, 2017, the CSRC issued a press release in connection with the launch of the H share full circulation pilot project (H股全流通試點項目) (the "Pilot Project"). A participating company, which is an H share company listed on the Stock Exchange, in the Pilot Project would be allowed to convert certain of its domestic shares into H shares, which are eligible to be listed and traded on the Stock Exchange. On November 14, 2019, the CSRC announced to fully promote its "full circulation" reform of the H shares by covering both qualified H share companies already listed on the Stock Exchange and companies planning initial public offerings of the H shares on the Stock Exchange.

We have obtained the approval from the CSRC for the [**REDACTED**] of [**REDACTED**] Domestic Shares and [**REDACTED**] Unlisted Foreign Shares into [**REDACTED**] H Shares, and the [**REDACTED**] H Shares may be [**REDACTED**] on the Stock Exchange upon completion of the [**REDACTED**]. Such [**REDACTED**] will increase the number of H Shares to [**REDACTED**] H Shares (assuming the [**REDACTED**] is not exercised) and in the case that there is any [**REDACTED**] of Domestic Shares and subsequent [**REDACTED**] into H Shares in the future, your shareholding under the class of holders of our H Shares will be diluted. Further, according to the PRC Company Law, the Shares [**REDACTED**] by our Company prior to the [**REDACTED**] (including a total of [**REDACTED**] Domestic Shares and [**REDACTED**] Unlisted Foreign Shares held by existing Shareholders) are restricted from [**REDACTED**] within one year from the [**REDACTED**]. Such restriction from [**REDACTED**] will limit the number of H Shares [**REDACTED**] on the [**REDACTED**], which will in turn adversely affect the [**REDACTED**] of the H Shares during such restriction period. Any future [**REDACTED**] (after the expiration of the restrictions set out above) of [**REDACTED**] H Shares by relevant Shareholders in the [**REDACTED**] may affect the [**REDACTED**] of our H Shares.

Since there will be a gap of several days between [REDACTED] and [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares could fall during the period before [REDACTED] of our H Shares begins.

The [**REDACTED**] of our H Shares is expected to be determined on the [**REDACTED**] Date. However, our H Shares will not commence [**REDACTED**] on the Stock Exchange until they are delivered, which is expected to be [five] Hong Kong business days after the [**REDACTED**] Date. As a result, [**REDACTED**] may not be able to sell or otherwise [**REDACTED**] in our H Shares during that period. Accordingly, holders of our H Shares are subject to the risk that the [**REDACTED**] of our H Shares could fall before [**REDACTED**] begins, as a result of unfavorable market conditions or other adverse developments that could occur between the time of [**REDACTED**] and the time [**REDACTED**] begins.

Because the [REDACTED] of our H Shares is substantially higher than the consolidated [REDACTED] book value per Share, purchasers in the [REDACTED] may experience immediate dilution.

As the [**REDACTED**] of our H Shares is higher than the consolidated [**REDACTED**] assets per Share immediately prior to the [**REDACTED**], [**REDACTED**] of our H Shares in the [**REDACTED**] will experience an immediate dilution in [**REDACTED**]. Our existing Shareholders will receive an increase in the [**REDACTED**] of their Shares. Please refer to Appendix II to this document for details. In addition, holders of our Shares may experience further dilution of their interest if the [**REDACTED**] exercise the [**REDACTED**] or if we [**REDACTED**] additional shares in the future to raise additional capital.

The [REDACTED] and [REDACTED] of our H Shares may be volatile, which could result in rapid and substantial losses for our Shareholders.

The [**REDACTED**] of our H Shares may be highly volatile and could be subject to significant fluctuations. In addition, the [**REDACTED**] of our Shares may fluctuate, which may cause significant [**REDACTED**] variations. Some of the factors that could negatively affect the [**REDACTED**] of our H Shares, or result in fluctuations in the [**REDACTED**] or [**REDACTED**] of our H Shares following the [**REDACTED**] include:

- variations in our operating and financial results, such as turnovers, earnings and cash flow;
- our failure to execute our strategies;
- an unexpected business interruption resulting from operational breakdowns, natural disasters, or major changes in our key personnel or senior management;
- adverse market reaction to any indebtedness that we may incur or securities that we may issue in the future;
- changes in market valuations of similar companies;
- changes or proposed changes in laws or regulations, or differing interpretations thereof, affecting our ability to obtain or maintain regulatory approval for our products;
- inadequate protection of our intellectual property rights or legal proceedings brought against us for infringement of third parties' intellectual property rights;
- unexpected costs of litigations and unfavorable outcomes of claims arising out of defective products and safety related governmental investigations and actions; and
- general political, financial, social and economic conditions.

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

Our management may spend the [**REDACTED**] from the [**REDACTED**] in ways you may not agree with or that do not yield a favorable return. For details of our intended [**REDACTED**], see "Future Plans and [**REDACTED**]." However, our management will have discretion as to the actual application of our [**REDACTED**]. You are entrusting your funds to our management, upon whose judgment you must depend, for the specific use we will make of the [**REDACTED**] from this [**REDACTED**].

Future sales or perceived sales or [REDACTED] of substantial amounts of our securities in the [REDACTED], including any future [REDACTED] in China or [REDACTED] of our Domestic Shares and Unlisted Foreign Shares into H Shares, could have a material and adverse effect on the prevailing [REDACTED] of our H Shares and our ability to raise additional capital in the future, or may result in dilution of your shareholdings.

Future sales of substantial amounts of our H Shares or other securities relating to our H Shares in the public [**REDACTED**], or the [**REDACTED**] of new H Shares or other securities relating to our H Shares, or the perception that such [**REDACTED**] or [**REDACTED**] may occur could all cause a decline in the [**REDACTED**] of our H Shares. Future [**REDACTED**], or perceived [**REDACTED**], of substantial amounts of our securities or other securities relating to our H Shares, including part of any future [**REDACTED**], could also materially and adversely affect the prevailing [**REDACTED**] of our H Shares and our ability to raise capital in the future at a time and at a [**REDACTED**] which we deem appropriate.

Our Domestic Shares and Unlisted Foreign Shares may be [**REDACTED**] into H Shares, and such [**REDACTED**] H Shares may be [**REDACTED**] or [**REDACTED**] on an overseas stock exchange, provided that prior to the [**REDACTED**] and [**REDACTED**] of such [**REDACTED**] shares, any requisite internal approval processes shall have been duly completed and the approval from the relevant Chinese regulatory authorities, including the CSRC, shall have been obtained (the "Arrangement"). In addition, such [**REDACTED**], [**REDACTED**] and [**REDACTED**] shall in all respects comply with the regulations prescribed by the State Council's securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. The Arrangement applies only to Domestic Shares and Unlisted Foreign Shares. All of our Domestic Shares and Unlisted Foreign Shares are subject to the Arrangement and may be [**REDACTED**] into H Shares upon the approval of the relevant regulatory authorities, including the CSRC and the Stock Exchange.

We may not be able to pay any dividends on our H Shares.

During the Track Record Period and up to the Latest Practicable Date, we paid dividend of RMB320.0 million to Lepu Medical in January 2021. We cannot guarantee when and in what form dividends will be paid on our H Shares following the [**REDACTED**]. The declaration of dividends is proposed by the Board and is based on, and limited by, various factors, including without limitation, our business and financial performance, capital and regulatory requirements, and general business conditions. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable. For details, see "Financial Information — Dividend Policy."

If securities or industry analysts do not publish research reports about our business, or if they adversely change their recommendations regarding our H Shares, the [REDACTED] and [REDACTED] of our H Shares may decline.

The [**REDACTED**] of our H Shares may be influenced by research reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our H Shares or publish negative opinions about us, the [**REDACTED**] of our H Shares would likely decline regardless of the accuracy of the information. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which, in turn, could cause the [**REDACTED**] or [**REDACTED**] of our H Shares to decline.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains forward-looking statements with respect to our business strategies, operating efficiencies, competitive positions, growth opportunities for existing operations, plans and objectives of management, certain [**REDACTED**] information and other matters.

The words "anticipate," "believe," "could," "potential," "continue," "expect," "intend," "may," "plan," "seek," "will," "would," "should" and the negative of these terms and other similar expressions identify a number of these forward-looking statements. These forward-looking statements, including, among others, those relating to our future business prospects, capital expenditure, cash flows, working capital, liquidity and capital resources are necessary estimates reflecting the best judgment of our Directors, Supervisors and senior management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. As a result, these forward-looking statements should be considered in light of various important factors, including those set out in "Risk Factors" in this document. Accordingly, such statements are not a guarantee of future performance and you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

The industry data and forecasts in this document obtained from various government publications and the industry report have not been independently verified.

This document includes industry data and forecasts that we obtained from various government publications and the industry report that we believe are reliable. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, we cannot assure you of the accuracy or completeness of information obtained from these sources. We have not independently verified any of the data, forecasts and other statistics from such sources, nor have we ascertained that the underlying economic assumptions relied upon in those sources.

Also, these facts, forecasts and other statistics have not been independently verified by the [**REDACTED**], their respective directors and advisors or any other parties involved in the [**REDACTED**] and none of them make any representation as to the accuracy or completeness of such information in respect of the F&S Report and the information therein. Moreover, such facts, forecasts and other statistics may not be prepared on a comparable basis or may not be consistent with other information compiled within or outside China.

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

Prior to the publication of this document, there has been and there may also be, subsequent to the date of this document but prior to the completion of the [**REDACTED**], press and media coverage regarding us, our business, our industries and the [**REDACTED**], which contained, 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 such 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.