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

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed "Forward-Looking Statements" in this document.

RISKS RELATING TO OUR EXISTING AND PIPELINE PRODUCTS

We are dependent on the sales of our endovascular interventional medical devices. Our business prospects, financial condition and results of operations would be materially and adversely affected if sales of these products were to decline.

We are dependent on the sales of our endovascular interventional medical devices, including balloons and stents used in PCI (coronary)/PTA (peripheral) procedures. During the Track Record Period, substantially all of our revenue was generated from sales of our endovascular interventional medical device products. We expect to continue to derive a substantial majority of our revenue from endovascular interventional medical devices in the foreseeable future.

Continued market acceptance and demand for our endovascular interventional medical device products will be critical to our success. 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, our revenue would significantly decline, and our business, financial condition and results of operations would be materially and adversely affected.

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

Our current and future products may cause undesirable or unintended severe adverse events as a result of a number of factors, many of which are outside of our control. These factors include potential complications not revealed in clinical trials, unusual but severe complications and adverse events in isolated cases, defective products not detected by our quality control policies and system or misuse of our products. Our products 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 may be perceived to cause severe adverse events if one or more regulators, such as the NMPA, FDA, PMDA or NB, determine that other companies' products containing the same or similar key parts or using the same delivery technologies as our products' 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 facilities;
- damage to the brand name of our products and the reputation of our Company;
- failure to include our products into the relevant medical insurance coverage; and/or
- exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties.

As a result of these consequences, our sales, profitability and business prospects could be materially and adversely affected.

If we do not successfully introduce new, innovative or competitive products and develop, enhance or adapt to new technologies and methodologies in a timely manner or at all, our products may become obsolete and our business prospects, financial condition and results of operations may suffer.

The global endovascular interventional instrument market is characterized by technological changes, frequent new product introductions, and evolving industry standards. Without the timely introduction of new and improved products, our products could become technologically obsolete or more susceptible to competition, and our revenue and results of operations may suffer. Even if we develop new or improved products, our ability to market them could be limited by the need for regulatory clearance, restrictions imposed on approved usage, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other factors.

We devote significant financial and other resources to our research and development activities. We incurred research and development costs of US$9.6 million, US$12.6 million, US$12.1 million and US$6.7 million for the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2022, respectively, representing 10.0%, 14.2%, 10.4% and 9.8% of our total revenue for the same periods, respectively.

The research and development process can be lengthy and entails considerable uncertainty. Products which we are currently developing may not complete the development process or obtain the regulatory or other approvals required to market such products in a timely manner or at all. Our competitors may apply for marketing approvals for medical device with the same intended use as our existing and pipeline products in countries where we have operations. When our products and its competing products are subject to the regulatory authorities' concurrent review, the estimated schedule may be affected, and the registration process of our products may be prolonged. Moreover, our competitors may obtain approval from the NMPA, FDA, PMDA, NB or other comparable regulatory authorities for their products faster than us, which could result in our competitors establishing a strong market position or gaining acceptance in the same markets that we are targeting before us. As a result, we may be unable to maintain or enhance our market share or achieve our targeted market share in this industry. Even if successfully developed and subsequently approved by regulatory authorities, our existing and pipeline products may face competition based on 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, patent position and other factors.

If products developed by our competitors continue to dominate certain major sub-segments of endovascular interventional instrument markets in which we operate, or our competitors consolidate the market faster than we do by introducing more advanced products to the end-customers, our business may not continue to grow as we expected. This could dampen the demand for our products or cause our products to become obsolete, and we may not be able to respond and adapt to the introduction of new products or technologies or develop products that will to be in demand, in which case our business prospects and results of operations will be materially and adversely affected.

We intend to spend approximately HK$[**REDACTED**] of the [**REDACTED**] from this [**REDACTED**] to continue to enhance our technical capabilities in research, development and manufacturing of our pipeline products, which require substantial technical, financial and human resources. We may not have the financial resources necessary to fund all of these projects. In addition, 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 prospects.

If we are unable to successfully complete clinical trials, obtain regulatory approval and filing and commercialize our pipeline products successfully, or if we experience significant delays in doing so, our business prospects will be materially and adversely affected.

Medical devices are classified according to a catalogue into different categories by NMPA, FDA, PMDA and NB, depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. As of the June 30, 2022, we had a robust product pipeline consisting around 40 products in various development stages, some of which are Class III medical devices. To obtain product registrations for medical devices of Class III, 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 trials may involve lengthy and expensive process with uncertain outcomes. A failure of one or more of our clinical trials can occur at any stage of testing and clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. In addition, there can be significant variability in safety and/or efficacy results between different trials of the same pipeline products due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations and the rate of dropout among clinical trial participants.

There can be no assurance that these clinical trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded usage. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or successfully commercialize our pipeline products, including but not limited to:

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

- clinical trials of our pipeline products 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, 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 pipeline products may be larger than anticipated;

- our inability to reach agreements on acceptable terms with prospective hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different hospitals as trial centers;

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

- we might have to suspend, delay or terminate clinical trials of our pipeline products for various reasons, including a finding of lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks or reasons outside of our control, such as occurrences of epidemics like 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 pipeline products may be greater than anticipated; and

- the supply or quality of our pipeline products for use in a clinical trial or other materials necessary to conduct clinical trials of our pipeline products may be insufficient or inadequate.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in relation to 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 protocol;

- the size of the study population required for analysis of the trial's primary endpoints;

- the proximity of patients to trial sites;

- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- the patients' perceptions as to the potential advantages and side effects of the pipeline products being studied in relation to other available product, pipeline products or therapies; and

- the risk that patients enrolled in clinical trials may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated.

Our clinical trials will likely compete with other clinical trials for pipeline products that are in the same therapeutic areas as our pipeline products. This competition will reduce the number and types of patients available to us as some patients who might have opted to enroll in a trial being conducted by one of our competitors instead of ours. 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 pipeline products.

We rely on relationships with key opinion leaders, physicians and hospitals in the development and marketing of our products. Any negative publicity on us or other harm to our reputation, which may affect the recognition and perception of these industry participants of us, may materially adversely affect our business prospects, financial condition and results of operations.

Our relationships with key opinion leaders, physicians and hospitals play an important role in our research and development and sales and marketing activities. We have cultivated long-term relationships and frequently interacted with key opinion leaders, physicians and hospitals to gain first-hand knowledge of unmet clinical needs, surgeons' preferences and clinical practice trends, which is critical to our ability to develop new market-responsive products and improve our existing products. In addition, we participate in major international conferences to interact with leading cardiologists, key opinion leaders and physicians to discuss new product development concepts and challenges faced in laboratories. Please refer to the paragraphs headed "Business – Our Competitive Strengths" and "Business – Sales, Marketing and Distribution – Our Marketing Model" in this document.

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 the successful development of new products or 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. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our research and development process, may be inaccurate and lead us to develop products that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Moreover, we cannot assure you that our marketing strategies will continue to be effective. Industry participants, particularly in the specialties of endovascular intervention area, may no longer want to collaborate with us, 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 key opinion leaders, physicians and hospitals that we focus on may not continue to have a significant demand for our products. If we are unable to develop new products or generate returns from our relationships with industry participants as anticipated, or at all, our business prospects, financial condition and results of operations may be materially and adversely affected.

Our reputation and the perception of these industry participants of our brand are critical to our business. If we are unable to maintain and further enhance our reputation and recognition, our relationship with industry participants may be impeded, and our business prospects may be materially adversely affected. In addition, any negative incident or negative publicity concerning us, our products, our management, our Shareholders, our employees, our affiliates or any entity that shares the name of our Company and our business partners, regardless of its veracity, could harm our image and diminish the trust from industry praticipants, which could in turn result in decreased sales of our products and materially and adversely affect our business prospects.

We are exposed to potential product liability claims and product recalls which would damage our reputation and have a material adverse effect on our reputation, business prospects, financial condition and results of operations.

Some of our existing and pipeline products are classified as Class III medical devices. Such classifications represent a high risk to the human body and requires a high level of supervision to ensure safety and effectiveness. We may be subject to product liability claims if our products have quality issues, including latent defects that can only be identified at a later stage. Complex medical devices may sometimes experience problems resulting from the use of the products, including the way physicians use such products, which could require review and corrective action. Component failures, manufacturing errors or design defects could result in danger or injuries to patients. Any serious failures or defects could cause us to withdraw or recall products, and subject us to product liability litigation. The occurrence of any market withdrawals or product recalls of our products may damage our brand name and may have a material adverse effect on our business prospects, financial condition and results of operations. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint or product return from customers.

In addition, despite we have purchased product liability insurance for our products, the coverage of our product liability insurance may not be adequate or sufficient to cover all such claims, in which case our reputation, business, results of operations or financial condition will be materially and adversely affected.

RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATIONS

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

All jurisdictions in which we conduct our research, development, manufacturing and commercialization activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of the PRC, U.S., Japan and the EU. These jurisdictions all have strict regulations on medical devices, and in doing so they employ broadly similar regulatory strategies, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, there may be differences in the regulatory regimes in different regions, which make regulatory compliance more complex and costly for companies like us that operate in each of these regions. Governmental authorities have become increasingly vigilant in enforcing laws in the medical devices industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or to obtain and maintain required licenses and permits may result in the suspension or termination of our business activities. We believe our strategy and approach is aligned and in compliance with the applicable laws, regulations or government policies, but we cannot ensure that our strategy and approach will continue to be aligned.

The process of obtaining regulatory approvals and compliance with applicable 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, a clinical hold, 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. The failure to comply with these regulations could have a material adverse effect on our business prospects and financial condition.

The regulatory approval processes are lengthy, time-consuming and inherently unpredictable.

We are subject to extensive regulatory approval processes for all material aspects of our operations. For example, we are required to obtain and renew registrations and licenses with the NMPA for the commercialization and manufacturing of our products in the PRC, as well as with competent regulatory authorities in other jurisdictions where we sell our products. Such processes are generally lengthy and time-consuming.

We currently market and intend to continue to market a substantial portion of our products in the countries where we have operations in the foreseeable future. We are required to obtain the NMPA, FDA, PMDA, NB or other counterparts approval before we can market our products in the countries where we operate. Significant time, effort and expense are required to bring our products to market in compliance with the regulatory process, and we cannot assure you that any of our products will be approved for sale. We are also required to report any serious or potentially serious incidents involving our products to the NMPA, FDA, PMDA, NB or other counterparts. Even if regulatory approval or clearance of our products is granted, the approval or clearance could limit the uses for which our products may be labeled and promoted, which may in turn limit the market for our products.

Furthermore, results of the regulatory approval process are unpredictable. We could fail to receive regulatory approval for our pipeline products for many reasons, including: (i) failing to begin or complete clinical trials; (ii) failing to demonstrate that a pipeline product is safe and effective; (iii) failing to deliver clinical trial results to meet the level of statistical significance required for approval; (iv) encountering data integrity issues related to our clinical trials; (v) encountering government authority's disagreement with our interpretation of data from pre-clinical studies or clinical trials; and (vi) failing to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols, among other factors. The regulatory authorities may require more information, including additional pre-clinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. In addition, before selling our products in international markets, we are required to obtain various governmental approvals in the relevant jurisdictions. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our products will be approved

for sale in those jurisdictions. Additional time, effort and expense may be required to bring our products to the international markets in compliance with different regulatory processes. Any failure to obtain, or delay in obtaining, regulatory approvals or clearances or to renew registrations for our products could prevent us from successfully marketing our products in the international markets.

Our failure to comply with applicable regulatory requirements could result in governmental agencies taking actions in the relevant jurisdictions, including imposing fines and penalties on us, preventing us from manufacturing or selling our products, bringing criminal charges against us, delaying the introduction of our new products into the market, recalling or seizing our products, and/or withdrawing or denying approvals or clearances for our products. We could also be subject to civil liabilities if we fail to comply with applicable regulatory requirements. If any or all of the foregoing were to occur, we may not be able to meet the demands of hospitals and physicians which use our products and they may cancel orders or purchase products from our competitors.

Aspects of the impending healthcare reform in countries where we have operations may adversely affect our business.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for medical devices. We cannot be sure whether additional legislative changes will be enacted, or whether NMPA, FDA, PMDA and NB regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our pipeline products, if any, may be.

For example, in the PRC, some provinces have implemented the "Two-Invoice System" in the field of medical consumables in order to reduce the circulation of high-value medical consumables and promote the transparency of purchase and sales. For further details, please refer to the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Laws and Regulations Relating to Medical Devices Administration – Two-Invoice System" in this document. As the interpretation and enforcement of the "Two-Invoice 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 the PRC, or whether and how that will affect our business prospects and results of operations in the future.

More of our products sold in the PRC market may be included in the scope of centralized procurement in the future and the end prices of such products may drop significantly, which in turn may have a material adverse impact on our revenue, financial condition and results of operations.

In recent years, the PRC government has strengthened the implementation of centralized procurement system of high-value medical consumables with the aim of improving the pricing mechanism and reducing the inflated prices of the high-value medical consumables. For example, on July 19, 2019, the General Office of the State Council of the PRC promulgated the Notice on Printing and Distributing the Reform Plan on Managing High-value Medical Consumables (關於印發《治理高值醫用耗材改革方案》的通知), according to which, (i) all the public medical institutions are required to purchase the high-value medical consumables on the procurement platforms via public trading or "sunlight" procurement; and (ii) it is encouraged to carry out the centralized procurement by means of collecting or combining the demand in high-value medical consumables from multiple hospitals in one provincial region or even several provincial regions and then making volume-based negotiations with bidders for preferential price. After the issuance of the above reform plan, vascular interventional balloon products were gradually brought into the scope of the centralized procurement (also known as volume-based procurement and/or the centralized volume-based procurement, hereinafter referred to as "centralized procurement") in multiple provincial regions and were expected to be implemented across the PRC.

The policies of the centralized procurement promulgated in recent years had following major implications on the PRC sales environment of the high-valued medial consumables: (i) the end prices of the high-value medical consumables within the scope of centralized procurement generally drop significantly caused by the pricing mechanism of the bidding or tender process and the volume-based negotiations for preferential price; and (ii) the manufacturers (including the deemed manufacturer, such as the general agent of the imported products) or the holders of the medical device registration certificate are required to directly participate in the bidding or tender process of the centralized procurement. For further details, please refer to the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Laws and Regulations Relating to Medical Devices Administration – Centralized Procurement of Medical Devices" in this document. As of the Latest Practicable Date, seven out of 13 products we sold in the PRC market were included in the scope of centralized procurement, and, to maintain our competitiveness to win bids in the centralized procurement, the end prices of our products had to be lowered. There are uncertainties whether the centralized procurement scope would be expanded in the future, resulting in the inclusions of more of our products or product pipeline. Moreover, if any products comparable or similar to our products were included in the scope of centralized procurement, patients' willingness to use our products might be materially and adversely affected and we might be forced to change our pricing strategy. If any or all of the foregoing were to occur, our sales revenue may decrease, which in turn will have a material adverse impact on our financial condition and results of operations.

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 institutional review boards or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

The process to develop, obtain regulatory approval for and commercialize medical devices can be long, complex and costly. Even if our pipeline products were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved usage, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following an approval for commercial sale of our pipeline product, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA, FDA, PMDA, NB and/or comparable regulatory authorities. Regulatory approvals for any of our pipeline products may also be withdrawn. If we are unable to obtain regulatory approval for our pipeline products in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our pipeline products will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of other pipeline products in the future.

We cannot be sure whether additional legislative changes will be enacted, or whether regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our pipeline products, if any, may be.

Undesirable adverse events caused by our pipeline products could delay or prevent regulatory approval, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events caused by our products or pipeline products, including but not limited to side effects, safety issues and other serious adverse events could result in the delay or denial of regulatory approval by the NMPA, FDA, PMDA, NB or other comparable regulatory authority, or could result in limitations or withdrawal following approvals. For example, in the event that results of our trials reveal a high and unacceptable severity or prevalence of adverse events, our trials may be suspended or terminated by the NMPA, FDA, PMDA, NB and other comparable regulatory authorities could order us to cease further development of, or deny approval of, our pipeline products.

Additionally, if our pipeline products receive regulatory approval, and undesirable side effects caused by such pipeline products are identified after such approval, a number of potentially significant negative consequences could follow, including, among others:

- we may be required to suspend marketing or remove relevant products from the marketplace;

- regulatory authorities may withdraw approvals of the product;

- we may be required to change the way our products are distributed or administered, conduct additional clinical trials, change the labeling or add additional warnings on the labeling of such products;
- we may be required to develop risk evaluation and mitigation measures for the product or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be subject to regulatory investigations and government enforcement action;
- a severe decrease in the demand for, and sales of, the relevant products;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular pipeline product, and could significantly harm our business prospects and results of operations.

Our existing and pipeline products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we experience unanticipated problems with our pipeline products.

Even after our products are approved, they will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities. 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, FDA, PMDA, NB or other authorities.

The NMPA, FDA, PMDA, NB or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if problems occur after the product reaches the market. Later discovery of previously unknown problems with our existing and pipeline products or with our manufacturing processes 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. Other potential consequences include, among other things:

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

- fines, warning letters, or hold on clinical trials;
- refusal by the NMPA, FDA, PMDA, NB or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our existing and pipeline products; and/or
- injunctions or the imposition of civil or criminal penalties.

The policies of the NMPA, FDA, PMDA, NB and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our pipeline products. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in the markets in which our products are sold, 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 policies, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

If our existing and pipeline products are not produced in compliance with the quality standards required under applicable laws, our business and reputation could be harmed, and our revenue and profitability could be materially and adversely affected.

Our production and manufacturing processes are required to meet certain quality standards. Our quality assurance and regulatory teams are involved in every aspect of our daily operations to ensure the quality assurance of our products. For further details of our quality control policies and system, please refer to the paragraph headed "Business – Quality Assurance" in this document. Despite our quality control policies and system, we cannot eliminate the risk of product defects or failure. Quality defects may fail to be detected or remediated as a result of a number of factors, many of which are outside of our control, including:

- manufacturing errors;
- technical or mechanical malfunctions in the manufacture process;
- human error or malfeasance by our quality control personnel;
- tempering by third parties; and/or
- quality issues with the raw materials we produce or purchase.

In addition, failure to detect quality defects in our existing and pipeline products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, product liabilities or other problems that could seriously harm our reputation and business, expose us to liability, and materially and adversely affect our revenue and profitability.

We, or parties on whom we rely may not be able to maintain or renew all the permits, licenses and certificates required for our business, and if we fail any inspections, examinations, audits or reviews by the relevant regulatory authorities, our reputation will be damaged and we may be subject to fines or other penalties.

Major aspects of our operations, including product registration or filing, manufacturing, packaging, sales and distribution, pricing, environmental protection, among other things, are regulated by comprehensive local, regional and national regulatory regimes. For example, in the PRC, in addition to the registration certificates, companies engaging in manufacturing of Class III medical devices are required to obtain and maintain the medical devices production license (醫療器械生產許可證) and companies engaging in the distribution and sale of Class III medical devices are also required to obtain and maintain the medical devices operation license (醫療器械經營許可證). Please refer to the paragraphs headed "Regulatory Overview – PRC Regulatory Overview – Laws and Regulations Relating to Medical Devices Administration – Medical Devices Production License" and "Regulatory Overview – PRC Regulatory Overview – Laws and Regulations Relating to Medical Devices Administration – Medical Device Operation License" in this document. Such permits, licenses and certificates are subject to periodic reviews and renewals by relevant government authorities, and the standards of such reviews and renewals may change from time to time. There can be no assurance that authorities will approve the application for such permits, licenses and certificates or their renewal in the future. Failure to comply with relevant regulations or obtain or renew any permits, licenses and certificates necessary for our operations may result in penalties, fines, governmental sanctions, proceedings and/or suspension or revocation of our permits, licenses or certificates necessary to conduct our business, and may also result in being ordered to suspend or cease operations and being subject to confiscation of income derived from non-compliant activities.

In addition, the regulatory frameworks for the medical device industry in countries where we have operations are constantly evolving, and we expect they will continue to evolve. For example, the healthcare regulatory framework in the PRC has undergone significant changes in recent years, in particular 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 the PRC, the United States, the European Union, Japan and other countries or regions. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional permits, licenses or certificates. There is no assurance that we will respond successfully and timely to such changes. Such changes may also result in increased compliance costs or prevent our successful development, manufacture or commercialization of products in the PRC and other countries or regions in the abovesaid jurisdictions, which would adversely affect our business prospects, financial condition and results of operations.

If we fail to comply with health, safety, social and environmental laws and regulations, we may be subject to fines or penalties, or incur costs, which may adversely impact our business.

We are subject to various health, safety, social and environmental laws and regulations, including laws and regulations governing laboratory procedures and handling, use, storage, treatment and disposal of hazardous materials and wastes. Failure to abide by such laws and regulations may also lead to substantial fines, penalties or other sanctions. Our manufacturing process may involve the use of hazardous and flammable chemical materials and special equipment. Our operations may also produce hazardous waste. We have entered into hazardous waste disposal agreements with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of pollution or injury caused by these materials. If we cause pollution or injury by using harmful materials, we may assume liability for any loss arising therefrom, and any liability may exceed our resources. We may also incur substantial costs related to civil or criminal fines and penalties.

In addition, the work-related injury insurance we purchased to cover the costs and expenses incurred by our employees who may be injured by using or exposure to hazardous materials may not provide adequate coverage against potential liabilities. We have not insured against environmental liability or toxic infringement claims that may be made against us due to our storage, use or disposal of biological or hazardous materials.

RISKS RELATING TO OUR BUSINESS AND OPERATIONS

The global medical device industry is rapidly evolving and highly competitive, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.

The global medical device industry is rapidly evolving and highly competitive and fragmented. We face competition from international competitors across most of our product lines based on safety and functionality, the timing and scope of the regulatory approvals, prices, sales and marketing capabilities, the availability and cost of supply, patent position and other factors. In general, we face pricing competition from competitors globally, and competition on product quality and brand recognition from international competitors. In particular, some of our competitors may have, among other things, greater pricing flexibility and more robust sales networks in our target markets, which may enable them to offer products with similar functions but lower prices to the end users. We may not be able to successfully compete with our competitors and cannot ensure you that we will be able to demonstrate compelling advantages in quality, functionality, convenience and/or safety to overcome price competition and to be commercially successful.

In addition, some of our competitors may have, among other things:

- greater financial and other resources;

- a greater variety of products;
- brands and products that are better recognized by physicians who recommend products to patients;
- more extensive research and development and technical capabilities and human resources;
- stronger manufacturing capabilities;
- more extensive sales networks; or
- better support in terms of technical training provided.

We may not be able to successfully manage the growth of our overall business or implement our business strategies.

Our business objectives and strategies as set out in this document are based on our existing plans and intentions. However, our objectives and strategies are based on prevailing circumstances and the development trends of our industry currently known to our Directors, the bases and assumptions that certain circumstances will or will not occur, as well as the risks and uncertainties inherent in various stages of development. There are significant challenges and uncertainties involved in our strategic plans, including whether (i) we will be able to complete these plans, such as expansion of our production capacity, product portfolio and sales and marketing capabilities, on schedule and within the anticipated budget, or at all; (ii) we will be able to generate anticipated revenues and profits from these plans to cover our indebtedness, costs or contingent liabilities associated with such plans; and (iii) these plans will be in line with the market demand and national and local policies in the future. Our future prospects should be considered in light of the risks, expenses and difficulties which may be encountered by us in our various stages of development of business. We cannot assure you that we will be successful in implementing our strategies or that our strategies, even if implemented, will lead to successful achievement of our objectives. If we are not able to implement our strategies effectively, our business prospects, financial condition and results of operations may be adversely affected.

Our operations, business plans and financial position may be adversely affected by various infectious diseases, such as the COVID-19 pandemic.

Our business could also be under the threat of epidemics such as the Severe Acute Respiratory Syndrome, or SARS, the H5N1 avian flu, the human swine flu, also known as Influenza A (H1N1), or, most recently, the outbreak of COVID-19. The World Health Organization declared the outbreak of COVID-19 constitutes a Public Health Emergency of International Concern on January 30, 2020, and in March 2020, amid the escalating situation, the World Health Organization declared COVID-19 as a global pandemic.

The outbreak, which has already resulted in a high number of fatalities, is likely to have an adverse impact on the livelihood of the people and the economy globally. Our multi-national business operation has also been, and may continue to be, negatively affected by the outbreak. For example, many hospitals allocated significant resources to contain COVID-19, and patients suffering from other diseases generally avoided going to hospitals in order to prevent being infected. As a result, many endovascular interventional procedures were delayed or cancelled, and the demand for our products decreased. In addition, we are uncertain as to when, or whether, the outbreak will be contained, and we also cannot predict if the impact will be short-lived or long-lasting. If the outbreak of the coronavirus is not effectively controlled, the negative impact on our business prospects, results of operations and financial position may be even more material.

Future acquisitions of businesses, products, product pipeline, 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, products, technologies or know-how into our existing operations or if we discover previously undisclosed liabilities.

As part of our business strategy, we may consider to pursue acquisitions that we believe would benefit our business in the future. Our ability to grow through such means depends upon our ability to identify, negotiate, complete and integrate suitable opportunities as well as to obtain the necessary financing and required governmental or third-party consents, approvals and permits in a timely manner. Even if we engage in such acquisitions in the future, we may have limited experience and we may be exposed to the following risks, among others:

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

- 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;

- increased operating expenses, including research and development expenses due to an increased number of pipeline products, administrative expenses as well as selling and distribution expenses, which result in an increased cash requirements;

- the assumption of additional indebtedness or contingents;

- the issuance of our equity securities;

- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and pipeline products and regulatory approvals; and/or

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

We may also discover deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in businesses we acquire which we did not uncover prior to such acquisition. As a consequence, we may become subject to penalties, lawsuits or other liabilities. Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our business prospects, financial condition and results of operations. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

We have entered into collaborations, and may establish or seek collaborations or strategic alliances or enter into joint venture arrangements or licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, joint venture arrangements or licensing arrangements.

We may from time to time establish or seek strategic alliances, form joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our products and any pipeline products. In October 2020, we entered into a joint venture agreement with Products & Features International, LDA ("**P&F Int'l**"). Pursuant to the joint venture agreement, P&F Int'l agreed to subscribe 50% of the equity interest in OrbusNeich P+F Company Limited ("**ON P&F**"), and agreed that ON P&F and its subsidiaries are entitled to manufacture, register and distribute certain heart valve products developed by an affiliate of P&F Int'l in certain countries in the APAC region. For further details, please refer to the paragraph headed "Business – Our Collaborations with P&F Int'l" in this document.

We face significant competition in seeking appropriate strategic partners and the negotiation process for the collaboration, alliances joint venture arrangements or licensing arrangements can be time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our pipeline products because they may be deemed to be at too early of a development stage for collaborative effort and third parties may not view our pipeline products as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a pipeline product, we

might relinquish some or all of the control over the future success of that pipeline product to the third party. For any pipeline products 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.

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

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our existing and pipeline products;

- a collaborator 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 litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our pipeline products, or that result in costly litigation or arbitration that diverts management 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 applicable pipeline products; and/or

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

There is no guarantee that we will continue to agree on management matters with our joint venture partners due to possible conflict of interest, and any disagreement may result in a dispute between us and the relevant joint venture partner. In the event of a deadlock at a board meeting of such joint venture company, if we cannot resolve the disagreement in a timely manner through the dispute resolution mechanisms provided in our joint venture agreements, such deadlock may cause the board of directors of the relevant joint venture company to fail to make, or delay in making, an important decision.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships 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 transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a pipeline product, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our pipeline products or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

Failure to pass regulatory inspections and any other disruption or suspension of manufacturing activities may affect our business prospects and results of operations.

We manufacture, assemble and test our products at our production facilities located in Shenzhen, the PRC and Hoevelaken, Netherlands. Our production facilities are subject to regular inspections by the NMPA, FDA, PMDA, NB as part of the process of maintaining or renewing the permits, licenses and certificates required for our business and operations. Such inspections require us to comply with, among other things, GMP requirements. We cannot guarantee that we will be able to adequately follow and document our adherence to such GMP requirements or other regulatory requirements. When inspecting our manufacturing facilities, the NMPA, FDA, PMDA, NB or other comparable regulatory authorities may cite GMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the NMPA, FDA, PMDA, NB or other comparable regulatory authorities will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction, and may note further deficiencies during re-inspection. We may be required to delay, suspend or cease manufacturing activities if we fail to pass these regulatory inspections, which will affect our ability to fulfill product orders and sell our products, and in turn, have a material and adverse effect on our business prospects, financial condition and results of operations. We may be unable to secure temporary, alternative manufacturers for our products with the terms, quality and costs acceptable to us, or at all.

We may also encounter problems with maintaining consistent and acceptable production costs, experience shortages of qualified personnel and raw materials, unexpected damage to our facilities and equipment malfunction.

We had net current liabilities and net liabilities as of December 31, 2019 and we cannot guarantee that we will not have net current liabilities and net liabilities in the future.

We had net current liabilities of US$70.5 million and net liabilities of US$152.3 million as of December 31, 2019. Our net current liabilities and net liabilities position as of December 31, 2019 were primarily attributable to amount due to a related company and certain bank borrowings to support our research and development and other operating activities. During the year ended December 31, 2020, the current portion and non-current portion of amount due to a related company as deemed contribution of US$88.2 million and US$99.8 million has been capitalized as capital contribution to the Group. As a result, the Company turned into net current asset of US$19.0 million as of December 31, 2020. However, we cannot assure you that we would not incur net liabilities position in the future which can expose us to the risk of shortfalls in liquidity. This in turn would require us to undertake additional equity financing, which could result in dilution of your equity interests. Any difficulty or failure to meet our liquidity needs as and when needed can have a material adverse effect on our prospects.

We incurred net losses in the year ended December 31, 2021.

We recorded net losses of US$4.4 million in 2021 primarily due to (i) unwinding of interests on convertible redeemable preferred shares of US$4.9 million, (ii) share-based compensation expenses of US$1.3 million, (iii) fair value losses and loss on derecognition of convertible redeemable preferred shares of US$14.4 million and US$0.6 million respectively, and (iv) [**REDACTED**] of US$[**REDACTED**]. Our results of operations fluctuated and may continue to fluctuate from time to time, and we cannot guarantee that we will not incur losses in the future.

We may incur impairment losses on our intangible assets and goodwill.

We recorded intangible assets of US$0.3 million, US$4.0 million, US$4.3 million and US$4.1 million as of December 31, 2019, 2020 and 2021, and June 30, 2022, respectively, which mainly represented capitalized development costs and customer relationship. We also recorded goodwill of US$1.7 million as of December 31, 2020 and 2021 and June 30, 2022, which primarily arose from our acquisition of ON AG. See "History, Development and Corporate Structure" for details. Such goodwill recorded reflected the excess of the total acquisition consideration in the acquired company over the total fair value of identifiable net assets of the company we acquired.

Goodwill is tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Intangible assets that have a useful life are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. For details on the impairment assessment methods for our

intangible assets and goodwill, see Notes 2.7 and 2.8 to Appendix I to this document. Adverse changes in the future may result in decreases in the value of our intangible assets, which in turn would result in an impairment loss. In addition, we make certain assumptions when assessing the value of our intangible assets, including assumptions on their useful life. There are inherent uncertainties relating to these assumptions. We cannot assure you that our assumptions will prove to be correct. Any such change in our assumptions may require us to re-valuate our intangible assets, which may in turn result in impairment losses. Significant impairment losses on intangible assets may have a material adverse effect on our financial condition and results of operations and may in turn limit our ability to obtain financing in the future.

We may fail to maintain and predict inventory levels in line with demand for our products, which could cause us to lose sales or face the risk of obsolescence for our inventories.

Our inventories consist of raw materials, work in progress and finished goods. We regularly monitor our inventories to reduce the risk of overstocking. We physically count all of our raw materials, work in progress and finished goods on a regular basis to identify products that are expired or soon-to-be expired. Our Directors confirm that our inventory control system and policies have been effective and we did not experience any material shortage in supply or overstock of inventories during the Track Record Period and up to the Latest Practicable Date.

As of December 31, 2019, 2020, 2021 and June 30, 2022, we had inventories of US$26.0 million, US$30.0 million, US$29.6 million and US$27.9 million, respectively. During the Track Record Period, we made provision for inventories amounting to US$48,000, US$16,000, US$0.3 million and US$0.8 million for each of the years ended December 31, 2019, 2020 and 2021, and for the six months ended June 30, 2022, respectively. For the years ended December 31, 2019, 2020 and 2021, and for the six months ended June 30, 2022, our inventory turnover days were 302 days, 337 days, 310 days and 250 days, respectively. As our business expands, our inventory level may increase and our inventory obsolescence risk may also increase accordingly. We cannot guarantee that we will be able to maintain proper inventory levels for our raw materials, work in progress and finished goods. Our coronary and peripheral interventional products generally have shelf lives ranging from approximately 1.5 to 2 years. As of November 16, 2022, 84% of the finished goods aged over 12 months as of June 30, 2022 of US$1.6 million remained unsold and their average remaining shelf lives from November 16, 2022 were around 6 months. If these inventories are not sold within the shelf lives, we would make provision for impairment on these inventories in the subsequent financial period and our financial performance would be adversely affected. Inventory levels in excess of product demand may result in inventory write-downs, expiration of products and increase in inventory holding costs. Furthermore, any unexpected material fluctuations or irregularities in supply, or changes in customers' preferences may lead to decreased demand and overstocking of supplies and increase the risk of obsolescence. Conversely, we may experience inventory shortages if we underestimate demand for our products, which may result in unfilled orders and have a negative impact on our relationship with distributors and hospitals.

There is no assurance that information relating to the business plans and/or sales results of our distributors would be reported to us by our distributors accurately and/or in a timely manner. As our ability to assess our distributors' performance and creditworthiness is limited and may not be on a real-time basis, it is difficult for us to gather sufficient information and data regarding the market acceptance of our products and predict sales trends. Therefore, we may not be able to implement effective marketing or product strategies, and our business prospects, financial condition and results of operations will be materially and adversely affected.

We may face a heightened risk of inventory obsolescence arising from the prolonged lock-downs and other restrictive measures due to COVID-19.

In order to prevent and control the outbreak of COVID-19, many countries and regions, implement various control measures, including prolonged lock-downs and other restrictive measures. In severe pandemic situation where the operation of hospitals in these countries/regions were significantly affected by COVID-19, which could result in drop of the number of PCI/PTA procedures, our sales volume may decrease significantly. In such event, if we fail to manage our inventory levels effectively in response to prolonged lock-downs and other restrictive measures due to COVID-19, we may be subject to a heightened risk of inventory obsolescence, a decline in the value of inventories, and potential inventory write-downs or write-offs, which may materially and adversely affect our results of operations and financial condition.

We are subject to liquidity risk in our interests in a joint venture and if the joint venture do not perform as expected or do not generate sufficient revenue in any financial period, our financial condition or results of operations could be materially and adversely affected.

In 2020, 2021 and the first six months of 2021 and 2022, we recorded share of losses of a joint venture of approximately US$46,000, US$0.2 million, US$149,000 and US$71,000, respectively, which reflected our investments in ON P&F which engages in the manufacturing and distribution of heart valve products and our share of such joint venture's results of operations under equity method of accounting. For further details, please refer to the paragraph headed "Business – Our Collaborations with P&F Int'l" in this document.

Our interests in the joint venture may not guarantee a share of profits, and any loss incurred by such joint venture shall be apportioned between our Group and the other investor. If the joint venture do not perform as expected or do not generate sufficient revenue in any financial period, our return of interests in the joint venture, and our financial condition or results of operations, could be materially and adversely affected. We are also subject to the risk that the joint venture may make business, financial or management decisions with which we do not agree, and over which we do not have control, or the management, of the joint venture may take risks or otherwise act in a manner that does not serve our interests. In particular, the carrying value of our investment in a joint venture may be affected by a number of factors such as share of results, impairment, dilution, issuance of equity securities, and currency translation differences. Any of those above may adversely affect our business and results of operations.

In addition, our interests in the joint venture are subject to liquidity risk. Our interests in the joint venture are not as liquid as other investment products as there is no cash flow until dividends are received even if the joint venture reported profits under the equity accounting. Furthermore, our ability to promptly sell one or more of our interests in the joint venture in response to any changing economic, financial and investment conditions is limited. The market is affected by various factors, such as general economic conditions, availability of financing, interest rates and supply and demand, many of which are beyond our control. We cannot predict whether we will be able to sell any of our interests in the joint venture for the price or on the terms set by us, or whether any price or other terms offered by a prospective purchaser would be acceptable to us. Therefore, the illiquid nature of our interests in the joint venture may significantly limit our ability to respond to adverse changes in the performance of the joint venture. In addition, if there is no share of results or dividends from the joint venture, we will also be subjected to liquidity risk and our financial condition or results of operations could be adversely affected.

We are exposed to fair value change for financial assets at fair value through profit or loss and valuation uncertainty due to the use of unobservable inputs.

As of December 31, 2019, 2020 and 2021, and June 30, 2022, our financial assets at fair value through profit or loss were US$1.8 million, US$2.0 million, US$2.0 million and US$20.5 million, respectively. The significant increase in our financial assets at fair value through profit or loss from December 31, 2021 to June 30, 2022 was primarily due to the purchase of the Commodity Linked Fixed Rate Note of US$20.0 million for the purpose of generating interest income with minimal credit and liquidity risk, partially offset by the fair value loss thereof. Our financial assets are measured at fair value, and the changes in their fair values are recorded under other gains or losses in the consolidated statements of profit or loss, which will directly affect our profit and results of operations. We recognized fair value losses on financial assets at fair value through profit or loss of US$76,000, US$29,000 and US$1.3 million for each of the years ended December 31, 2020 and 2021 and for the six months ended June 30, 2022, respectively. The increase in fair value losses on financial assets at fair value through profit or loss in the first six months of 2022 was due to the increase in fair value loss of the Commodity Linked Fixed Rate Note of US$1.3 million. We recognized a fair value gain of US$60,000 for the year ended December 31, 2019. We cannot assure you that we will generate fair value gain in the future. If our investments incur a fair value loss, our results of operations and financial condition may be adversely affected.

During the Track Record Period, the fair value of our financial assets at fair value through profit or loss was determined by reference to unobservable inputs to the price of the underlying investments using a valuation pricing model and is classified as a level 3 fair value measurement. Changes in these unobservable inputs will affect the estimated fair value of our financial assets at the end of each financial reporting period. Given the inherent uncertainty in the fair value of financial assets at fair value through profit or loss, any significant and adverse changes in fair value could have an adverse effect on our financial position and results of operations. Details of our valuation techniques and sensitivity analysis of fair value to the unobservable inputs are set forth in note 3.3 to the Accountant's Report set out in Appendix I to this document.

We may not be able to recruit or retain a sufficient number of qualified employees. If we fail to globally retain and attract key personnel, our operations could be adversely affected.

Our business and growth depend on the continuous service of our senior management, the products under research by our research and development team and future products to be promoted by sales and marketing team. We have signed formal employment agreements with our employees, but these agreements do not prevent them from terminating their employment relationship with us at any time. We have not purchased key person insurance for any of our senior executives or other employees. The resignation of any of these personnel may hinder us from achieving our research and development, and commercialization goals.

The turnover of our senior executives or other key employees may prevent us from achieving our research, development and commercialization goals and severely undermine our ability to successfully implement business strategies.

In addition, changing senior executives or key employees may be difficult and time-consuming due to the limited number of people in our industry with extensive skills and experiences required for successful development, regulatory approval obtainment and product commercialization. The competition for talents from a limited talent pool is fierce. Given many medical device companies are competing for similar type of personnel, we may not stand a chance of hiring, training, retaining, or motivating these key personnel on acceptable terms.

Our success also depends on our ability to attract and retain qualified and skilled technical, research and development, sales and marketing, production and other personnel. We cannot assure you that we will be able to attract, hire and retain sufficient personnel for our business. Our Company also cannot guarantee that any shortages in qualified and skilled personnel will not increase our staff costs as the competition for these individuals could cause us to offer higher compensation and other benefits in order to attract and retain them and consequently materially and adversely affect our financial condition and results of operations.

We are also in face of competition from universities and research institutions for hiring research and development and clinical personnel. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue growth strategies will be restricted.

To induce valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided share options to our employees. The value to employees of these equity grants may be significantly affected by movements in the Share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical trials and commercialization strategy. Our consultants and advisors may be engaged by our competitors and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We cannot assure you that labor disputes will not occur between us and our employees in the future. If such incidents do occur, we may be subject to fines by relevant governmental authorities and may incur settlement costs in order to resolve labor disputes. In addition, we may become subject to higher labor costs in the future when recruiting new employees due to the reputational damage caused by labor disputes. Such potential incidents could disrupt our operations, harm our reputation and divert our management's attention, which may have a material and adverse effect on our business prospects, financial condition and results of operations.

We rely on third party logistics providers for delivering our products from our production facilities in the PRC and the Netherlands to customers throughout the world.

We rely on our third-party logistics service providers for the transportation of our products. The services provided by these logistics service providers may be suspended and cause interruption to the supply of our products due to unforeseen events. Delivery delays may occur for various reasons beyond our control, including poor handling by our logistics companies, labor disputes or strikes, acts of war or terrorism, health epidemics, earthquakes and other natural disasters, and could lead to delayed or lost deliveries. Poor handling of our products could also result in product contamination or damage, which may in turn lead to product recalls, product returns or exchanges, product liability, increased costs and damage to our reputation, thereby adversely affect our business prospects, financial condition and results of operations.

We have relied on and expect to continue to rely on third parties to supply raw materials to manufacture our products, and our business could be harmed if we are unable to obtain such raw materials in sufficient quantities or at acceptable quality or prices.

Our production processes require substantial amounts of raw materials and components. We rely on our suppliers for our business, which exposes us to risks associated with fluctuations in prices of raw materials, and reductions in the availability of raw materials may disrupt our operations. Significant fluctuations in raw material and component prices and availability will have a direct and negative impact on our gross profit margins. The principal raw materials for our products include medical grade stainless steel, polyester and nylon.

Any disruption in production or inability of our suppliers to produce adequate quantities to meet our needs could impair our ability to manufacture products as scheduled and to operate our business on a day-to-day basis. Moreover, we expect our demand for such raw materials to increase as we expand our business scale and commercialize our products, and we cannot guarantee that current suppliers have the capacity to meet our demand.

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers, and as a result, lower our profitability. For example, the average price of medical grade stainless steel in the PRC increased from RMB14.3 per kilogram in 2020 to RMB14.9 per kilogram in 2021, while the average price of polyester in the PRC increased from RMB5.4 per kilogram in 2020 to RMB5.6 per kilogram in 2021. The prices of medical grade

stainless steel, polyester, nylon or other raw materials may be affected by a number of factors, including market supply and demand, the international environmental and regulatory requirements, natural disasters such as fires, outbreak of epidemics or diseases and the global 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 prospects, financial condition and results of operations.

We cannot guarantee that we will be able to detect all quality issues in the supplies we use. We also cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the raw materials supplied to us. If we are unable to do so and the quality of our products suffers as a result, we may have to delay manufacturing and sales, recall our products, be subject to product liability claims, fail to comply with continuing regulatory requirements and incur significant costs to rectify such issue, which may have a material and adverse effect on our business prospects, financial condition and results of operations.

If we become subject to litigations, legal or contract disputes, government investigations, administrative proceedings or international economic sanctions, it may divert the attention of the management, and 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. On June 3, 2021, OIBV, one of our Material Subsidiaries incorporated in the Netherlands, accepted an out-of-court settlement agreement offered by the Dutch Public Prosecution Service in relation to a criminal investigation conducted by the Fiscal Intelligence and Investigation Service of the Netherlands and the Dutch Public Prosecution Service, which relates to certain unusual transactions regarding a suspicion of OIBV having given gifts to certain Belgian cardiologists between 2011 and 2015, by which OIBV allegedly gained a more favorable position concerning the supply of medical products to six hospitals in Belgium where those cardiologists worked. Please refer to section headed "Business — Legal Compliance and Proceedings" in the document for further details. 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 pipeline products, business prospects and results of operations. On-going or threatened litigation, legal or contractual disputes, government investigations, administrative proceedings or international economic sanctions may divert our management's attention and consume their time and our other resources. In addition, any similar claims, disputes or legal proceedings involving us or our employees may result in damages or liabilities, as well as legal and other costs and may cause a distraction to our management. Furthermore, any litigation, legal or contractual disputes, government investigations, administrative proceedings or international economic sanctions 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 any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. Consequently, our business prospects, financial condition and results of operations may be materially and adversely affected.

Our internal procedures and controls may fail to protect us from reckless or criminal acts committed by our employees or agents under applicable anti-bribery and anti-corruption laws.

We are subject to the anti-bribery laws of various jurisdictions, particularly in the PRC, the United States, the European Union and Japan. As our business expands, the applicability of the applicable anti-bribery laws to our operations has increased. The relevant laws 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. In addition, some of our customers may require us to follow strict anti-bribery and anti-money laundering policies as part of doing business with us. Our internal procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or agents. We could be liable for actions taken by our employees or distributors that violate anti-bribery, anti-corruption and other related laws and regulations in the PRC or other jurisdictions such as the United States, the European Union and Japan. The government authorities may seize the products involved in any illegal or improper conduct engaged in by our employees or distributors. As a reasonable portion of our business depends substantially on distributors for the sale of our products, any misconduct by our distributors or changes in the regulatory environment regarding the sale of medical devices could have a material adverse impact on our business prospects, financial condition and results of operations.

Our operation and business prospects may be adversely affected by natural disasters, terrorist attacks and political unrest.

Natural disasters, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets.

Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business prospects, financial condition and results of operations.

Our internal IT systems may fail, be subject to cyber-attacks, or have security breaches.

Despite the implementation of security measures, our internal IT systems are vulnerable to damage from computer viruses and unauthorized access. If such an event were to occur and cause interruption in our operations, it could result in material disruption of our development programs and business operations.

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

Furthermore, external parties may attempt to penetrate our systems or those of our vendors or deceptively induce our personnel or personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. The number and complexity of these threats will continue to increase over time. If there is a serious intrusion into our or our vendors' information technology systems, the market's perception of the effectiveness of our security measures could be damaged, and our reputation and credibility could be damaged. We may need 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 due to 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 and unfair or deceptive practices.

We have limited insurance coverage to adequately cover all the risks and hazards associated with our operations.

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, such as personal accident insurance. For details, please refer to the paragraph headed "Business – Insurance" in this document. We maintain insurance policies that are required under laws and regulations where we have operations, as well as based on our assessment of our operational needs and industry

practice. In line with industry practice in the countries where we have operations, we have elected not to maintain certain types of insurances, such as property damage insurance, keyman insurance and inland transit/marine cargo insurance. 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 operations if such losses or liabilities are not covered by our insurance policies.

RISKS RELATING TO MANUFACTURING AND SUPPLY OF OUR PRODUCTS

We mainly rely on our production facilities in Shenzhen and the Netherlands for substantially all of our revenue. Damage to, destruction of or interruption of production at our production facilities, or delays in completing our new production facilities could adversely affect our business prospects, financial condition and results of operations, and delay our development plans or commercialization efforts.

As of the Latest Practicable Date, we had two production facilities in the PRC and the Netherlands. The operation of our production facilities may be substantially interrupted due to a number of factors, many of which are outside of our control, including but not limited to fires, floods, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities, and regulatory changes. Any interruption in manufacturing operations at our production facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. We may not be able to replace the equipment at such facilities, or use a different facility to continue production in a timely and cost-effective manner. As a result, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenue and profitability could be materially adversely affected.

There can be no assurance that our existing manufacturing facilities will produce products in sufficient volumes in the event of any significant change in market demand. In such event, we may have to engage third parties to produce a portion of such products. Consequently, we are exposed to the risks of increased pricing for our sub-contracted production and that the third parties may not manufacture products meeting our specifications or in sufficient volumes to meet market demand. As a result, our sales volumes and margins for the relevant products could be materially and adversely affected.

Advances in manufacturing techniques may render our facilities 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, or if the process to do so is delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, 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.

The manufacture of our products is highly complex and subject to strict quality controls. If we or any of our suppliers or logistics partners fail to maintain effective quality control over our products, encounter manufacturing, logistics, or quality problems, or in anyway not in compliance with all the applicable quality standards, including as a result of natural disasters, it may adversely affect our business.

The manufacture of our products is highly complex and subject to strict quality controls. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Despite our quality control and assurance system and procedures, we cannot eliminate the risk of product defects or failure. Problems can arise during the manufacturing process for a number of reasons, including facilities and equipment malfunction, failure to follow protocols and procedures, defects or other issues in raw material, or human error. 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, lost revenue, damage to customer relationships, 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 raw materials, products or in the manufacturing facilities, such manufacturing 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 manufacture of our products or pipeline products 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.

As we expand into new markets, we may face unanticipated surges in demands for our products which could strain our production capacity. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the NMPA, FDA, PMDA, NB or other applicable regulatory body, which include detailed record-keeping requirements, our reputation could be damaged. We could become subject to a safety alert or a recall, incur product liability and other costs Product approvals could be delayed, and our business would be adversely affected.

If we fail to increase our production capacity as planned, our business prospects could be materially and adversely affected.

We may need to increase or scale up the production capacity and utilization rate to supply our products in sufficient volumes to meet market demand. Advances in manufacturing techniques may render our facilities 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 Also, we may need to employ more task personnel to enhance our production capacity. If we are unable to do so, or if the process to do so is delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, 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.

To further scale up our production capacity, we plan to use approximately HK$[**REDACTED**] of the [**REDACTED**] from this [**REDACTED**] to expand our production capacities by constructing, renovating and purchasing machinery and equipment for the new facility to be built on a new land parcel. New manufacturing facilities are intended to be used for manufacturing our pipeline products upon approval. Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured, 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 prevent the launch of a product. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the products made at the new facility are equivalent to the products made at the former facility and thus satisfying the relevant product requirements, 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 delay. In the event we fail to increase our production capacity or develop the new manufacturing facility, we may not capture the expected growth in demand for our products, or to successfully commercialize new products, each of which could materially and adversely affect our business prospects.

Our ability to successfully implement our expansion plan is subject to a number of risks, including our ability to obtain the requisite permits, licenses and approvals for the construction and operation of the new production lines, the risk of construction delays, as well as our ability to timely recruit sufficient qualified staff to support the increase in production capacity. Consequently, there can be no assurance that we will be able to increase our overall production capacity or develop advanced manufacturing techniques and process controls in the manner we contemplate, or at all. In the event we fail to increase our production capacity or develop advanced manufacturing techniques and process controls, we may not capture the expected growth in demand for our products, or to successfully commercialize new products, each of which could materially and adversely affect our business prospects. 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.

RISKS RELATING TO COMMERCIALIZATION AND DISTRIBUTION OF OUR PRODUCTS

We may be unable to effectively manage our network of distributors, and actions taken by our distributors and violation of distribution agreements could materially adversely affect our business prospects and reputation.

Consistent with the industry practice, we sell a substantial portion of our endovascular interventional medical devices to distributors in overseas countries, which then sell these devices to hospitals. As of June 30, 2022, we had approximately 207 distributors globally. The performance of our distributors and the ability of our distributors to on-sell our products, uphold our brand, expand their businesses and sales network are crucial to the growth of our business and may directly affect our sales volume and profitability. Due to our dependence on

our distributors for the sale and distribution of our products, any reduction, delay or cancellation of orders from our distributors, or our failure to renew distribution agreements, maintain good relationships with existing distributors, or timely identify and engage additional or replacement distributors upon the loss of one or more of our distributors, may cause material fluctuations or declines in our revenue or the sustainability of our growth and have a material and adverse effect on our business prospects, financial condition and results of operations. In addition, a decline in our distributors' performance could lead to a decline in the productivity of our network of distributors and could have a negative impact on our results of operations.

We intend to continue engaging distributors to sell our products and pipeline products in the foreseeable future. However, we may not be able to identify or engage a sufficient number of distributors with an extensive sales network. If our distributors fail to expand or maintain their sales network, or otherwise encounter any difficulties in selling our products, our sales will decline and our business prospects and results of operations may be materially and adversely affected.

We provide our distributors with technical support, including training in the basic technologies of our products, participating in presentations to physicians and hospitals, and assisting in preparing documents for contracts awarded through competitive biddings and tenders. Our distributors face a learning process with respect to our existing and pipeline products, particularly for those newly introduced to the market. We cannot assure you that our distributors will be able to gain the required knowledge in order to market our products and pipeline products effectively in a timely manner or at all.

We may have limited control over the operations and actions of our distributors and their associated partners. 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 and regulations. Please refer to "Business – Sales, Marketing and Distribution – Selection and Management of Distributors" in this document. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach our agreements and policies. If our distributors take one or more of the following actions, our business prospects, results of operations and reputation may be adversely affected:

- breaching the distribution agreements or our policies and measures, including by selling competing products, by selling products outside their designated territories or to hospitals without further authorization, possibly in violation of the exclusive distribution rights of our other distributors, or by selling products that they are not authorized to sell;

- failing to adequately promote our products;

- failing to meet certain target sales amounts;

- failing to provide proper training and after-sales services to our end-users;

- failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements when marketing and selling our products; or

- violating anti-corruption, anti-bribery, competition or other laws and regulations.

Any disputes between us and our distributors, complaints by our distributors, violation or alleged violation by our 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 prospects, financial condition and results of operations.

We have distributors located in different jurisdictions. Our arrangements with those distributors are thus subject to the respective laws and regulations of those particular jurisdictions. Therefore, enforcement of our distribution agreements might involve complicated legal process, including but not limited to, service of foreign business partners, cross-border legal actions, application of foreign laws and recognition of foreign judgements, which may result diverting the Company's attention from our operations and also adversely impact our business prospects, financial condition and results of operations.

Moreover, some of our distributors may engage sub-distributors to distribute our products. We mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors and our policies and measures that our distributors agree to comply with. There is no assurance that the sub-distributors will comply with the geographical restrictions we have agreed with our distributors, distribute only to authorized hospitals or other medical institutions, or comply with other distribution requirements under our distribution agreements and policies. Furthermore, we cannot assure you that we will be able to identify or correct all the sub-distributors' practices that are detrimental to our business in a timely manner or at all, which may adversely affect our results of operations and reputation. As there is no contractual relationship between us and these sub-distributors, we have no direct legal recourse against them if their activities cause harm to our business or reputation.

We review the performance of our distributors from time to time, and seek to retain and engage more competent distributors to maintain and expand our overall network of distributors. We may experience challenges when developing our network of distributors, especially in regions where we have relatively low or no presence, such as unfamiliarity with local business and market practices and local laws and regulations, as well as fierce competition with local or overseas competing brands. The competition for distributors is intense in our industry. We may not be able to offer the most favorable arrangements to our distributors as compared to competitors who may be larger and have better-funded sales and marketing campaigns. Competitors may require their distributors to sign exclusive distribution agreements that prohibit such distributors from selling our products.

We prevent the occurrence of channel stuffing through adopting a strict product return policy. We generally do not accept product return or exchange except in case of any product defect or product expiration. We cannot guarantee that such strict product return policy will be effective in the future at the same level as in the Track Record Period. The failure in avoiding the occurrence of channel stuffing may result in reduction of the number of distributors and hence adversely affecting our financial condition and results of operation.

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

Our future growth and success significantly depend on our ability to successfully market our products to hospitals and other medical institutions through our in-house sales and marketing team and our distributors. Hospitals and medical institutions may organize public tenders either by themselves or through local governments. The procedures of such public tenders vary from hospital to hospital and from region to region, and there could be uncertainties with respect to the timing of such procedures. Other than our in-house sales and marketing team, we are also dependent 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 and other medical institutions.

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: (i) our prices are not competitive; (ii) our products fail to meet the technical or quality requirements imposed by the hospitals or are less clinically effective than competing products;(iii) our reputation is adversely affected by unforeseeable events; or (iv) 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 pipeline products (upon commercialization) and our revenue may decline, materially adversely affecting our results of operations and financial condition.

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

The commercial success of our current and future products depends upon the degree of market acceptance they achieve, particularly among physicians and hospitals. Physicians and patients may prefer other treatments to vascular diseases. If our products or pipeline products fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the industry, the sales of our products will be adversely affected. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our products and pipeline products do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our products and pipeline products, if approved for commercial sale, will depend on a number of factors, including:

- the usage for which our products and pipeline products are approved;

- physicians and hospitals considering our products and pipeline products (upon commercialization) as a safe and effective treatment;
- the potential and perceived advantages and disadvantages of our products, pipeline products (upon commercialization) and relevant treatments compared to alternative products and treatments;
- the prevalence and severity of any side effects, adverse effects or complications;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our existing products and pipeline products (upon commercialization) as well as competitive products;
- the cost in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and/or
- the effectiveness of our sales and marketing efforts.

Physicians face a learning process to become proficient in the use of some of our existing and pipeline products, which may take longer than expected and therefore affect our ability to sell our products. Encouraging physicians to dedicate the time and energy necessary for adequate training remains challenging, and we may not be successful in these efforts. If physicians are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our reputation, business prospects, financial condition and results of operations. Following completion of training, we also rely on trained physicians to advocate the benefits of our products in the marketplace. If we do not receive support from such physicians, other physicians and hospitals may not use our products, and our results of operations may be adversely affected. If we are unable to attract a sufficient number of qualified sales personnel to support our hospital penetration strategy, sales volumes or margin of our future products may be adversely affected and we may be unable to extend our hospital coverage and deepen our market penetration as contemplated.

We may be unable to maintain long-term relationships with our customers.

In 2019, 2020, 2021 and for the six months ended June 30, 2022, sales to our largest distributor customer in each year/period of the Track Record Period amounted to US$8.3 million, US$6.2 million, US$7.2 million and US$7.0 million, respectively, accounting for 8.6%, 7.0%, 6.2% and 10.2% of our total revenue for the same periods, respectively. In 2019, 2020, 2021 and for the six months ended June 30, 2022, sales to our largest direct customer in each year/period of the Track Record Period amounted to US$3.0 million, US$2.0 million, US$2.2 million and US$1.0 million, respectively, representing 3.1%, 2.3%, 1.9% and 1.5% of our total revenue for the same periods, respectively. Please refer to the paragraph headed "Business – Our Customers" in this document. We have built amicable and long-term business relationships with most of our customers, with no less than 50% of our top five customers during the Track Record Period having over 12 years of business relationship with us. However, there is no assurance that we will be able to maintain strong relationships with these customers, or that these customers will continue to work with us or renew their sales contracts with us on similar or commercially reasonable terms in the future. Moreover, we cannot guarantee that our major customers will not have a change in business scope or business model, will not cease to operate, will operate in compliance with applicable laws, will be able to maintain their sales network and appropriate licenses and approvals for their operations or will not experience operational or financial difficulties. Any material adverse change to the business prospects, results of operations and financial condition of these customers may have a significant adverse impact on us, and if we are unable to find new customers on comparable commercial terms within a reasonable period of time, our business prospects, financial condition and results of operations may be adversely affected.

Our products may be subject to decreasing pricing trends and reduced margins. If we are unable to successfully replace the products subject to those trends with newer, more profitable products, our business prospects, financial condition and results of operations could suffer.

We may experience reduced pricing power and gross profit margin erosion from our existing products generally as their sales decrease in a given mature market, while manufacturing and material costs may remain constant or increase. For example, according to CIC Report, the average retail price of each of same model of standard PCI balloons, same model of standard PTA balloons and same model of drug eluting stents is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch. The growing pricing pressure may arise in the future due to procurement policies from government authorities and/or increased competition. Our profitability depends on our ability to successfully launch new products, enter new markets, control costs during the manufacturing process by increasing the efficiency of our manufacturing processes and increasing production yields. If we are unable to successfully design, develop, manufacture and market new products, which typically generate higher gross profit margins, or if we fail to effectively increase the efficiency of our manufacturing processes or control manufacturing costs, our business, financial condition and results of operations could be harmed.

Our sales depend to a certain extent on the level of insurance reimbursement patients receive for treatments using our products.

Our ability to sell our products depends to a certain extent on the availability of governmental and private health insurance in the countries where we have operations. We have pursued, and plan to actively pursue reimbursement opportunities globally. However, we cannot be sure that reimbursement will be available for our products and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with newly introduced technology or medical devices. In the absence of sufficient medical insurance coverage for the use of our products, patients may choose alternative treatment methods, and hospitals may recommend such alternative treatments, which would reduce demand for our products and our sales which could in turn materially and adversely affect our business prospects, financial condition and results of operations. 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.

RISKS RELATING TO DOING BUSINESS IN COUNTRIES WHERE WE HAVE OPERATIONS

Economic, political, social conditions as well as government policies in jurisdictions where we have operations, and the relationships between countries where we have operations, could adversely affect our business prospects, financial condition and results of operations.

During the Track Record Period, we had significant operations in the PRC, Japan, EMEA, the U.S. and the APAC region. Our business is therefore subject to constantly changing international economic, social and political conditions, and local conditions in these countries and regions.

The political relationships between these countries and regions may affect the prospects of our relationship with third parties, such as customers, suppliers, and global partners. It is notable that the United States government has made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including the PRC and members of the European Union, imposing tariffs against the United States in response. These trade wars may escalate going forward and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between the PRC and the relevant foreign countries or regions. Any tensions, political concerns, and trade frictions between countries where we have operations may cause a decline in the demand for our products and adversely affect our business prospects, financial condition, results of operations and cash flows.

International expansion may be costly, time consuming and difficult.

We will seek product registration in overseas markets, such as countries in the Latin America. However, we may expose us to risks and uncertainties, including the risks related to:

- A plenty of time may be spent in obtaining registration and approval to sell our products in other countries (especially in developed countries);
- Some emerging markets where we are building our brand awareness may lack the necessary resources;
- Commercializing products in new markets with limited operating experience and no sales and marketing foundation;
- Some physicians in the new markets may lack the knowledge about our products in performing interventional procedures, and therefore we may need to provide product training to improve their awareness and recognition of our products and related procedures;
- Distributing, commercializing, and marketing our products through overseas partners or distributors;
- Product liability lawsuits arising from marketing and sales of products in overseas markets and regulatory review and processing costs incurred by such procedures, and our ability to obtain insurance to fully protect us from any liability arising therefrom;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness and inflation;
- Difficulties in effectively enforcing contract provisions in local jurisdictions;
- Compliance with taxation, employment, immigration, and labor laws for employees traveling abroad;
- The impact of applicable foreign tax structures and potential adverse tax consequences;
- Currency fluctuations that may lead to operating expense increase and revenue decrease;
- Workforce uncertainties and labor unrest; and
- Business interruption caused by geopolitical actions (including war and terrorism), sanctions or natural disasters (including earthquakes, volcanoes, typhoons, floods, hurricanes, and fires).

There are uncertainties regarding the interpretation and enforcement of laws, rules and regulations of different jurisdictions.

We have business operations in different jurisdictions globally. For example, we have distribution networks in over 70 countries and regions, and we have relied on our manufacturing facilities located in the PRC and the Netherlands to produce most of our products. Our operations in the different jurisdictions are therefore governed by the relevant laws and regulations.

For example, the PRC legal system and the German legal system are civil law systems based on written statutes and prior court decisions have limited precedential value. Additionally, some laws and regulations are constantly changing and some laws and regulations are often principle-oriented which may require detailed interpretations by the enforcement bodies to apply and enforce and thus may cause the uncertainties in the course of the interpretation and enforcement. For example, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect.

Fluctuations in exchange rates of foreign currencies could result in foreign currency exchange losses, and adversely affect our business prospects, results of operations and financial condition.

We have significant operations in the Mainland China, Hong Kong, Japan, Europe, the U.S. and several other jurisdictions, and our cash and cash equivalents are denominated in various foreign currencies while we report revenues, costs and earnings in U.S. dollars. Thus, we are subject to foreign exchange fluctuations and are exposed to foreign currency risk.

The exchange rate of the Renminbi, Euro, Japanese Yen against the U.S. dollar fluctuates and is affected by, among other things, the policies of the government in the PRC, Europe, Japan and the United States, and changes in international political and economic conditions, as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may influence the exchange rates. In addition, the People's Bank of China regularly intervenes in the foreign exchange market to limit fluctuations in Renminbi exchange rates and achieve policy goals. The fluctuations in currency exchange rates could result in a significant appreciation of Renminbi against the U.S. dollar, the Hong Kong dollar or other foreign currencies, thereby adversely affect our business prospects, results of operations and financial condition.

Our global transfer pricing model may subject to challenges raised by tax authorities in different jurisdictions.

Our Company's tax position may be subject to review and possible challenge by the relevant government authorities and any possible change or challenge in laws. If our tax position is subject to review and possible challenge by the Hong Kong, the Mainland China, the Netherlands, Japan and/or other tax authorities or there is a change in the tax policy and

relevant tax laws in Hong Kong, the Mainland China, the Netherlands, Japan and/or other jurisdictions, it may adversely affect our Company's financial position and results of operations. In preparing our Company's financial information, our Directors have reviewed and assessed our Company's transfer pricing risk as it is possible that the tax authorities may challenge our Company's transfer pricing arrangements. Yet, there can be no assurance that our Company will not be found to be operating in breach of the relevant transfer pricing laws and regulations, or that such laws will not be modified, which, as a result, may require changes to our Company's transfer pricing arrangements. Any determination of income reallocations or modifications of the relevant transfer pricing laws and regulations could result in an income tax assessment and other relevant charges on the portion of income deemed to be derived from the taxing jurisdiction that so reallocates the income or modifies its relevant transfer pricing-related laws.

The discontinuation of the preferential tax treatment currently available to us could adversely affect our results of operations and financial condition.

According to the PRC Enterprise Income Tax Law (中華人民共和國企業所得税法) and its implementation rules, foreign-invested and domestic enterprises are subject to a unified enterprise income tax rate of 25% and a high and new technology enterprise is entitled to a reduced enterprise income tax rate of 15%.

Our PRC subsidiary, ONM Shenzhen, was recognized as a high and new technology enterprise in 2017 and 2020, respectively, and has been entitled to the reduced enterprise income tax rate of 15% during the Track Record Period. The current high and new technology certificate of ONM Shenzhen was issued on December 11, 2020 with the validity of three years therefrom. To renew the high and new technology enterprise certificate, ONM Shenzhen is required to remain or meet various criteria, including among others, a certain level of research and development spending and a certain number of the research and development employees, which are subject to the review and approval of the relevant authorities.

There can be no assurance that ONM Shenzhen will be able to meet such requirements and will successfully renew the high and new technology enterprise certificate or continue to enjoy the preferential tax treatment for high and new technology enterprises in the future. In the event that ONM Shenzhen fails to renew the high and new technology certificate or the PRC government changes its tax policy of supporting high and new technology enterprises, we may be subject to a higher enterprise income tax rate (i.e. 25%) in the PRC and our results of operations and financial condition may be adversely affected.

Save as disclosed above, ONM Shenzhen enjoyed other preferential tax treatments in the PRC, such as pre-tax additional deductions for research and development expenses. Pursuant to the Notice on Increasing the Percentage of Pre-tax Additional Deduction of Research and Development Expenses (關於提高研究開發費用税前加計扣除比例的通知) promulgated by the Ministry of Finance, the State Administration of Taxation and the Ministry of Science and Technology of the PRC, with respect to the research and development expenses that are actually incurred in the research and development activities of an enterprise, an extra 75% of

the actual amount of expenses is deductible before tax, in addition to the deduction of actual expenses as prescribed by laws, during the period from January 1, 2018, to December 31, 2020, provided that the said expenses are not converted into the intangible asset and balanced into the enterprise's current gains and losses. The said preferential tax treatment policy was extended to December 31, 2023 according to Announcement of the Ministry of Finance and the State Taxation Administration on Extending the Implementation Period of Certain Preferential Tax Policies (財政部、税務總局關於延長部分税收優惠政策執行期限的公告). The percentage of pre-tax additional deduction for research and development expenses of manufacturing enterprises has been increased to 100% since January 1, 2021, according to the Announcement on Further Improving the Policies Regarding Pre-tax Additional Deduction of Research and Development Expenses (關於進一步完善研發費用税前加計扣除政策的公告) promulgated by the Ministry of Finance and the State Administration of Taxation on March 31, 2021. ONM Shenzhen was entitled to enjoy an extra 75%, 75%, 100%, 100% and 100% of pre-tax deduction for its eligible research and development expenses for the purpose of enterprise income tax for the years ended December 31, 2019, 2020 and 2021 and for the six months ended June 30, 2021 and 2022, respectively. However, there is no guarantee such preferential tax treatment will continue to be valid in the future. If the relevant preferential tax treatment policies are cancelled or we are not entitled to enjoy the relevant preferential tax treatments, our financial condition may be adversely affected.

Shortages in the availability of foreign currency may limit the ability of us to utilize our revenues effectively to pay dividends or perform other obligations.

Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends to our Shareholders or satisfy our foreign currency demands for other purposes.

Under the current PRC foreign exchange regulations, international payments of current account items, such as profit distribution, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with SAFE or its designated banks is required where RMB is to be converted into foreign currency and remitted out of the PRC under capital account items such as repayment of offshore loans or outbound investment. There is no assurance whether the PRC government will at its discretion restrict access to foreign currencies for current account items or capital account items. If the foreign exchange control policies prevent us from purchasing sufficient foreign currencies and remitting outside the PRC, it may limit our ability to utilize revenue generated in RMB to fund our business activities outside the PRC or to pay dividends in foreign currencies to holders of our Shares.

You may experience difficulties in effecting service of legal process and enforcing judgments or bringing original actions in the Mainland China or Hong Kong based on foreign laws against us and our Directors and management.

Most of our executive Directors and senior management reside in Hong Kong and a considerable portion of our assets are located in the PRC. Therefore, it may not be possible to effect service of process within or elsewhere outside of Hong Kong and the Mainland China upon us or our Directors or senior management. Moreover, the PRC government has not entered into treaties for the reciprocal recognition and enforcement of court judgments with Japan, the United Kingdom, the United States and many other countries, and Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in Hong Kong or the Mainland China of a court judgment obtained in other jurisdictions may be difficult or impossible.

On July 14, 2006, the Supreme People's Court of the PRC and the Hong Kong government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《最高人民法院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 "**Arrangement**"). Pursuant to the Arrangement, a party with a final court 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 the Mainland China. Similarly, a party with a final judgment rendered by a PRC court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong or PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it may not be possible to enforce a judgment rendered by a Hong Kong court in the Mainland China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. Although the Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain.

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, our Group sold balloon catheters and medical stents to distributors located in the Relevant Regions. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our revenue generated from such transactions related to the Relevant Regions was US$6.5 million, US$5.5 million, US$6.3 million and US$1.5 million respectively, representing 6.9%, 6.2%, 5.4% and 2.2% of our total revenue for the same periods, respectively. These sales included sales to distributors located in Iran and the Syria Arab Republic as well as sales to distributors located in Russian Federation, Belarus and Ukraine. Sales to Iran and Syria in 2019, 2020, 2021 and for the six months ended June 30, 2022 was US$1.1 million, US$1.4 million, US$2.9 million and US$0.6 million, respectively, representing 1.1%, 1.6%, 2.5% and 0.9% of our Group's total revenue for the same periods, respectively. Syria and Iran are subject to general and comprehensive embargoes under sanctions imposed by OFAC. In addition, our aggregated sales to Russian Federation, Belarus and Ukraine in 2019, 2020, 2021 and for the six months ended June 30, 2022 was US$3.1 million, US$2.7 million, US$1.9 million and US$0.3 million, respectively, representing 3.2%, 3.1%, 1.6% and 0.4% of our Group's total revenue for the same periods, respectively.

As advised by our International Sanctions Legal Advisors, our Group's transactions related to Iran and Syria did not violate U.S. sanctions (or sanctions laws of other Relevant Jurisdictions). This is due to a combination of factors, namely that (1) none of the U.S. Group entities or any U.S. Persons employed by or acting on behalf of our Group were involved in business dealings with Iran or Syria; (2) the payments for sales to Iran were not made in U.S. dollars, and did not involve the U.S. financial system; and (3) while payments for the export to Syria were carried out using U.S. dollars, this does not raise an issue in relation to the sales of medical devices to Syria in light of the General Licence which allows for the exportation of services (including clearing of USD payments) incidental to sales of non-U.S. origin medical devices which would be designated as EAR 99 under the EAR, if they were subject to the EAR. Further, our Group has made sales to distributors in the Russian Federation, Ukraine (but not the Crimea region, and since February 21, 2022 the regions of Donetsk and Luhansk of Ukraine), Egypt, Lebanon, Myanmar, Belarus, Serbia and Tunisia. These countries were subject to certain limited sanctions during the Track Record Period and up to the Latest Practicable Date (including the sanctions newly imposed in relation to Russia and Belarus as a result of the recent Russo-Ukrainian conflict). As advised by International Sanctions Legal Advisors, our Group's transactions related to these countries also did not violate U.S. sanctions (or sanctions laws of other Relevant Jurisdictions). Consequently, based on the above we are advised by International Sanctions Legal Advisors that our Group did not engage in any Primary Sanctioned Activity during the Track Record Period and up to the Latest Practicable Date that violate applicable law or regulation.

None of our contracting parties located in the Relevant Regions are specifically identified on the Specially Designated Nationals and Blocked Persons List or the Sectoral Sanctions Identifications List maintained by OFAC or other restricted parties lists, including those maintained by the European Union, the United Nations, the United Kingdom, and Australia. In the absence of any information to the contrary, we have no reasonable grounds to believe that any of the owners, controllers or directors of the contracting parties are on such lists either. Further, our sales do not involve industries or sectors that are currently subject to specific

sanctions imposed by the United States, the European Union, the United Nations, the United Kingdom, and Australia. Consequently, we are advised by International Sanctions Legal Advisors that our secondary sanctions exposure is low.

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 Relevant Regions. We have no intention to undertake and will not conduct any future business with persons on the SDN Lists, although we will continue to have the dealings that present low sanctions risks as described and explained above, including sales to Iran and Syria through distributors located in those countries. In addition, we have implemented and will implement enhanced internal control and risk management measures which we believe enable us to monitor and evaluate our business to address economic sanctions risks. Please refer to the paragraph headed "Business – Internal Control over Business Operations – Internal Control." in this document. 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 [**REDACTED**] and group companies, or any person involved in the [**REDACTED**] and accordingly, the sanction risk exposure to our Company, its investors and shareholders, and persons who might, directly or indirectly, be involved in permitting the [**REDACTED**], trading and clearing of our Shares (including the Stock Exchange, its [**REDACTED**] and related group companies) is low.

We cannot 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, sanctions laws and regulations are constantly evolving and new requirements or restrictions could come into effect which might increase the scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions or being sanctionable. We cannot entirely exclude the risk of any changes in sanctions laws and regulations resulting in our Group having greater exposure to International Sanctions penalties in connection with future sales to the Relevant Regions. 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.

RISKS RELATING TO OUR FINANCIAL POSITION

Our business requires certain amount of capital to finance our ongoing operations and expansion. Failure to manage our liquidity and cash flows or inability to obtain additional financing or refinancing of our banking facilities may adversely affect our business prospects, financial condition and results of operations.

Our operations require significant capital investment. Historically, we had financed our business activities primarily through cash generated from our operations. If our current sources are insufficient to satisfy our cash requirements, we may seek additional debt or equity financing or obtain a credit facility. The issuance of additional equity securities or convertible debt securities could result in dilution to our Shareholders. The incurrence of indebtedness could result in increased debt service obligations, increased finance costs and operating and financing covenants that would restrict our operations and liquidity and negatively impact our financial performance.

Our ability to obtain additional capital on acceptable terms is subject to, among other things, investors' perception of and demand for our securities, our financial performance and gearing ratio, and the economic, market, political and regulatory conditions in the countries where we have operations. Any failure by us to raise additional funds that are necessary for our operations on terms favorable to us could have a material adverse effect on our liquidity and financial condition.

Furthermore, if we raise additional funds through debt financing, we may be subject to covenants or other restrictions. We may also not be able to secure sufficient debt financing and/or refinancing to fund our required capital expenditures or support our future investment strategies or operations on acceptable terms or at all. If we are unable to secure such funding, we may have to reduce our planned capital expenditures and delay or abandon our expansion plans.

Our historical operating results may not be representative of future performances.

Our revenue decreased from US$96.3 million in 2019 to US$88.5 million in 2020, and increased to US$116.5 million in 2021. Our revenue increased from US$57.3 million for the six months ended June 30, 2021 to US$68.9 million for the six months ended June 30, 2022. Our gross profit decreased from US$65.4 million in 2019 to US$58.0 million in 2020, and increased to US$81.2 million in 2021, and our gross profit margin decreased from 67.9% in 2019 to 65.6% in 2020 and increased to 69.7% in 2021. Our gross profit increased from US$40.5 million for the six months ended June 30, 2021 to US$47.7 million for the six months ended June 30, 2022, while our gross profit margin decreased from 70.7% for the six months ended June 30, 2021 to 69.3% for the six months ended June 30, 2022. Our adjusted profit (non-HKFRS measure) increased from US$7.0 million in 2019 to US$7.1 million in 2020 and further increased to US$21.4 million in 2021. Our adjusted net profit margin (non-HKFRS measure) increased from 7.2% in 2019 to 8.0% in 2020 and further increased to 18.3% in 2021. Our adjusted profit for the period (non-HKFRS measure) increased by 23.6% from US$11.0

million for the six months ended June 30, 2021 to US$13.6 million for the six months ended June 30, 2022, and our adjusted net profit margin increased from 19.2% for the six months ended June 30, 2021 to 19.8% for the six months ended June 30, 2022. We cannot assure you that our historical operating results, such as our revenue, gross profit, net profit, gross profit margin and net profit margin, will be indicative of future performance for various reasons, including uncertainties of the success of our existing and new products, and in the market and the regulatory environment, as well as our ability to expand production capacity and improve manufacturing capabilities as planned, and manage our sales network and intensified competition in the global endovascular interventional instrument market worldwide. Investors should not rely on our historical results as an indication of our future financial or operating performance.

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

We have 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 the years ended December 31, 2019, 2020 and 2021 and for the six months ended June 30, 2022, we recognized government grants under other net income of US$1.1 million, US$2.3 million, US$1.2 million and US$0.3 million, respectively. For details, please refer to the paragraph headed "Financial Information – Description of Consolidated Statements of Profit or Loss – Other Income" in this document. Our eligibility for government grants is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the 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. There is no assurance that we will continue to receive such government grants or receive similar level of government grants, or at all, in the future.

We might experience delays in collecting trade receivables, which could adversely affect our cash flow.

Our cash flow and profitability would be affected by the timely settlement of payments by our customers. We sell our products to distributors in different jurisdictions such as the PRC, the United States, EMEA and Japan. We generally grant our distributors a credit term of 30 days to 180 days, and we typically only grant longer credit terms to major distributors on a case-by-case basis based on our assessment. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had trade receivables of US$32.6 million, US$26.3 million, US$26.8 million and US$29.7 million, respectively. For the years ended December 31, 2019, 2020 and 2021 and for the six months ended June 30, 2022, our trade receivable turnover days were 129 days, 132 days, 89 days and 78 days, respectively. Our sales and marketing employees monitor and manage our distributors and are responsible for collecting amounts due from distributors. We cannot assure you that our distributors could settle trade receivables in a timely manner, or at all, or that we can properly assess and respond in a timely manner to changes in their credit

profile and financial condition. Adverse changes in their financial condition may negatively affect the length of time that it will take us to collect associated trade receivables or impact the likelihood of ultimate collection, which would in turn have an adverse and material effect on our business prospects, financial condition and results of operations. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with distributors in a manner that will impair the effective distribution of our products. Therefore, we may be exposed to credit risk in relation to our customers. Moreover, as we continue to grow our business, the amount of trade receivables we record may increase, which may have a negative impact on our cash flow.

Share-based compensation expenses may cause shareholding dilution to our existing Shareholders and affect our financial performance.

We have adopted the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme, the principal terms of which are summarized in the paragraph headed "D. Share Incentive Schemes" in Appendix IV to this document. For 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, we incurred share-based compensation expenses of nil, nil, US$1.3 million, US$0.7 million and US$0.4 million, respectively. Issuance of additional Shares with respect to such share-based compensation may dilute the shareholding percentage of our existing Shareholders. Expenses with respect to such share-based compensation may also increase our operating expenses and therefore may affect our financial performance.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain and maintain patent protection for our existing and pipeline products 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 technology, products and pipeline products from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technology, products and pipeline products that we consider commercially important by filing patent applications in the PRC, the United States and other jurisdictions such as the European Union and Japan, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. We may also fail to identify patentable aspects of our research and development output in time to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. For instance, in some jurisdictions, patent applications for inventions are typically not published until 18 months after filing, or in some cases, not at all. For example, under the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the Standing Committee of the National People's Congress, as amended, patent applications for inventions are generally maintained in confidence until their publication at the end of 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and the date on which patent applications were filed. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions.

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, the United States and other jurisdictions such as the European Union and Japan. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA, the United States Patent and Trademark Office (USPTO) or other related intellectual property 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 technology, products or pipeline products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize existing and pipeline products without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the CNIPA, the USPTO or other related intellectual property 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 held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and pipeline products. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or pipeline products 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 existing products and approved pipeline products even if we successfully obtain patent protection once the patent life has expired for the product. The issued patents and pending patent applications, if issued, for our existing and pipeline products are expected to expire on various dates. Please refer to the paragraph headed "Business – Intellectual Property Rights" in 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 prospects and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of pipeline products, patents protecting such pipeline products might expire before or shortly after such pipeline products are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be

able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents 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 prospects, financial condition and results of operations.

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

As of the Latest Practicable Date, we have patents granted in various jurisdictions, including the Mainland China, the European Union, the U.S. and Japan, and have published patent applications in various jurisdictions, including the Mainland China, Hong Kong, the EU, the U.S. and Japan, which we believe are material to our business. As of the Latest Practicable Date, we also own a number of registered trademarks for our brand name "OrbusNeich", "ORBUSNEICH", "業聚" or "业聚" in various jurisdictions, including the Mainland China, Hong Kong, the European Union, the U.S., and Japan. Please refer to the paragraph headed "B. Further Information about the Business of the Company – 2. Our Material Intellectual Property Rights" in Appendix IV to this document. Our products are offered to the market under various brands, such as "COMBO", "Jade", "Sapphire", "Scoreflex" and "Teleport". Our registered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest.

During the Track Record Period, some of our distributors used our trademarks and brand name when conducting sales and marketing activities on our behalf or promoting our products. We may not be able to prevent unauthorized use of our trademarks and trade names by distributors, which may harm our brand and reputation. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Moreover, we cannot assure you that our trademarks will not be imitated, or there will be no counterfeits sold to our customers under our trademarks. End users may suffer from safety incidents caused by counterfeit products, which may subject us to costly investigations and counterfeit crack downs, and materially and adversely affect our business and reputation. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business prospects, financial condition and results of operations.

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, renewal fees, annual fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, USPTO, the European Patent Office (EPO) and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO, EPO and other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process.

Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which 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 official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, know-how, product expertise and technologies, 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, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality arrangements with component vendors, consultants, advisors and contractors. We have entered into confidentiality and non-compete agreements with our key employees and employees involved in research and development that include undertakings regarding assignment of inventions and discoveries. However, such confidentiality and non-compete agreements may not adequately prevent disclosures of our trade secrets and other proprietary information. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated such information can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets, know-how, technology and product expertise were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, some 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 may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. 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 in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may be unsuccessful in enforcing the confidentiality and non-compete agreements that we entered into with our employees who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Changes in patent law may diminish the value of patents in general, thereby impairing our ability to protect our existing and pipeline products.

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation in the PRC, the United States, the European Union, Japan and other jurisdictions may diminish our ability to protect our inventions, 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 and 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 coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance.

Even if patent applications we own currently or 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 highly uncertain.

If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and financial penalties and may have to redesign or discontinue selling the affected product.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves an analysis of complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties' intellectual property rights in the countries where we operate. In addition, a number of our employees have previously worked for one or more of our competitors. There can be no assurance that such employees have not used, or will not use in the future, their previous employers' proprietary know-how or trade secrets in their work for us, which could result in litigation against us. Prior to developing major new products, we evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection which is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our searches of relevant public records. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management; or
- result in hospitals and physicians terminating, deferring or limiting their purchase of the affected products until resolution of the litigation.

In addition, new patents obtained by our competitors could threaten a product's continued life in the market even after it has already been introduced.

Failure to adequately prosecute patent applications may hinder our Group's ability to enforce intellectual property rights. Failure to adequately protect our intellectual property rights may adversely affect our reputation and disrupt our business.

Filing, prosecuting, maintaining and defending patents on our existing and pipeline products in all jurisdictions throughout the world could be prohibitively expensive for us, and our intellectual property rights in some jurisdictions can have a different scope and strength from those in some other jurisdictions. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of certain other jurisdictions do. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling or importing medical products made using our 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 jurisdictions. These products may compete with our existing and pipeline products and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Our success depends, in part, on our ability to protect our proprietary technologies. We have built a comprehensive intellectual property portfolio in the countries where we have operations to protect our technologies, inventions and know-how and ensure our future success with commercializing our products. Please refer to the paragraph headed "Business – Intellectual Property Rights" in this document. Due to the different regulatory bodies and varying requirements in these jurisdictions, we cannot assure you that we will be able to obtain patent protection for all or any aspects of our products in all or any of these jurisdictions. The process of seeking patent protection can be lengthy and expensive, and we cannot assure you that our patent applications will result in patents being issued, or that our existing or future issued patents will be sufficient to provide us with meaningful protection or commercial advantage. We cannot assure you that our current or potential competitors, many of which have substantial resources and have made substantial investments in competing technologies, do not have, and will not obtain, patents that will prevent, limit or interfere with our ability to make, use or sell our products in jurisdictions such as the PRC, the United States, the European Union and Japan. In addition, 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.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

RISKS RELATING TO THE [REDACTED]

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

Prior to the [**REDACTED**], there has been no [**REDACTED**] for our Shares. The initial [**REDACTED**] for our Shares was the result of negotiations between us, and the [**REDACTED**] (for themselves and on behalf of the [**REDACTED**]) and the [**REDACTED**] may differ significantly from the [**REDACTED**] for our Shares following the [**REDACTED**]. We have applied for [**REDACTED**] of and permission to [**REDACTED**] in our Shares on the [**REDACTED**]. A [**REDACTED**] on the [**REDACTED**] does not guarantee that an active and liquid [**REDACTED**] for our Shares will develop, especially during the period when a significant portion of our Shares are subject to lock-up undertakings, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the Shares will rise following the [**REDACTED**]. Furthermore, the price and [**REDACTED**] of our Shares may be volatile. Factors such as variations in our revenue, earnings and cash flows or any other developments relating to our Company may affect the [**REDACTED**] and [**REDACTED**] at which the Shares will be [**REDACTED**].

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

You will incur immediate and significant dilution and raising additional capital may cause further dilution or restrict our operation.

There can be no assurance that if we were to immediately liquidate after the [**REDACTED**], any assets will be distributed to Shareholders after the creditors' claims. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, limitations on our ability to acquire or license intellectual property rights or declaring dividends, or other operating restrictions.

The costs of the options were or may to be granted under the Pre-[REDACTED] Share Option Scheme and the Post-[REDACTED] Share Option Scheme may adversely affect our results of operations and any exercise of the options granted may results in dilution to our Shareholders.

We have granted certain options to subscribe for an aggregate of [9,274,900] Shares (as adjusted after the Share Consolidation) to 102 grantees under the Pre-[**REDACTED**] Share Option Scheme. Such options if exercised in full will represent approximately

[**REDACTED**]% of our issued share capital immediately after completion of the [**REDACTED**] (without taking into account the options which may be granted under the Share Option Schemes). We have also adopted the Post-[**REDACTED**] Share Option Scheme pursuant to which we will in the future grant to employees options to subscribe for Shares.

The fair value of the options at the date of which they are granted with reference to the valuer's valuation under the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme will be charged as share-based compensation which may have a negative effect on our results of operations. Issuance of Shares for the purpose of satisfying any award made under the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme will also increase the number of Shares in issue after such issuance, and thus may result in the dilution to the percentage of ownership of the Shareholders, the earnings per Share and the net asset value per Share.

Details of the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme and the options granted and to be granted thereunder are set out in the paragraph headed "D. Share Incentive Schemes" in Appendix IV to this document.

Because the initial [REDACTED] price of our Shares is higher than the consolidated net tangible book value per share, purchasers of our Shares in the [REDACTED] may experience immediate dilution upon such purchases.

As the [**REDACTED**] of our Shares is higher than the consolidated net tangible assets per share immediately prior to the [**REDACTED**], purchasers of our Shares in the [**REDACTED**] will experience an immediate dilution in pro forma adjusted consolidated net tangible assets. Our existing Shareholders will receive an increase in the pro forma adjusted consolidated net tangible asset value per share of their shares. In addition, holders of our Shares may experience further dilution of their interest if we [**REDACTED**] additional shares in the future to raise additional capital.

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

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

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

The interests of our Controlling Shareholders may differ from the interests of our other Shareholders. Our Controlling Shareholders could have significant influence in determining the outcome of any corporate transaction or other matters submitted to our Shareholders for approval. This concentration of ownership, as a result, may discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for their Shares in a sale of our Company or may reduce the market price of our Shares. In addition, to the extent the interests of our Controlling Shareholders conflict with the interest of our other Shareholders, the interests of our other Shareholders may be disadvantaged or harmed.

There will be a time gap between pricing and [REDACTED] of our Shares, and the price of our Shares when [REDACTED] begins may be lower than the [REDACTED] in this document.

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

Future issuance, sales or perceived issuance or sales of a substantial number of our Shares in the [REDACTED] following the [REDACTED] may have a material adverse effect on the price of our Shares and our ability to raise additional capital in the future, and may result in dilution of your shareholding.

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

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

Sales of substantial amounts of Shares in the [**REDACTED**] after the completion of the [**REDACTED**], or the perception that these sales could occur, could adversely affect the market price of our Shares. Although our Controlling Shareholders are subject to restrictions on its sales of Shares within six months from the [**REDACTED**] as described in "[**REDACTED**]" in this document, future sales of a significant number of our Shares by our Controlling Shareholders in the [**REDACTED**] after the [**REDACTED**], or the perception that these sales could occur, could cause the market price of our Shares to decline and could materially impair our future ability to raise capital through offerings of our Shares. We cannot assure you that our Controlling Shareholders will not dispose of Shares held by them or that we will not issue Shares pursuant to the general mandate to issue shares granted to our Directors as described in "Statutory and General Information" in Appendix IV to this document or otherwise, upon the expiration of restrictions set out above. We cannot predict the effect, if any, that any future sales of Shares by our Controlling Shareholders, or the availability of Shares for sale by our Controlling Shareholders, or the issuance of Shares by the Company may have on the market price of the Shares. Sale or issuance of a substantial amount of Shares by our Controlling Shareholders or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing market price of the Shares.

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

We currently intend to retain most, if not all, of our available funds and any future earnings after the [**REDACTED**] to fund the development and growth of our business. As a result, we cannot guarantee when and in what form dividends will be paid on our Shares following the [**REDACTED**]. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our business and financial performance, capital and regulatory requirements and general business conditions. Accordingly, the return on your investment in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [**REDACTED**] or even maintain the price at which you [**REDACTED**] the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

We cannot guarantee the accuracy of certain statistics derived from official governmental sources contained in this document.

Certain statistics in this document relating to the market in which we operate are derived from various official government sources that we believe are reliable. However, we cannot guarantee the quality or reliability of such information derived from official government sources. Such information has not been independently verified by us, the Joint Sponsors, the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**] or any of their respective directors, senior management, representative and advisers, or any other persons or parties involved in the [**REDACTED**], and

no representation is given as to its accuracy. Due to possibly flawed or ineffective collection methods or discrepancies between official government sources and market practice, such statistics in this document may be inaccurate or may not be comparable to statistics produced from other sources. In all cases, investors should give consideration as to how much weight or importance they should attach to or place on such information from any official government source.

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

Our management may spend the net [**REDACTED**] from the [**REDACTED**] in ways with which you may not agree or which do not yield a favorable return to our Shareholders. Please refer to the paragraph headed "Future Plans and [**REDACTED**]" in this document for details. However, our management will have discretion as to the actual application of our net [**REDACTED**]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [**REDACTED**] from this [**REDACTED**].

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

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

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

There may be difficulties in protecting your interests under the laws of the Cayman Islands.

Our corporate affairs are governed by, among other things, our Memorandum of Association and Articles of Association, the Companies Act and common law of the Cayman Islands. The rights of Shareholders to take action against our Directors, actions by minority shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those in other jurisdictions. Such differences may mean that the remedies available to the minority shareholders may be different from those they would have under the laws of other jurisdictions.

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

This document contains certain forward-looking statements and information relating to us that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words "aim", "anticipate", "believe", "can", "continue", "could", "estimate", "expect", "intend", "ought to", "may", "might", "plan", "potential", "predict", "project", "seek", "should", "will", "would" and similar expressions, as they relate to our Company or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. Investors should not place undue reliance on such forward-looking statements and information.