OVERVIEW

We are a major global medical device manufacturer specialized in interventional instruments for PCI/PTA procedures. The PCI and PTA markets are niche, small and concentrated markets. According to the CIC Report, we are a major player of PCI/PTA balloon markets in each of the following geographical markets in terms of sales volume in 2021:

PCI Balloon Market:

- Japan – Ranked No. 2 with a 20% market share
- Europe – Ranked No. 4 with a 11% market share
- PRC – Ranked No. 6 with a 8% market share
- U.S. – Ranked No. 6 with a 3% market share

PTA Balloon Market:

- Japan – Ranked No. 3 with a 13% market share
- U.S. – Ranked No. 4 with a 12% market share

Headquartered in Hong Kong, China, we sell products to over 70 countries and regions worldwide, and we are also the only PCI balloon manufacturer headquartered in China that ranked among the top 6 players in all major overseas PCI balloon markets including Japan, Europe and the U.S. In addition to PCI/PTA balloons, we also specialize in coronary stent products and are actively expanding into neuro vascular intervention and structural heart disease areas.

Medical treatment of coronary artery disease (CAD) and peripheral artery disease (PAD) depends on their symptoms, cardiac function, and presence of other disorders. There are three primary methods of treating CAD/PAD, namely: (i) medical therapy, (ii) interventional treatment, including PCI for CAD and PTA for PAD, and (iii) invasive surgical treatment. Since PCI/PTA procedures carry lower risk and costs, but still enjoy a similar treatment success rate compared to surgical treatment, it is often the preferred form of treating CAD/PAD.

The coronary interventional instruments market in the PRC, the U.S. and Europe is expected to grow from 2021 to 2025 at a CAGR of 14.0%, 13.1% and 10.0%, respectively, while the peripheral interventional instruments market in the PRC, the U.S. and Europe is expected to grow from 2021 to 2025 at a CAGR of 14.6%, 11.9% and 9.2%, respectively. We strategically focus on these fast-growing markets as well as large established markets such as Japan, and the sales volume of our PCI balloon products globally reached approximately 866,000 units in 2021, ranking top six amongst all global cardiovascular interventional instrument developers and manufacturers in Japan, Europe, the U.S. and the PRC. We have also expanded the geographical coverage of our products to over 70 countries and regions in six continents as of June 30, 2022. Our long operating history, high quality products and wide geographic reach have formed a well-established reputation and brand recognition of the "OrbusNeich" and "業聚" brands in our target markets globally.

Our diversified product portfolio covers all major treatment processes in PCI and PTA procedures. Our approved and marketed products are indicated for lesion access, lesion preparation, lesion therapy and lesion optimization, encompassing semi-compliant balloons and scoring balloons for pre-dilatation and lesion preparation, coronary stents for implantation, non-compliant balloons for post-dilatation, and specialty catheters. In particular, we focus on

developing innovative products with high performances, which enable us to meet the physicians' and patients' clinical needs and to benefit from first-mover advantages. For example, we were the first company that developed the 1.75mm scoring balloon with high crossability and trackability which became the first approved scoring balloon in Japan in 2017, and our Scoreflex NC product is the smallest profile non-compliant scoring balloon as of the Latest Practicable Date which offers higher procedural success rate in smaller diameter vessels that are not ideal for stenting. Our proprietary "drug plus antibody" COMBO dual therapy stent is the first and the only commercialized double-coated stent in the world that promotes effective healing and that has obtained CE Mark and NMPA and PMDA approvals. In addition, our Sapphire II Pro is the first 1.0mm CTO balloon approved by the FDA in 2018, which helps the pretreatment of the most challenged and complex lesion in PTCA procedure. Furthermore, our JADE non-compliant peripheral balloon launched in the U.S. in June 2021 is the first and the only non-compliant PTA balloon approved by the FDA that is compatible with all available guidewire systems in the U.S., making it an ideal choice in the treatment of the peripheral vascular disease.

As of the Latest Practicable Date, we own more than 100 granted patents globally across key jurisdictions, including 32 and 45 granted patents in the U.S. and in the PRC, respectively. Our strong in-house R&D capabilities with over twenty years of accumulated product development experience and continued investment in R&D activities empowered us with abundant proprietary knowhow in product design, material treatment, manufacturing processes, and enabled us to successfully develop various proprietary technologies, including our world leading antibody coating technology that features the "pro-healing" function and has been applied to our COMBO and COMBO Plus dual therapy stent products. We are also developing the second generation of such antibody coating technology and intend to apply it in a wider spectrum of medical devices. As of June 30, 2022, we had a robust pipeline consisting of around 40 products under development. Leveraging our world leading technologies and strong R&D capabilities, we also intend to expand our product lines into new intervention areas such as neuro-intervention and structural heart disease intervention.

Headquartered in Hong Kong, we maintain an established global sales network which consists of both direct sales and distributorship. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our direct sales channel covered eight, nine, ten and ten countries and regions, respectively. Our direct sales team works closely with each other to facilitate physician education and product promotions among different jurisdictions. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, our revenue generated from direct sales was US$50.5 million, US$49.1 million, US$63.9 million, US$31.0 million and US$33.6 million, respectively, representing 52.4%, 55.5%, 54.9%, 54.1% and 48.9% of our total revenue, respectively.

As of June 30, 2022, our sales network covered over 70 countries and regions worldwide, among which we also built our direct sales force in the Mainland China, Hong Kong, Macau, Japan, Malaysia, Singapore, Germany, France, Switzerland and Spain. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our distributorship channel covered 61, 59, 65 and 65 countries and regions, respectively. Our global distributor network consists of approximately

207 distributors as of June 30, 2022. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, our revenue generated from sales to distributors was US$44.8 million, US$38.3 million, US$52.3 million, US$26.3 million and US$35.2 million, respectively, representing 46.5%, 43.3%, 44.9%, 45.8% and 51.1% of our total revenue, respectively. Our experienced and dedicated global sales and marketing team is in charge of managing our distributor network. In addition, our in-house sales and marketing team also leverages our knowledge base and relationship with hospitals and key opinion leaders to promote and sell our products directly to hospital customers.

Our production facilities in Shenzhen, the PRC and Hoevelaken, the Netherlands are equipped with advanced equipment that are either customized based on our design input or purchased from renowned suppliers, which enabled us to manufacture all of our self-developed products in-house. For the six months ended June 30, 2022, our production facilities in the PRC and the Netherlands have an aggregate annualized production capacity of approximately 1,352,000 units of balloon products and approximately 56,400 units of stent annualized products per year, thereby enabling us to supply large-scale and stable high-quality products and providing us with more flexible market access to customers around the world. Leveraging our strict and well-established Quality Management System (QMS), our production facilities have passed the audits and inspections by various regulatory bodies. In particular, our production facilities in the PRC have passed onsite inspections by the FDA with Zero Observations in 2020. In addition, our production facilities in the PRC have passed audits from NB in 2020 and 2021 and audits from NMPA in 2021. Our production facilities in the Netherlands are subject to annual audits from NB and have passed such audits in 2020, 2021 and 2022, and have passed inspection from PMDA in 2019.

In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, our revenue was US$96.3 million, US$88.5 million, US$116.5 million, US$57.3 million and US$68.9 million, respectively, and our gross profit was US$65.4 million, US$58.0 million, US$81.2 million, US$40.5 million and US$47.7 million, respectively. In addition, we recorded an adjusted profit (non-HKFRS measure) of US$7.0 million, US$7.1 million, US$21.4 million, US$11.0 million and US$13.6 million, in 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, respectively.

OUR COMPETITIVE STRENGTHS

A major player in the fast-growing global PCI/PTA balloons markets, with well-established reputation and brand awareness

We are a major global medical device manufacturer specialized in interventional instruments for PCI/PTA procedures. The sales volume of our PCI balloon products globally reached approximately 866,000 units in 2021, ranking top six amongst all global cardiovascular interventional instrument developers and manufacturers in Japan, Europe, the U.S. and the PRC, and we have expanded the geographical coverage of our products to over

70 countries and regions in six continents as of June 30, 2022. Our long operating history, high quality products and wide geographic reach have formed a well-established reputation and brand recognition of the "OrbusNeich" and "業聚" brands in our target markets globally.

In terms of sales volume of PCI balloons in 2021, we ranked No. 2 with 20% market share in Japan, No. 4 with 11% market share in Europe, No. 6 with 8% market share in the PRC and No. 6 with 3% market share in the U.S., respectively, according to the CIC Report. In addition, in terms of sales volume of PTA balloons in 2021, we ranked No. 3 with 13% market share in Japan and No. 4 with 12% market share in the U.S., respectively, according to the CIC Report. In the PRC, our Scoreflex scoring balloon series seized an market share of approximately 30% in terms of sales volume in 2021. We also recorded excellent market share in various countries/regions in terms of sales volume in 2021, with a market share over 50% in Hong Kong, Singapore and Pakistan, over 40% in each of Malaysia, Taiwan and Slovakia and over 20% in Switzerland, Russia, Czech Republic, the Netherlands and Italy.

We strategically focus on the fast-growing coronary and peripheral vascular intervention markets. According to the CIC Report, the global market sizes of PCI instruments and PTA instruments reached US$6.2 billion and US$1.1 billion in 2021, respectively, and are expected to grow at a CAGR of 12.1% and 11.1% from 2021 to 2030, respectively. According to the CIC Report, China-based endovascular interventional instrument developers and manufacturers have a relatively low penetration rate and market share in these markets, which provides us with enormous opportunities. Specifically, we lay great emphasis on coronary intervention field to satisfy the fast growing demand for quality balloon products. The market size for PCI balloons, catheters and accessories reached approximately US$2.1 billion worldwide in 2021, and is expected to grow at a CAGR of 17.2% from 2021 to 2030. We believe we are well-positioned to leverage favorable market trends in the large and fast-growing endovascular interventional instrument market.

Diversified product portfolio indicating different endovascular interventional procedures

We specialize in the coronary and peripheral vascular intervention areas, and have developed a number of proprietary, world leading technologies that are applied to our products. Our diversified product portfolio covers all major treatment processes in PCI and PTA procedures. Our approved and marketed products are indicated for lesion access, lesion preparation, lesion therapy and lesion optimization, encompassing semi-compliant balloons and scoring balloons for pre-dilatation and lesion preparation, coronary stents for implantation, non-compliant balloons for post-dilatation, and specialty catheters.

We focus on developing innovative products with high performances, which enable us to meet the physicians' and patients' clinical needs and to benefit from first-mover advantages. For example, we were the first company that developed the 1.75mm scoring balloon with high crossability and trackability which became the first approved scoring balloon in Japan in 2017, and our Scoreflex NC product is the smallest profile non-compliant scoring balloon as of the Latest Practicable Date which offers higher procedural success rate in smaller diameter vessels that are not ideal for stenting. Our proprietary "drug plus antibody" COMBO dual therapy stent

combines our device-surface antibody coating technology, which effectively capture endothelial progenitor cells in circulating blood to facilitate natural healing of the coronary stented vessel, with our drug-eluting and coating technology, which effectively suppresses smooth muscle cells proliferation and prevents restenosis, leading to the first and the only commercialized double-coated stent in the world that promotes effective healing and that has obtained CE Mark and approvals from NMPA and PMDA.

In addition, our Sapphire II Pro product is the first 1.0mm CTO balloon approved by the FDA in 2018, which helps the pretreatment of the most challenged and complex lesion in PTCA procedure. With our first mover advantage in CTO balloon products, we actively expanded into the CTO balloon markets in APAC and Europe, where we also achieved 7% and 24% market share in terms of sales volume, respectively, shortly after our product launch. Furthermore, our JADE non-compliant peripheral balloon launched in the U.S. in June 2021 is the first and the only non-compliant PTA balloon approved by the FDA that is compatible with all available guidewire systems in the U.S., making it an ideal choice in the treatment of the peripheral vascular disease. Our solid technical capabilities to penetrate the complex endovascular intervention market not only helped us to acquire an increasing market shares, but may also promote our customers' willingness in applying other products manufactured by us.

Leveraging on the novelty and high performance of our products and our market position, we have benefitted, and anticipate to continue to benefit, from the rapid growth in the endovascular interventional instrument market globally.

Robust and novel pipeline products backed by world leading technologies and strong R&D capabilities

As of the Latest Practicable Date, we own more than 100 granted patents globally across key jurisdictions, including 32 and 45 granted patents in the U.S. and in the PRC, respectively. Our patents enjoyed a high number of citations as of September 2021. Our strong in-house R&D capabilities with over twenty years of accumulated product development experience and continued investment in R&D activities empowered us with abundant proprietary knowhow in product design, material treatment, manufacturing processes, and enabled us to successfully develop various proprietary technologies, including our world leading antibody coating technology that features the "pro-healing" function and has been applied to our COMBO and COMBO Plus dual therapy stent products. We are also developing the second generation of such antibody coating technology and intend to apply it in a wider spectrum of medical devices.

Leveraging on our world leading technologies and proprietary know-how, we have developed a robust product pipeline which is expected to further contribute to our endovascular interventional solutions. As of June 30, 2022, we had a robust pipeline consisting of around 40 products under development. We are in the process of developing a new generation drug eluting balloon product for various clinical indications, dedicating to accurately deliver the active pharmaceutical ingredient to the lesions. Different from current mainstream paclitaxel-carrying

balloons, we applied matrix drug-loading and biofilm-covering techniques to carry sirolimus, which significantly reduces the risk of paclitaxel particle abscission and thrombus it induced. In addition, our new drug-eluting balloon product may load drugs several times more than present products to promote lesion repair, thereby achieving greater safety and efficacy.

Based on our technology reserve and knowledge in the conventional endovascular intervention area, we strategically opt to further penetrate and expand our product portfolio into complex cardiovascular intervention, structural heart disease intervention and neuro-intervention fields which we believe to have high unmet medical needs. Our diversified CTO toolbox includes antegrade and retrograde microcatheters, shape steerable tip microcatheters, guide catheter extension systems, dual lumen microcatheters, and re-entry microcatheters. We expect that this CTO tool box will effectively meet the clinical needs and simplify complex coronary interventions. We are in the process of developing an ECMO left ventricle assist device, which is currently under preclinical studies. We are also in the process of developing neuro-intervention products including neuro balloons which are under type testing for NMPA submission, neuro microcatheters, neuro occlusion balloons and neuro drug-coated balloons, which enables us to broaden our product offerings and seize market opportunities.

In the structural heart disease interventional arena, we intend to broaden our product offering by developing certain catheter-based medical devices used for structural heart interventional procedures such as valvuloplasty balloon catheter. Leveraging our world leading technologies and strong R&D capabilities, we believe we will successfully expand our product lines into new intervention areas.

Established global sales network and distinctive commercial competency

We maintain an established global sales network which consists of both distributorship and direct sales models that provide us with more flexible and effective sales strategies in our target markets. For certain countries, we would opt to utilize a mixture of distribution and direct sales and adopt different sales tactics based on the local regulatory requirements, economic conditions and effectiveness considerations. As of June 30, 2022, our sales network covered over 70 countries and regions worldwide, among which we also built our direct sales force in the Mainland China, Hong Kong, Macau, Japan, Malaysia, Singapore, Germany, France, Switzerland and Spain.

Our global distributor network consists of approximately 207 distributors as of June 30, 2022. For the six months ended June 30, 2022, sales generated from our distributors around the world was US$35.2 million, representing 51.1% of our total revenue in such period. Our support to our distributors include offering distributors with training packs/training programs or participating in local conferences/trade shows, thereby building solid and long-term relationships with them. We believe our close cooperation with distributors around the world enable us to take advantage of their knowledge of local business and regulatory environments and of their capabilities to serve end-customers.

In addition, we have established an experienced and dedicated global sales and marketing team consisting of 142 members as of June 30, 2022. In addition to training and actively managing our distributor network to enhance efficiency, our direct sales force is also in charge of selling our products directly to hospital customers in the Mainland China, Hong Kong, Macau, Japan, Malaysia, Singapore, Germany, France, Switzerland and Spain. Our global sales and marketing team is responsible for promoting our products in multiple ways, including ground-level marketing, peer-to-peer marketing, and electronic marketing. As part of our sales and marketing efforts, we may regularly organize doctor training seminars, conduct joint research and development projects with hospitals, as well as collecting feedbacks on our products for developing new generation products. As of June 30, 2022, our direct sales team covered an aggregate of nine countries/regions, and worked closely with each other to facilitate physician education and product promotions among different jurisdictions. Leveraging on our well-established global sales network, we were able to attract and cooperate with various medical device manufacturers to distribute their products indicating CAD, PAD and structural heart diseases in multiple countries/regions and create additional revenue stream.

Aside from our distributors or hospital customers, we have cultivated long-term relationships and frequently interact with KOLs and physicians in our target markets. During the Track Record Period, we have held or participated in around 140 seminars, workshops, conferences or discussion panels for physician education or product promotions globally, reaching out to a large number of physicians and KOLs specialized in the endovascular interventional area. We are one of the major players in global conferences. We were a gold member of EuroPCR during the Track Record Period, and are a silver industry partner of AICT-Asia PCR 2021, each being one of the world's premier conferences in the cardiovascular intervention field. Our distinctive commercial competency combining our extensive network of physicians and KOLs, hospitals and distributors enables us to gain first-hand knowledge of unmet clinical needs, physicians' preferences and clinical trends, as well as to identify potential pipeline products with high market potential.

Advanced production facilities and strict quality control system which ensure stable supply for global markets

Our production facilities in Shenzhen, the PRC and Hoevelaken, the Netherlands are equipped with advanced equipment that are either customized based on our design input or purchased from renowned suppliers, which enabled us to manufacture all of our self-developed products in-house. Leveraging on our advanced technical expertise, our production facilities in the PRC and the Netherlands had an aggregate annualized production capacity of approximately 1,352,000 units of balloon products and approximately 56,400 units of stent annualized products per year, thereby enabling us to supply large-scale and stable high-quality products to customers around the world.

Product quality has been our top priority since inception. We monitor and control each step of our production throughout the entire manufacturing process. We have adopted comprehensive quality control policies and systems covering all major aspects of our operations, from raw material procurement, product manufacturing to inventory management.

Leveraging on our well-established Quality Management System (QMS), our production facilities have passed the audits and inspections by regulatory bodies like the NMPA, FDA, PMDA and NB to certify our QMS. We maintain various certification to QMS standards such as ISO 13485 certifications. In particular, our production facilities in the PRC have passed onsite inspections by the FDA with Zero Observations in 2020. We believe our advanced production facilities and well-established quality control system will ensure a stable supply of our products to meet global demands.

Experienced management team supported by energetic and cohesive talent pool

We are led by Mr. David CHIEN, our chairman, executive Director, chief executive officer and controlling shareholder. With over 30 years of experience in the medical device industry, Mr. Chien has been well-respected in the industry for his leadership of our Company. In addition, our balanced and complementary senior management team possess diverse and extensive knowledge and industry insights. We have industry veterans with an average of over 20 years of experience leading our R&D, sales and marketing, product manufacturing, quality assurance and business development functions, while we have other dedicated senior management members with legal, finance and investment expertise focusing on collaborations and other aspects of our operations. Mr. Robert John COTTONE JR, our chief technical officer, is responsible for the design and research and development of our products. Mr. Alain Djamel KHAIR, our chief commercial officer, oversees the strategy and development of our product portfolio and develops the market penetration strategies of our products. With international and diversified professional backgrounds, our management team is adaptive to various cultures and operates with flexibility and quality.

Our senior management team is supported by our energetic talent pool with strong execution capabilities. We have developed a cohesive corporate culture that embraces "Integrity, Passion, Innovation and Performance". In addition, we value diversification and growth, encouraging personal growth within the organization, which forges the employees' loyalty, entrepreneurial sense and their own professional development. We have built a comprehensive training and retention program to extract and retain the best out of our talents. In order to attract, motivate and retain talent, we have also adopted a share incentive scheme to provide incentives to our employees and align their interest with us. We believe our dedicated management team and energetic and cohesive talent pool set the foundation for our long term success.

OUR STRATEGIES

Our vision is to become a global leading medical device developer and manufacturer that offers a variety of endovascular and structural heart intervention products to effectively improve patients' quality of life. We plan to execute the following strategies to achieve this goal:

Leverage on our well-established brand recognition to further enhance our market penetration

We plan to leverage the well-established brand recognition of our renowned "OrbusNeich" and "業聚" brands and continue to increase our market share by devoting resources to further solidify our brand awareness and expand our distribution network through setting up additional sales offices and/or collaborating with more distributors, and further strengthening our marketing efforts in relevant markets.

Japan/Europe markets

The PCI procedural instrument market in Japan and Europe is expected to grow at CAGRs of 6.1% and 9.4% from 2021 to 2030, respectively, according to the CIC Report, while the PTA procedural instrument market is expected to grow at CAGRs of 7.9% and 8.3% in Japan and Europe for the same period. For established markets such as Japan or Europe where we have built a diversified product portfolio of endovascular intervention devices, we plan to leverage our existing brand strength, customer base and distribution channels to open up opportunities for new product distribution. Therefore, we expect to leverage our established market position, such as the market share of our PCI balloon of 20% and 11% in Japan and Europe in terms of sales volume in 2021, to further increase our market share of other products by broadening our product offerings to existing customers, as well as developing new customers. We launched our Scoreflex TRIO non-slip balloon products in Japan in 2021 and we plan to commercialize matrix drug-eluting coronary and/or peripheral balloons in Japan in 2025, which we believe will drive an increase in our market share in such market.

The PRC/U.S. markets

The PCI procedural instrument market in the PRC and the U.S. is expected to grow at CAGRs of 12.8% and 12.3% from 2021 to 2030, respectively, according to the CIC Report, while the PTA procedural instrument market is expected to grow at CAGRs of 14.9% and 10.8% in the PRC and the U.S. for the same period. For high growth markets such as the PRC or the U.S. where we intend to expand our presence and enhance our market share, we plan to capitalize on opportunities brought by the ongoing healthcare reforms, as well as to increase market adoption for our existing and pipeline products.

In the PRC, we strive to strengthen our sales capabilities and enhance management of our distributors to capture fast-growing market demand. For example, we adopt a combination of distributorship and direct sales model to expand our market penetration. As of June 30, 2022, our sales network in the PRC covered approximately 2,000 hospitals, and we plan to continue to expand our coverage. With the support of our experienced and dedicated global sales and marketing team to form the product commercialization, sales and distribution strategies, we believe the quality and performance of our products will lead to their further adoption by the medical insurance system in the PRC, and we plan to launch newer generations of existing products, such as Scoreflex NC, to maintain our market position. In addition, we will actively seek and cooperate with strategic partners as part of our market penetration efforts.

In the U.S., we plan to continue to roll out new products in our pipeline and to increase our market adoption for relevant products. For example, we launched Sapphire II Pro, the first FDA-approved 1.0mm coronary balloon available in the U.S., in 2018, which helps the pretreatment of the most challenged and complex lesion in PTCA procedure. Riding on the success of Sapphire II Pro, we launched our Sapphire NC 24 balloon in the U.S. market in 2022 to continue to capture market share. We also launched our new JADE NC balloon (OTW series) in the U.S. in June 2021 to further improve our market position in the peripheral space.

Further enrich product offerings both vertically and horizontally

Our success depends on our ability to continuously develop innovative products that address the patients' evolving needs and growing market demand, as well as to maintain and further improve our market position. As part of our business strategy, our R&D staff will continue to develop and expand our pipeline products both vertically and horizontally.

Vertically, our product portfolio strategically focuses on "simplifying the complex" where we aim to deepen our diversified product portfolio for PCI/PTA procedures covering the lesion access, lesion preparation, lesion therapy and lesion optimization functions. For example, for our Sapphire series, we are applying for CE Mark for our Sapphire II Pro OTW series; for our Scoreflex series, we are developing a Scoreflex II series scoring balloon tailored for the Japanese market in addition to the with ScoreFlex TRIO (PTCA) product which was recently approved by the PMDA; for our Jade series and microcatheter products, we are developing a Jade II series PTA balloon and Teleport II series microcatheter for newer generation of product offerings. Besides expansion or upgrade of existing products, we are also widening our product offering in our existing vascular treatment product portfolio. For example, we are in the process of developing a new generation drug eluting balloon product for various clinical indications, a diversified CTO toolbox including various microcatheter products, and an ECMO left ventricle assist device.

Horizontally, in addition to our PCI/PTA instrument products, we intend to leverage our technical expertise and expand our product offerings to cover structural heart disease intervention products and neuro intervention products. For example, as of the Latest Practicable Date, there were no commercialized TTVR product in the PRC, according to CIC. As a result, we expect TricValve Bicaval System, a pipeline product developed by our joint venture partner which ON P&F has the exclusive right to commercialize and distribute such product in the PRC, to become the first commercialized bicaval valve system in the PRC market upon completion of the NMPA registration. TricValve Bicaval System has received the CE Mark in May 2021 and we currently expect to conduct relevant registration submission with the NMPA in 2023, and to commercialize the product in the PRC in 2024. In addition, we plan to expand into the structural heart disease intervention field by developing certain catheter-based medical devices, such as valvuloplasty balloon catheter. We also focused on the development of a variety of neuro-intervention products devices including neuro balloons which are under type testing for NMPA submission, neuro microcatheters, neuro occlusion balloons and neuro drug-coated balloons.

We also plan to recruit additional talent specialized in R&D in order to further enrich product offerings. We believe that our product matrix strategy focusing on the endovascular interventional instrument and the structural heart interventional instrument markets enables us to offer a full range of medical devices including cardiovascular, peripheral and neurological, and structural heart intervention solutions that address the challenging daily procedural needs, and will further cement our market position.

Work closely with physicians and KOLs in different therapeutic areas to further enhance our brand recognition and R&D capabilities

We strive to continuously enhance our brand recognition and R&D capabilities to solidify our market position and to maintain long-term growth. Our reserve of proprietary technologies, which, together with our manufacturing, R&D and strategic marketing expertise, will enable us to identify and rapidly address the evolving clinical needs with innovative solutions. As a result, we intend to work closely with physicians and KOLs in the vascular, neuro, cardiac and valvular intervention areas, actively conduct trainings and physician education in hospitals and participate in major conferences in the U.S., Europe, the PRC, Japan and other Asian countries.

We regularly attend major international conferences for interventional endovascular medical practitioners and physicians, which gives our engineers the opportunity to interact with top cardiologists, KOLs and physicians on new product development concepts and challenges faced in laboratories. Such events not only provide a platform for us to market our Company, but also allows us to evaluate or validate our existing product offerings, and gauge our competitors. Knowledge and insights gathered from these conferences are subsequently integrated into our product development.

In addition, we maintain a "Physician Exchange Programme (PEP)", whereby we engage physicians who are skilled in chronic total occlusion (CTO) or complex lesions to train other physicians in other countries, in particular certain developing countries with strong needs to enhance their PCI capabilities and experience. For example, Japan is a world-leading country in the study and treatment of CTO, and therefore Japanese interventional cardiologists are among the best in the world in treating CTO cases. Through our PEP, we invite renowned Japanese experts to travel to other Asian countries and regions, including the Mainland China, Hong Kong, Indonesia, Malaysia, Myanmar, Nepal, Sri Lanka, Taiwan, Thailand, and Vietnam, to share with local cardiologists their expertise and knowledge on CTO treatment and to demonstrate the features and benefits of our products for CTO cases. We also plan to engage certain physicians to provide their valuable input in the development of our new products so that we can tap into such expertise of the physicians for our new product development.

Based on our long-term relationships and regular communications with these physicians and KOLs, we are able to maintain a sense of where new clinical platforms are emerging and where the hurdles in clinical performance still need resolve. We believe such cooperation with physicians and KOLs will further enhance our R&D capabilities, fostering an environment for us to expedite our development of new and next-generation products to an expanding clinical market.

Pursue strategic acquisitions, partnerships and/or collaborations

We intend to explore technology-focused acquisitions opportunities, in particular those that are complementary to our existing expertise, which we believe will enhance our ability to implement our market-driven R&D capabilities. We also plan to focus on acquisitions involving innovative medical device products that have strong growth potential and/or high synergy with our existing and pipeline products to further expand our product portfolio. Please refer to the section headed "Future Plans and [**REDACTED**]" in this document for the criteria adopted by us for potential strategic acquisitions in the future. Leveraging our deep understanding of the interventional instrument industry, we believe that we are well-positioned to identify innovative medical device projects that are complementary to our current product portfolio.

We may consider acquisition, in-licensing, or other forms of collaborations with projects or start-up companies that have advanced technologies or R&D capabilities. We believe our reputation and proven track record in the endovascular interventional instrument space allow us to identify attractive acquisition/collaboration targets and consummate successful transaction that complement our existing businesses and product offerings. When appropriate, we may also seek partnership or acquisition opportunities with local distributors or medical device companies that provide us with enhanced market access. We believe this will further expand our coverage of hospitals, better manage our distributor network and provide better customer services and physician education. We may also internalize professional marketing capabilities of local distributors, thereby increasing our penetration rate across markets. As of the Latest Practicable Date, we have not identified nor entered into any substantive discussion with any potential candidate for acquisition, partnership or collaboration.

Expand production capacity and continuously improve operational efficiencies

Our production volumes have been increasing over the years and the overall utilization rate of our production facilities in the PRC and the Netherlands in 2021 and for the six months ended June 30, 2022 was approximately 87.6% and 81.5% for balloon products and approximately 46.4% and 46.4% for stent products, respectively. According to the CIC Report, the CAGR for the global endovascular interventional instrument market is expected to be 12.9% from 2021 to 2030, and therefore we expect the demand for our products will continue to grow in the near future. We intend to construct a new manufacturing site to increase our overall production capacity to meet such growing market demand. In addition, we also plan to build up manufacturing capabilities for our pipeline products at the manufacturing site. Please refer to the section headed "Future Plans and [**REDACTED**]" in this document for details.

Along with the planned construction of the new manufacturing site, we will provide trainings to our production staff on the new machinery and equipment and/or the manufacturing processes of our new products, and may recruit additional production staff as needed.

OUR PRODUCTS AND PRODUCT PIPELINE

Overview

We design, develop, manufacture, distribute and sell a variety of medical devices that treat coronary and peripheral vascular diseases during interventional procedures, which include products we develop in-house and hold relevant intellectual property rights, as well as certain third party products. Our diversified product portfolio covers all major treatment processes in PCI and PTA procedures. Our approved and marketed products are indicated for lesion access, lesion preparation, lesion therapy and lesion optimization, encompassing semi-compliant balloons, specialty catheters, scoring balloons, non-compliant balloons. As of June 30, 2022, we had an aggregate of over 40 approved products, including 25 PMDA approved products (all of which are classified as Class IV), 22 products with CE Mark (four of which are classified as Class IIa and 18 of which are classified as Class III), 14 FDA cleared or approved products (13 of which are classified as Class II and one of which are classified as Class III) and 15 NMPA approved products (all of which are classified as Class III), respectively, which were widely adopted by hospitals in around 70 countries around the world as of June 30, 2022. For details of our major coronary and peripheral intervention products, please refer to the paragraphs headed "– Our Products and Product Pipeline" in this section. In addition, as of June 30, 2022, we had around 40 pipeline products under different development stages, including 15 coronary intervention pipeline products, five peripheral intervention pipeline products, seven neuro intervention pipeline products and 11 structural heart piepline products. Among our pipeline products, 19 are in the process of applying for PMDA approval (one of which being Class III product and 18 of which being Class IV products), 33 are in the process of applying for CE Mark approval (one of which being Class IIa products, one of which being

Class IIb product and 31 of which being Class III products), 14 are in the process of applying for FDA approval (nine of which being Class II products and five of which being Class III products), and 35 are in the process of applying for NMPA approval (all of which being Class III products).

Percutaneous Coronary Intervention (PCI) Products

Coronary artery disease (CAD) develops when a blockage or narrowing occurs in the coronary arteries. Coronary arteries run over the surface of the heart and provide nutrients for the highly active heart muscle. Excess lipids and cholesterol in bloodstream can accumulate and eventually form atherosclerotic lesions.

PCI products are products used in the coronary treatment relating to narrowed coronary blood vessel to improve blood flow to the body. We design, develop and produce a range of coronary intervention medical devices, with a focus on semi-compliant/non-compliant balloons, scoring balloons, specialty catheters and dual therapy stents. The sales revenue generated from our PCI products represented 85.3%, 83.4%, 82.8% and 84.4% of our total revenue in 2019, 2020, 2021 and for the six months ended June 30, 2022.

Benefiting from our strong R&D capabilities and technical expertise, our balloon and stent products for PCI procedures achieve high performances and enjoy first-mover advantages. For example:

- we were the first company globally that developed the 1.75mm scoring balloons;
- our Sapphire 3 semi-compliant balloon series have an industry-leading 0.85mm outer diameter;
- our Sapphire II Pro is the first 1.0mm diameter balloon cleared by the FDA;
- our Coronary R Stent platform is mechanically superior in its balance of form, fit, function and design offering a wide range of clinical utility in complex coronary anatomy;
- our Scoreflex series scoring balloon has the smallest profile non-compliant scoring balloon as of the Latest Practicable Date with relatively high procedural success rate in smaller diameter vessels that are not ideal for stenting; and
- our COMBO Plus dual therapy stent is the first and only commercialized "drug plus antibody" double-coated stent that promotes effective coronary vessel healing in the world.

The table below sets forth certain information of our major coronary intervention products, which are all under Class III in EU and the PRC, Class IV in Japan, and Class II in the US except for Scoreflex NC which is Class III in the U.S.:

No.	Product category	Product	Approvals obtained	Features and applications	
1	Coronary Balloons	Sapphire 3 Semi compliant balloon[(1)] (1.5mm – 4.0mm)	CE Mark - March 26, 2020/ PMDA: January 11, 2019	Sapphire 3 is a conventional rapid exchange balloon catheter intended to be used in percutaneous transluminal coronary angioplasty ("**PTCA**") procedure to dilate/expand narrowed vessels to improve blood flow. It has 1.5mm to 4.0mm diameter balloons with a rated burst pressure up to 16 ATM. It is compatible with a standard 0.014 inch guidewire.	
		Sapphire II PRO Semi compliant balloon[(1)] (1.75mm – 4.0mm)	CE Mark - February 3, 2015/PMDA - September 9, 2014/FDA - January 5, 2017/NMPA: September 29, 2017	Sapphire II Pro is the predecessor of Sapphire 3 with same indication but a balloon diameter range from 1.75mm to 4.0mm at a rated burst pressure of 14 ATM, and is also compatible with a 0.014 inch guidewire.	
		Sapphire NC 24 Non compliant balloon[(2)] (1.5mm – 5.0mm)	CE Mark - March 25, 2020/PMDA - November 19, 2018 FDA - Oct 14, 2021	Sapphire NC 24 is also a typical rapid exchange balloon catheter, but the rated burst pressure is 24ATM, and balloon diameter is 1.5mm to 5.0mm. It is mainly used in PTCA procedure for post dilation including post stent dilatation for stenting optimization and dilation of mildly to moderately calcified lesions.	
		Sapphire II NC Non compliant balloon[(2)] (1.75mm – 5.0mm)	CE Mark - February 20, 2014/PMDA - March 27, 2013/NMPA - May 29, 2015	Sapphire II NC is the predecessor of Sapphire NC 24 with same indication but with a balloon diameter ranging from 1.75mm to 5.0mm at a rated burst pressure of 20ATM, and is also compatible with a 0.014 inch guidewire.	

No.	Product category	Product	Approvals obtained	Features and applications	
2	Specialty Balloons	Sapphire 3 (CTO balloon)[3] (0.85mm – 1.25mm)	CE Mark - March 26, 2020/PMDA - January 11, 2019	Sapphire 3 CTO balloon has the finest balloon diameter of 0.85mm and the rated burst pressure of 16 ATM. The balloon is typically used for chronic total occlusion where the other conventional balloon cannot access and it helps the pretreatment of the most challenged and complex lesion in PTCA procedure.	
		Sapphire II PRO (CTO balloon)[3] (1.0mm – 1.5mm)	CE Mark - February 3, 2015/PMDA - September 9, 2014/FDA - March 1, 2018/NMPA - September 29, 2017	Sapphire II Pro CTO balloon has a diameter of 1.0mm to 1.5mm and the rated burst pressure of 16 ATM. The balloon is commonly used for chronic total occlusion with over 7 years of clinical history and it helps the pretreatment of the most challenged and complex lesion in PTCA procedure.	
		Scoreflex NC scoring balloon[4] (1.75mm – 4.0mm)	CE Mark - January 31, 2017/PMDA - May 25, 2017/ NMPA - June 15, 2021 FDA - Dec 21, 2021	Scoreflex NC is a specially designed scoring balloon made of non-compliant balloon material with enhanced flexibility and cross-ability. The scoring wire works together with the standard 0.014inch guidewire to cut calcified lesion with focused force during the PTCA procedure, which is safer than the other traditional scoring technology. Its balloon diameter is from 1.75mm to 4.0mm at a rated burst pressure of 20 ATM.	
		Scoreflex scoring balloon[4] (2.0mm – 4.0mm)	CE Mark - May 27, 2008/ PMDA - April 23, 2009/NMPA - August 27, 2009	Scoreflex is a semi-compliant focused force scoring balloon with enhanced flexibility and cross-ability. The scoring wire works together with the standard 0.014 inch guidewire to cut calcified lesion with focused force during the PTCA procedure, which is safer than the other traditional scoring technology. Its balloon diameter is from 2.0mm to 4.0mm at a rated burst pressure of 16 ATM.	

No.	Product category	Product	Approvals obtained	Features and applications	
3	Stents	Azule Bare Metal Stent (2.5mm – 4.0mm)	CE Mark - January 11, 2011/NMPA - March 15, 2013	Azule is a balloon expandable bare metal stent intended to be used to treat patients in coronary stenting procedure. It has a stent diameter from 2.5mm to 4.0mm.	
		COMBO Plus dual therapy stent (2.5mm – 4.0mm)	CE Mark - July 22, 2016/ PMDA - September 18, 2019	Combo Plus is a bio-engineered dual therapy balloon expandable stent. Its drug coating prevents the hyperplasia of the vessel to maintain the stented vessel diameter, and its antibody coating is aimed to form a natural endothelium within the stent to reduce the long-term risk of in-stent thrombosis. The stent diameter is from 2.5mm to 4.0mm which can help patients in coronary stenting procedure.	

Notes:

(1) Sapphire 3 semi-compliant balloon and Sapphire II Pro semi-compliant balloon are both semi-compliant balloons which are mainly used for pre-dilation of the calcified lesion so as to optimize the lesion morphology to facilitate the stent implantation. The two products have different balloon dimensions and rated burst pressures.

(2) Sapphire NC 24 non-compliant balloon and Sapphire II NC non-compliant balloon are both non-compliant conventional balloon which are mainly used for post-dilation of a deployed stent to push the stent to the vessel wall more closely. The two products have different balloon dimensions and rated burst pressures.

(3) Sapphire 3 (CTO balloon) and Sapphire II Pro (CTO balloon) are both CTO balloons which are designed specially to treat CTO lesions. The two products have different balloon diameter ranges.

(4) Scoreflex NC scoring balloon and Scoreflex scoring balloon are both scoring balloons which have scoring wires outside the balloon with the intension to cut the plaque of the lesion in a controlled manner to obtain an optimized plaque morphology. The two products have different balloon diameter ranges and rated burst pressures.

Percutaneous Transluminal Angioplasty (PTA) Products

A PTA interventional medical device is a medical apparatus used in clinical procedures that are used to treat peripheral artery disease with minimally invasive technique. We design, develop and produce a range of peripheral intervention medical devices, with a focus on non-compliant and scoring balloons. Our JADE non-compliant peripheral balloon is the first and the only non-compliant over-the-wire PTA balloon approved by the FDA that is compatible with all guidewire systems in the U.S., making it an ideal choice in the treatment of the peripheral vascular disease. The sales revenue generated from our peripheral interventional products represented 7.2%, 8.5%, 10.0% and 8.1% of our total revenue in 2019, 2020, 2021 and for the six months ended June 30, 2022.

The table below sets forth certain information of our major peripheral intervention products, which are all under class III in the PRC, Class IV in Japan, Class IIa in EU and Class II in the U.S.:

No.	Product category	Product	Approvals obtained	Features and applications	
1	Peripheral Balloons	JADE NC Balloon Catheter (1.5mm to 6.0mm)	CE Mark - July 31, 2015/ PMDA - May 29, 2014/ FDA - February 9, 2018/NMPA - June 24, 2019	Jade PTA is a high pressure balloon dilation catheter intended to be used in PTA procedure to regain the original diameter of peripheral vessel with stenosis. Its balloon diameter is from 1.5mm to 6.0mm with a rated burst pressure up to 22 ATM. The product is compatible with 0.014 inch, 0.018 inch and 0.035 inch guidewires.	
2	Peripheral Specialty Balloons	Scoreflex PTA BTK scoring balloon (2.0mm to 4.0mm)	CE Mark - July 31, 2015/ PMDA - September 25, 2014/FDA - June 11, 2019/ NMPA - May 23, 2019	Scoreflex PTA BTK is a semi-compliant PTA balloon catheter. It is a design variant of OrbusNeich Scoreflex poduct family. The scoring wire will work together with the standard 0.014/0.018 guidewire to provide focused force to cut the lesion during PTA procedure. The products offers a coiled version and a non-coiled version with 2.0mm to 4.0mm balloon diameters with a rated burst pressure up to 14 ATM, and catheter length in 40cm, 90cm, 150cm catering for a wide range of PTA clinical needs.	

No.	Product category	Product	Approvals obtained	Features and applications
		Scoreflex PTA AVF scoring balloon (4.0mm to 6.0mm)	CE Mark - July 31, 2015/ PMDA - May 8, 2015/FDA - June 11, 2019	Scoreflex PTA AVF is part of the Scoreflex PTA family. The scoring wire works together with the 0.018 inch guidewire to cut the lesion during PTA procedure. The balloon diameters are 4.0mm, 5.0mm and 6.0mm with a rated burst pressure up to 14 ATM indicated for arteriovenous (AV) fistula use.
		Scoreflex PTA SFA scoring balloon (2.0mm to 6.0mm)	CE Mark - July 31, 2015/ PMDA - May 8, 2015/FDA - June 11, 2019	The Scoreflex PTA SFA balloon has similar scoring mechanism to Scoreflex PTA BTK with a 0.018 inch guide wire system. The 90cm and 0.018 inch coil version ScoreFlex PTA is designed for the clinical use in SVA (Superficial Femoral Artery). The balloon diameters range from 2.0mm to 6.0mm with a rated burst pressure of 14 ATM.

Other Medical Accessories

Aside from the coronary and peripheral intervention products, we also develop and manufacture other medical accessories for use in the coronary and peripheral minimally invasive procedures. We developed the Teleport microcatheter, a specialty catheter for assisting device delivery and for guide wire exchange. The sales revenue generated from our other medical accessories represented 5.3%, 5.4%, 3.2% and 3.6% of our total revenue in 2019, 2020, 2021 and for the six months ended June 30, 2022.

The table below sets forth certain information of our major other medical accessory, which is under Class III in EU and the PRC, Class IV in Japan, Class II in the U.S.:

No.	Product category	Product	Approvals obtained	Features and applications	
1	Microcatheter	Teleport microcatheter	CE Mark - March 6, 2018/PMDA - May 25, 2017/ FDA - November 9, 2018/NMPA - November 19, 2019	Teleport microcatheter is a single lumen catheters designed for supporting and facilitating the placement of guidewires and for exchanging guidewires in the coronary and peripheral vasculature. It is also intended for the delivery of contrast media into the coronary, peripheral, and abdominal vasculature.	

Third Party Products

In addition to the products developed by us, we also leverage our well-established global sales network and cooperate with various medical device manufacturers to distribute their products indicating CAD, PAD and structural heart diseases. The sales revenue generated from the distribution of these third party products represented 2.2%, 2.7%, 4.0% and 3.9% of our total revenue in 2019, 2020, 2021 and for the six months ended June 30, 2022.

The table below sets forth certain information of the third party products distributed by us, which are all under Class III in all relevant jurisdictions except in Japan, where such products are under Class IV:

No.	Product category	Product	Approvals obtained	Coverage in authorized countries and regions	Features and applications
1	Structural Heart	TricValve	CE Mark	France, Saudi Arabia, United Arab Emirates, Egypt	The TricValve system is specifically developed for patients with severe tricuspid backflow (right heart leaky valve) particularly those who are unable to control their symptoms through other treatments and at high risk for for open heart surgery. Tricvalve is specifically made of dry tissue technology and pre-mounted on the delivery system. TricValve will be implanted using minimally invasive procedure into the inferior and superior vena cava to control the leakage of blood into the right heart chambers.
2	Coronary DEB	SELUTION SLR Sirolimus Eluting PTCA balloon catheter	CE Mark	Spain, Malaysia, Hong Kong	SELUTION SLR PTCA is a novel Sirolimus Drug Eluting Balloon (DEB), for the treatment of coronary arterial disease. It is intended for use to dilate de novo or restenotic coronary lesions, for the purpose of improving myocardial perfusion and decreasing the incidence of restenosis. The product offers a broad range of balloon sizes, from 1.5mm to 5.0mm and lengths from 10mm to 40mm.
3	Peripheral DEB	SELUTION SLR Sirolimus Eluting PTA balloon catheter	CE Mark	Spain	SELUTION SLR PTA is a novel Sirolimus Drug Eluting Balloon (DEB), for the treatment of peripheral arterial disease. It is intended for use to dilate de novo or restenotic coronary lesions, for the purpose of improving myocardial perfusion and decreasing the incidence of restenosis. The product offers a broad range of balloon sizes, from 2.0mm to 7.0mm and lengths from 20mm to 150mm.

No.	Product category	Product	Approvals obtained	Coverage in authorized countries and regions	Features and applications
4	Peripheral Orbital Atherectomy System	Stealth 360	CE Mark FDA	Hong Kong, Singapore, Malaysia, Egypt, Saudi Arabia, Kuwait, United Arab Emirates, Switzerland, Italy, Spain, Germany	A bidirectional peripheral atherectomy device for removal and modification of calcium in severely calcified lesions. Use to treat the calcified lesions commonly seen in the peripheral vasculature.
5	Coronary Orbital Atherectomy System	Diamondback 360	CE Mark PMDA FDA	Hong Kong, Singapore, Malaysia, Egypt, Saudi Arabia, Kuwait, United Arab Emirates, Switzerland, Italy, Spain, Germany	A bidirectional coronary atherectomy device for removal and modification of calcium in severely calcified lesions. This will create a good lumen for better stent apposition in the vessel wall and hence improved the procedural outcome.

Our Product Pipeline

As of June 30, 2022, we had a robust product pipeline consisting of around 40 products in various development stages. Capitalizing our world leading technologies, we are able to develop a variety of products that are expected to further advance our current endovascular interventional solutions as well as structural heart disease interventional solutions.

Vertically, we continue to expand and upgrade our existing product portfolio across different product series by adopting the "simplifying the complex" philosophy and with an aim to building a diversified product portfolio for PCI/PTA procedures covering the lesion access, lesion preparation, lesion therapy and lesion optimization functions.

Our Sapphire balloon series is already in the fourth generation with the latest models indicated for lesion access and lesion preparation before stenting. Sapphire II Pro and Sapphire 3 series are one of the most crossable balloons in the market for tight and chronic total occlusion lesions, and we are applying for CE Mark for our Sapphire II Pro OTW series. To expand the ScoreFlex series, we are developing a Scoreflex II series scoring balloon tailored for the Japanese market in addition to the ScoreFlex TRIO (PTCA) product which was recently approved by the PMDA. We are also developing a Jade II series PTA balloon for our next generation Jade series products.

In addition to the new Teleport II microcatheter products that are under development, we are developing a CTO toolbox with a variety of products such as microcatheters, shapeable steerable tip microcatheters, guide catheter extension systems, dual lumen microcatheters that are expected to effectively meet the challenging clinical needs and simplify the complex interventional procedures. As an example to our strategy of meeting the clinical needs of all physicians, we have also developed an ECMO left ventricle assist device, which is currently at preclinical stage.

In addition, we are developing a new generation drug eluting balloon (DEB) product for various clinical indications. We believe this new DEB can accurately deliver sufficient dose of the active pharmaceutical ingredient (API) to the lesions. Different from current mainstream paclitaxel-carrying balloons, we applied matrix drug-loading and biofilm-covering techniques to carry sirolimus, which significantly reduces the risk of paclitaxel particle abscission and thrombus it induced. In addition, our new drug-eluting balloon product can load drugs several times more than present products to promote lesion repair, thereby achieving greater safety and efficacy.

Horizontally, we intend to leverage our technical expertise in the PCI/PTA instrument field and expand our product offerings to include structural heart interventional products and neuro intervention products. In the structural heart interventional arena, we intend to broaden our product offering by developing certain catheter-based medical devices used for structural heart interventional procedures such as valvuloplasty balloon catheter products. In addition, we are also working closely with ON P&F to develop of a balloon expandable heart valve products, and with our partner P&F Int'l to co-develop the next generation of heart valve products. We also focused on the development of a variety of neuro-intervention products devices including neuro balloons which are under type testing for NMPA submission, neuro microcatheters, neuro occlusion balloons and neuro drug-coated balloons. Having a variety of neuro intervention products will enable us to effectively penetrate and compete in the neuro intervention market.

The charts below sets forth certain information of our product pipeline:

Product category	Product	Regulatory Approval	Class	R&D Progress	Upcoming Milestones
				Pre-Clinical / Clinical / Registration & Approval	
Coronary[1]	**Sapphire 3 Balloon Catheter**	PMDA	IV		
		CE	III		
		NMPA	III		
		FDA	II	Supplemental design verification	Est. IDE submission in 2022 Q4
	Sapphire II PRO OTW Balloon Catheter	CE	III		Est. submission in 2023 Q3
		FDA	II		
	Drug Eluting Balloon	NMPA	III	Design concept	Animal study in 2023 Q3
		PMDA	IV	Design concept	Animal study in 2023 Q3
		CE	III	Design concept	Animal study in 2023 Q3
		FDA	III	Design concept	Animal study in 2023 Q3
	Sapphire X NC Balloon Catheter	NMPA	III	Type testing for NMPA submission	Submission in 2022 Q4
	Sapphire X Balloon Catheter	NMPA	III	Type testing for NMPA submission	Submission in 2023 Q1
	Aspiration Catheter	NMPA	III	Design concept	Design freeze in 2023 Q2
		CE	III	Design concept	Design freeze in 2023 Q2
		PMDA	IV	Design concept	Design freeze in 2023 Q2
		FDA	II	Design concept	Design freeze in 2023 Q2
	ScoreFlex TRIO Non-slip Scoring Catheter	PMDA	IV		
		NMPA	III		Clinical study in 2022 Q4
		FDA	III		IDE submission in 2023 Q2
		CE	III		Submitted in 2021 Q4, pending approval
	Teleport 2 Microcatheter	PMDA	IV	Design verification	Submission in 2022 Q4
		NMPA	III	Design verification	Submission in 2023 Q2
		CE	III	Design verification	Submission in 2023 Q1
		FDA	II	Design verification	Submission in 2023 Q1

Product category	Product	Regulatory Approval	Class	R&D Progress Pre-Clinical	R&D Progress Clinical	Registration & Approval	Upcoming Milestones
Coronary[1]	Modular Antegrade and Retrograde Microcatheter	FDA	II	Design concept			Design verification in 2023 Q1
		CE	III	Design concept			Design verification in 2023 Q1
	Modular Shape Steerable Tip Microcatheter	FDA	II	Design concept			Verification testing in 2023 Q3
		CE	III	Design concept			Verification testing in 2023 Q3
	Modular Guide Catheter Extension System	FDA	II	Design concept			Verification testing in 2023 Q4
		CE	III	Design concept			Verification testing in 2023 Q4
	Modular Dual Lumen Microcatheter	FDA	II	Design concept			Design freeze in 2023 Q2
		CE	III	Design concept			Design freeze in 2023 Q2
	Modular Re-entry Microcatheter	FDA	II	Design concept			Design freeze in 2023 Q2
		CE	III	Design concept			Design freeze in 2023 Q2
		PMDA	IV				
	EZ Guide Catheter Extension System	NMPA	III	Type testing for NMPA submission			Est. submission in 2022 Q4
		CE	III				Submitted, Est. approval in 2023 Q3
	ECMO Left Ventricular Assist Device	NMPA	III	Design concept			Design Freeze in 2022 Q4
		CE	III	Design concept			Design Freeze in 2022 Q4
Peripheral[2]	ScoreFlex AVF Balloon Catheter	NMPA	III	Design concept			Design Freeze in 2023 Q1
		PMDA	IV	Design concept			Design Freeze in 2023 Q1
		CE	IIa	Design concept			Design Freeze in 2023 Q1
		FDA	II	Design concept			Design Freeze in 2023 Q1
	JADE II PTA Balloon Catheter	NMPA	III	Design concept			Design Freeze in 2022 Q4
		PMDA	IV				Submitted, est. approval in 2022 Q4
		CE	IIa				
	JADE 14/18/35 OTW PTA Balloon Catheter	FDA	II				
		PMDA	IV				
		NMPA	III				Est. submission in 2023 Q1
	Drug Eluting Balloon	NMPA	III	Design concept			Animal study in 2023 Q3
		PMDA	IV	Design concept			Animal study in 2023 Q3
		CE	III	Design concept			Animal study in 2023 Q3
		FDA	III	Design concept			Animal study in 2023 Q3
	Self-expandable PTA Stent	NMPA	III	Design concept			Prototype in 2023 Q2
		PMDA	IV	Design concept			Prototype in 2023 Q2
		CE	IIb	Design concept			Prototype in 2023 Q2
		FDA	III	Design concept			Prototype in 2023 Q2

Product category	Product	Regulatory Approval	Class	R&D Progress Pre-Clinical	R&D Progress Clinical	Registration & Approval	Upcoming Milestones
Neuro[3]	Neuro Balloon Catheter	NMPA	III				Submitted in Oct 2021, estimated approval in Q4 2022
		CE	III				Commencement of Clinical Trial in 2023 Q1
	Neuro Microcatheter	NMPA	III	Design concept			Est. submission in 2022 Q4
		CE	III	Design concept			Commencement of Clinical Trial in 2023 Q4
	Neuro Aspiration Catheter	NMPA	III	Design concept			Design Freeze in 2023 Q1
		CE	III	Design concept			Design Freeze in 2023 Q1
	Neuro Occulsion Balloon Catheter	NMPA	III	Design concept			Prototype in 2023 Q1
		CE	III	Design concept			Prototype in 2023 Q1
	Neuro Retriever Device	NMPA	III	Design concept			Design Freeze in 2023 Q3
		CE	III	Design concept			Design Freeze in 2023 Q3
	Neuro Distal Protection Device	NMPA	III	Design concept			Prototype in 2023 Q1
		CE	III	Design concept			Prototype in 2023 Q1
	Flow Diverter Device	NMPA	III	Design concept			Prototype in 2022 Q4
		CE	III	Design concept			Prototype in 2022 Q4
Structural Heart[4]	TricValve Transcatheter Bicaval Valve System	CE	III				
		NMPA	III				Commencement of Clinical Trial in 2023 Q1
		PMDA	IV				Commencement of Clinical Trial in 2023 Q1
	Vienna Aortic Valve	NMPA	III		Clinical Trial		Commencement of Clinical Trial in 2023 Q4
		PMDA	IV		Clinical Trial		Commencement of Clinical Trial in 2023 Q3
		CE	III		Clinical Trial		Completion of Clinical Trial in 2022 Q4
	Vienna Mitral Valve – replacement	NMPA	III	Design concept			FIM in 2022 Q4
		PMDA	IV	Design concept			FIM in 2022 Q4
		CE	III	Design concept			FIM in 2022 Q4
	Vienna Pulmonary Valve – replacement	NMPA	III	Design concept			FIM in 2022 Q4
		PMDA	IV	Design concept			FIM in 2022 Q4
		CE	III	Design concept			FIM in 2022 Q4
	Balloon Expandable Valve	NMPA	III	Design concept			FIM in 2023 Q2
		PMDA	IV	Design concept			FIM in 2023 Q2
		CE	III	Design concept			FIM in 2023 Q2
		FDA	III	Design concept			FIM in 2023 Q2
	Endobentall Device	NMPA	III	Design concept			FIM in 2022 Q4
		PMDA	IV	Design concept			FIM in 2022 Q4
		CE	III	Design concept			FIM in 2022 Q4

Product category	Product	Regulatory Approval	Class	R&D Progress: Pre-Clinical / Clinical / Registration & Approval	Upcoming Milestones
Structural Heart[4]	Valvuloplasty Balloon Catheter (Pre/Post Dilation)	NMPA	III	Design concept	Design freeze in 2023 Q2
		PMDA	IV	Design concept	Design freeze in 2023 Q2
		CE	III	Design concept	Design freeze in 2023 Q2
	Floating Balloon Catheter with Electrode	NMPA	III	Design concept	Prototype around 2023 Q4
		PMDA	IV	Design concept	Prototype around 2023 Q4
		CE	III	Design concept	Prototype around 2023 Q4
	Mapping Catheter	NMPA	III	Design concept	Prototype around 2023 Q4
		PMDA	IV	Design concept	Prototype around 2023 Q4
		CE	III	Design concept	Prototype around 2023 Q4
	Ablation Catheter	NMPA	III	Design concept	Prototype around 2023 Q4
		PMDA	IV	Design concept	Prototype around 2023 Q4
		CE	III	Design concept	Prototype around 2023 Q4
	IABP Catheter	NMPA	III	Design concept	Prototype around 2023 Q4
		PMDA	IV	Design concept	Prototype around 2023 Q4
		CE	III	Design concept	Prototype around 2023 Q4
Other	Sheath Kits	NMPA	III	Design concept	Prototype around 2023 Q4
	Expandable Sheath	NMPA	III	Design concept	Prototype around 2023 Q4
	Catheter Sheath	NMPA	III	Design concept	Prototype around 2023 Q4
		PMDA	III	Design concept	Prototype around 2023 Q4
		CE	III	Design concept	Prototype around 2023 Q4
	Kyphoplasty Balloon catheter	NMPA	III	Design concept	Prototype around 2023 Q4

Legend:

- **(Solid) Product requiring clinical trials**
- **Product exempted from clinical trials**
- **Approved for commercialization**
- **Product Pipeline of ON P+F**

(1) Coronary catheter-based devices refer to the products used to treat coronary artery disease (CAD). These catheters will be used during Percutaneous Coronary Intervention (PCI) which is a non-surgical, minimally invasive procedure to open up narrowed blood vessels to restore blood flow in the heart that has been narrowed by plaque buildup, also known as atherosclerosis. If not treated, patient will be at risk of heart attack, when disease progresses.

(2) Peripheral catheter-based devices refer to the products used to treat Peripheral Artery Disease (PAD). These catheters will be used during minimally invasive procedure to open up the narrowed blood vessel and restores blood flow to the leg that has been narrowed by plaque buildup. If not treated, patient will be at risk of developing gangrene that may lead to amputation and death.

(3) Neuro catheter-based devices refer to the products aims to manage stroke patient. These catheter-based devices are developed to remove blood clot, open up narrowed blood vessel or to shrink the aneurysm.

(4) Structural heart refers to structures in the heart or associated with the heart, for example, the aorta or the valves. These structures can be diseased due to various reasons. These valves can be narrowed, prolapse or not closing properly. Minimally invasive procedure can be done to repair or replace these valves. Endobentall procedure can be performed on the aorta that is diseased.

RESEARCH AND DEVELOPMENT

Our research and development team aims to develop clinically effective and commercially attractive products focusing on coronary, peripheral and neuro intervention products and treatment of structural heart intervention disease by using our proprietary technology. As of the Latest Practicable Date, we own more than 100 granted patents globally across key jurisdictions, including 32 and 45 granted patents in the U.S. and in the PRC, respectively. Our strong in-house R&D capabilities with over twenty years of accumulated product development experience and continued investment in R&D activities empowered us with abundant proprietary knowhow in product design, material treatment, manufacturing processes, and enabled us to successfully develop various proprietary technologies, including our world leading antibody coating technology that features the "pro-healing" function and can be applied in our existing or pipeline products and has been applied to our COMBO and COMBO Plus dual therapy stent products. We are also developing the second generation of such antibody coating technology and intend to apply it in a wider spectrum of medical devices.

In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, our research and development expenses accounted for 10.0%, 14.2%, 10.4%, 10.2% and 9.8% of our total revenue, respectively. For more details of our research and development expenses, please refer to the paragraphs headed "Financial Information – Description of Consolidated Statements of Profit or Loss – Research and Development Expenses" in this document. We intend to expand and improve our product portfolio by strengthening our research and development of new products, extending our product lines, upgrading our existing products and expanding our research and development team.

Our Research and Development Team

Our in-house research and development teams are based in Fort Lauderdale, Florida, the United States and Shenzhen, the PRC, and consisted of an aggregate of 68 members, including 46 experienced engineers with more than four years of experience as of June 30, 2022. As of June 30, 2022, both the Florida and Shenzhen teams are responsible for the conceptualization and conducting feasibility assessment of prospective products, and for subsequent initiation of the relevant programs. The Florida team plays a prominent role in the conceptualization of the products while the Shenzhen team is primarily responsible for conducting extensive testing of products, and creating prototypes for conceptualized products. The two teams collaborate closely as "one-team", and share the responsibilities for design, testing, development and review process of the products. Our research and development teams work closely with our global sales and marketing team throughout the R&D process, including identifying opportunities and competition landscape of target markets, understanding market-specific patient/physician needs and collecting physicians' feedback on our existing and pipeline products for the development, modification or improvement of relevant products.

Product Development

Our research and development process typically involves the following steps:

- *Design planning*: we involve multiple function teams in the process of design planning, and prepare a design and development planning report with the objectives, specifics, staffing, timetable and equipment specified;

- *Design inputs*: we take into consideration the needs of physicians and patients, as well as expected functions, safety requirements and regulatory framework;

- *Design outputs*: we develop and implement specifications, with regard to, among others, raw materials, components, finished products, product quality requirements, production work instructions, product instructions for use and test methods and reports;

- *Design verification*: our research and development team makes samples, and with our quality control and regulatory team, evaluate the design outputs against the inputs, and if required by law, the samples are tested by third party institutions, after which a design verification report will be produced;

- *Design validation*: our research and development team assesses whether the resulting product meets user requirements, needs and specifications as documented by the design input and design output. This can be done by simulated use testing, animal testing and/or human clinical studies. After which we confirm whether the design meets the market demand and expected usage;

- *Design transfer*: before massive production, we manufacture a limited quantity of the output products and conduct further verification to ensure the suitability for commercialization;

- *Design review*: we review our product design, production process and market place throughout the stage review process led by our research and development team with multiple functional teams involved.

For the overview of our existing and pipeline products, please refer to the paragraphs headed "Our Products and Product Pipeline" in this section.

Collaboration with Clinical Trial Institutions

We typically have contractual relationships with academic and commercial clinical research organizations (ARO/CRO), with detailed statements of work covering activities the management and execution of our company-sponsored research programs along with a detailed program budget. Additionally, each of the individual participating clinical sites in a given study have their own individual study contracts which define the investigator and site responsibilities and remuneration.

The factors we consider when selecting such institutions include their credentials, personnel expertise, lab equipment and technology, clinical research experience and patient demographics. Before selecting institutions, we will meet with physicians at a participating institution to discuss our clinical trial's purpose and requirements. For each clinical trial, we and the institution enter into a new agreement setting out the clinical trial's purpose, timeline, structure, procedures, methods and risks. Then, we prepare a clinical trial protocol for submission to the clinical trial institution's ethics committee. The clinical trials must be conducted in accordance with the protocol approved by the internal review boards (IRB) ethics committee. The ethics committee must re-evaluate and approve any amendments to the protocol.

Pursuant to the legally-binding agreements with these participating institutions, the institutions are required to conduct clinical trials strictly in accordance with the protocol, which generally include selecting subjects, obtaining informed consent from said subjects, administering the test device, monitoring and reporting all safety findings, collecting and maintaining record of data, and issuing case reports at the end of each clinical trial. The lead institution will prepare formal reports based on the pooled case reports submitted by all participating institutions and subsequent analysis. In return for the institutions' services, we make scheduled payments as agreed in the agreements. Under the clinical trial agreements, we generally own all the intellectual property and clinical trial results while the participating institutions may use the clinical trial results for academic activities with our prior approval.

OUR COLLABORATIONS WITH P&F INT'L

With our expertise in developing and manufacturing PCI/PTA instruments, we have been actively seeking opportunities to expand our product offerings into other areas. In October 2020, our subsidiary ONHV entered into a joint venture arrangement with Products & Features International, LDA ("**P&F Int'l**"), an Independent Third Party of our Group that is a medical technology company organized under the laws of Portugal principally engaged in the research, development, manufacturing, commercialization and distribution of heart valve products with facilities in Brazil and Germany. We became acquainted with P&F Int'l through the introduction by one of our long-term distributors, who is an Independent Third Party. Since we were considering expanding into the structural heart arena at that time, and P&F Int'l was looking for a partner with a robust sales network and strong operational ability to expand its business into Asian markets, we entered into rounds of discussions to explore business opportunities to further our mutual commercial interests. 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, including the TricValve Bicaval System, the Vienna aortic valve self-expandable, the Vienna mitral valve, the Pulmonary valve and the Aortosave endobentall device, all of which were developed based on the proprietary dry pericardium technology owned by an affiliate of P&F Int'l. TricValve is the first pre-mounted heart valve product in the world for the upper and lower double-lumen caval valve implantation (CAVI) to treat severe tricuspid regurgitation, which relieves atrioventricular expansion and heart failure caused by tricuspid regurgitation. The CE Mark for the TricValve was granted in May 2021 and the breakthrough device designation in the U.S. in December 15, 2020. P&F Int'l and we each hold 50% of the equity interest in ON P&F as of the Latest Practicable Date, and it is expected that all future net profits generated by ON P&F will be shared between P&F Int'l and us by way of dividend distribution in accordance with the respective shareholding percentages in ON P&F.

Our collaborations with P&F Int'l primarily include the following:

Distribution of heart valve products

Pursuant to an exclusive manufacturing and distribution agreement between P&F Int'l and ON P&F dated October 27, 2020, ON P&F has the right to distribute certain heart valve products including the TricValve in certain countries of the APAC region. While TricValve is developed by an affiliate of P&F Int'l, ON P&F has the exclusive right to commercialize such product in Australia, Japan, Malaysia, New Zealand, Singapore, South Korea, the Mainland China, Hong Kong, Taiwan and Macau pursuant to our joint venture contract with P&F Int'l. Subsequent to the grant of CE Mark, ON P&F has completed local product registrations in Malaysia, Saudi Arabia and New Zealand as of the Latest Practicable Date. In addition, ON P&F currently expects to make the registration submission with the NMPA for TricValve in 2023, and to commercialize the product in the PRC in 2024.

Pursuant to an exclusive distribution agreement between P&F Products & Features GmbH and us dated June 29, 2021, our Group has the right to distribute certain heart valve products including the TricValve in France, Saudi Arabia, Egypt and United Arab Emirates.

Co-development with ON P&F of balloon expandable heart valve

Leveraging our proprietary technologies and technical capabilities, we also entered into co-development arrangement with ON P&F to develop certain pre-mounted balloon expandable heart valve products which are indicated for structural heart diseases. Under the co-development arrangement for balloon expandable heart valve products, our responsibility is to assist ON P&F with the design of balloon formation and delivery system based on our proprietary technologies, and we remain as the owner of the rights to such patents and knowhow so that ON P&F will further license from us such patent rights, while developing its own technology and intellectual property to commercialize the final products. An affiliate of

P&F Int'l ("**P&F Int'l Affiliate**") has assigned all relevant intellectual property rights owned by it (other than those exclusively related to the manufacturing of the dry pericardium and those already licensed to ON P&F) in the balloon expandable heart valve to ON P&F. ON P&F owns all these intellectual property rights assigned by P&F Int'l Affiliate, and relevant intellectual property rights derived based on future development or improvement of these assigned intellectual property rights. ON P&F will bear its development costs relating to the balloon expandable heart valve products and we do not have any milestone payment arrangement with P&F Int'l or ON P&F. As of June 30, 2022, relevant research and development projects were still in preclinical stage.

Co-development of antibody-coated dry pericardium material

As part of our research and development effort to build our next generation heart valve products, we entered into co-development arrangement with an affiliate of P&F Int'l to co-develop certain antibody coated dry pericardium material, which is intended for enhancing the efficacy or application of the existing dry pericardium heart valve products. Similar to the co-development arrangement for balloon expandable heart valve products, we contribute the technology and knowhow in the anti-body coating technology and P&F Int'l contributes the technology and knowhow in the dry pericardium technology. Each of our Group and P&F Int'l will own the intellectual properties of technologies developed by us/it, while we and P&F Int'l will license the necessary technology to ON P&F for further development of the antibody-coated dry pericardium material for the second generation of heart valve products to be manufactured and distributed by ON P&F. Each party will bear its own development costs relating to the antibody-coated dry pericardium material and we do not have any milestone payment arrangement with P&F Int'l or ON P&F. As of June 30, 2022, relevant research and development projects were still in preclinical stage.

OUR PRODUCTION FACILITIES AND PROCESSES

Production Facilities

Our production facilities are located in Shenzhen, the PRC, and in Hoevelaken, the Netherlands. As our largest production facility, the Shenzhen production facility is dedicated to the design and manufacturing of the PRC branded and finished products, in addition to manufacturing of sub-assemblies for further processing in our Netherlands facility. Our Netherlands production facility specializes in in-house stent crimping, final packaging and manages the outsourced antibody coating and sterilization processes of the Netherlands branded and finished products. The PRC and Netherlands originated products allow us to fulfil the needs of different countries in the global market, and to supply large-scale and stable high-quality products and providing us with more flexible market access to customers around the world.

The Shenzhen production facility is owned by our Group with a total area of approximately 10,000 sq.m. For more details of our properties, please refer to the paragraphs headed "Properties" in this section. As of June 30, 2022, we had a team of around 600 employees in the Shenzhen facility, in which around 420 employees were dedicated to operations and around 70 employees were dedicated to quality control. As of June 30, 2022, we had a team of 51 employees in the Netherlands facility, in which 19 are dedicated to product production and seven are dedicated for logistics. All employees at both facilities are employed full-time.

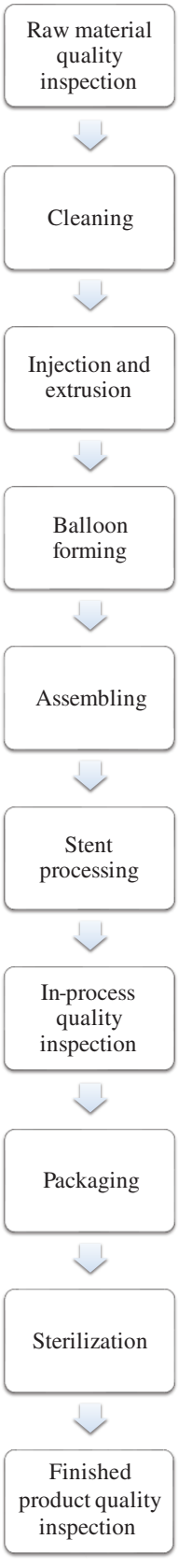
We believe that having production facilities both in the PRC and the Netherlands also gives us a competitive advantage over our international competitors in terms of labor cost management and operational flexibility. Typically, we require our employees to undergo health checks before they start producing medical devices, and we require new employees to undergo approximately three months of training before they commence work on our production lines. We believe that this comprehensive training enables us to increase our capacity utilization rate and product yield rate, and to enhance our production quality.

The machines we own and use for manufacturing our products mainly include sterilization, extrusion, injection, balloon forming, laser welding and other balloon production, catheter and drug eluted stent manufacturing and testing machines. As of the Latest Practicable Date, we own all of our machines and the estimated lifetime of these machines was approximately five to ten years, respectively. For details of the depreciation method of our machines, refer to Note 2.5 of the Appendix I to this document. We generally replace or upgrade our machines at the end of their lifetimes. We have multiple machinery suppliers so we are not dependent on any one supplier. Since we maintain our machines on a regular basis, we have not experienced any material or prolonged interruptions due to equipment or machinery failure as of the Latest Practicable Date.

Our Netherlands facility outsources the antibody coating function to third parties. It also outsources its sterilization function to third parties to maintain cost effectiveness. The third party responsible for carrying out the sterilization of the products are in the list of our key suppliers, which are monitored by our quality department, and are reviewed on an annual basis. We do not share any intellectual property with such third parties. Our Shenzhen facility outsources the production materials, including hypotubes and medical grade stainless stent frame from renowned medical components suppliers according to our own design. Such suppliers are subjected to confidentiality obligations relating to our Group's intellectual property.

Production Process for Our Commercialized Products

Our production process typically involves the following steps for our products:



- Raw material quality inspection: We examine the quality of the raw materials purchased.
- Cleaning: We determine whether the raw materials need to be cleaned based on their manufacturing environment, and carry out the cleaning before moving the raw materials into the production facility.
- Injection and extrusion: Polymer materials will be melt and shaped through molds into plastic components required for medical devices by extrusion or injection machines.
- Balloon forming: The extruded tube will be further processed into a balloon which is the key component of the balloon catheters.
- Assembling: By using welding, gluing, swaging and other applicable technologies, we assemble the semi-finished components and parts of the medical devices into a finished device.
- Stent processing (for stent products only): For stent product, the stent steel frame will be coated with drug/antibody and then crimped onto the catheter.
- In-process quality inspection: We conduct a comprehensive quality inspection on the work in progress products after they are assembled.
- Packaging: The finished product will be sealed into a Tyvek-mylar pouch in this process.
- Sterilization: The packaged medical devices will be transferred either to in-house sterilization room for Shenzhen products or to third party sterilization service providers for the Netherlands products for sterilization.
- Finished product quality inspection: We conduct a comprehensive quality data review on sterilized medical devices prior to release to our finished goods stock.

For our PRC facility, the entire production process for our balloon products generally takes four to eight weeks, while for our Netherlands facility, the entire production process for our balloon and stent products generally takes 10-14 weeks and 15 weeks, respectively. All the steps in our production process are conducted in compliance with the applicable GMP requirements. We have implemented quality management systems as part of our manufacturing processes. For more details, please refer to the paragraphs headed "Quality Assurance" in this section.

We typically conduct each of the above steps in-house, except that we engage third parties for the sterilization step and the antibody coating process for the Netherlands products. We select the third party service providers based on their qualifications and sterilization/coating ability, and we only enter into an agreement with service providers that meet our standards. Our integrated production process increases our production efficiency and reduces our dependence on third parties, and enables us to adjust our production quickly to respond to changes in market demand for our products.

Supply Chain and Logistics

Our supply chain and logistics team is based in Hong Kong and the Netherlands. As of June 30, 2022, our Hong Kong supply chain and logistics team had 13 employees, whilst our Netherlands supply chain and logistics team had seven employees. Our supply chain and logistic teams are generally responsible for our overall inventory and logistics management. Both teams will provide forecast data to the Shenzhen and Netherlands production facilities. In addition, the Hong Kong logistics department will also forecast the production and sales of products, and the factory will prepare raw materials based on the forecast.

As regards to the handling of purchase orders, the logistics department in our Hong Kong office sends purchase orders to our PRC and the Netherlands production facilities, with reference to the sales figures per the purchase order and our inventory level. After our PRC and the Netherlands production facilities complete the production processes, our Hong Kong office will then distribute the finished products to various locations around the world according to relevant purchase orders.

Production Volume, Production Capacity and Utilization Rates for Our Commercialized Products

The following table sets forth the production capacity, actual production volume for our commercialized products and utilization rate at our production facilities for the periods indicated:

	For the year ended December 31,									For the six months ended June 30,					
	2019			2020			2021			2021			2022		
	Production capacity[1] *(thousand units)*	Production volume *(thousand units)*	Utilization rate[2]	Production capacity[1] *(thousand units)*	Production volume *(thousand units)*	Utilization rate[2]	Production capacity[1] *(thousand units)*	Production volume *(thousand units)*	Utilization rate[2]	Production capacity[1] *(thousand units)*	Production volume *(thousand units)*	Utilization rate[2]	Production capacity[1] *(thousand units)*	Production volume *(thousand units)*	Utilization rate[2]
Balloons	1,066	815	76.4%	1,066	791	74.2%	1,222[3]	1,071	87.6%	611	514	84.1%	676[4]	551	81.5%
Stents	57	25	44.7%	57	34	60.8%	57	26	46.4%	28	15	52.1%	28	13	46.4%

(1) Production capacity refers to the theoretical maximum units of products that our manufacturing facilities can produce in a period. For our balloon products which are primarily manufactured in the PRC, we estimated the theoretical maximum units that could be produced assuming our production line is operating 21 hours each working day, six working days per week and 52 weeks per year. For our stent products manufactured in the Netherlands, we estimated the theoretical maximum units that could be produced assuming our production line is operating 7 hours each working day, five working days per week and 50 weeks per year.

(2) Utilization rate refers to the percentage of the production volume to production capacity during the year/period.

(3) The increases in our production capacity in 2021 primarily reflected our installation of additional machinery and equipment in our PRC facility.

(4) The increases in our production capacity during the first six months of 2022 primarily reflected our upgrade of existing and additional machinery and equipment in our PRC facility.

Our production workers were trained to be able to produce different products. Our production workers were allocated to produce different products based on our production plan, which we design with reference to the market demands for the relevant product. If the demand for a certain product increases, we would allocate more working hours of our production workers on such product.

During the Track Record Period, the production capacity for our balloon products was generally stable. The increases in our production capacity in 2021 primarily reflected our installation of additional machinery and equipment in our PRC facility while increases in our production capacity during the first six months of 2022 primarily reflected our upgrade of existing and additional machinery and equipment in our PRC facility. We will continue to expand our production facilities in the PRC to further increase our production capacity and address the growing market demand for our products, which is driven by the increasing CAD and PAD prevalence, rising demand for PCI and PTA operations and continuous product development, as advised by the Industry Consultant. The increase in production volume for our balloon products from 2020 to 2021 and from the first six months of 2021 to the first six months of 2022 was consistent with the increase in our sales volume during the respective periods. The decrease in production volume for our balloon products from 2019 to 2020 was primarily due to the impact of COVID-19 pandemic.

The relatively high production capacity for stents during the Track Record Period was because we ramped up the production capacity of our facility in the Netherlands before the Track Record Period in anticipation of the introduction of COMBO Plus in Japan in late 2019, which was impacted by the COVID-19 pandemic. The relatively low production volume for stents in 2019 was because we strategically decreased sales in a few European markets that generally had lower profit margins and the relatively low production volume for stents in 2021 was because the Japan market was impacted by the COVID-19 pandemic, which adversely affected the introduction of our new stent products in the country. As a result, the utilization rate for stent products was lower than the management's expectation during the Track Record Period. We anticipate that the utilization rate for stent products will increase after the recovery of Japan market from the COVID-19 pandemic. Although the Japan market had not fully recovered from the COVID-19 pandemic in the first half of 2022, there has been an increasing trend of the production volume and utilization rate of stents. The production volume for stents increased from approximately 11,000 units in the second half of 2021 to approximately 13,000 units in the first half of 2022 while the production capacity remained the same over the same periods. As such, as the Japan market gradually recovers from the COVID-19 pandemic, we anticipate that the utilization rate for stents will increase.

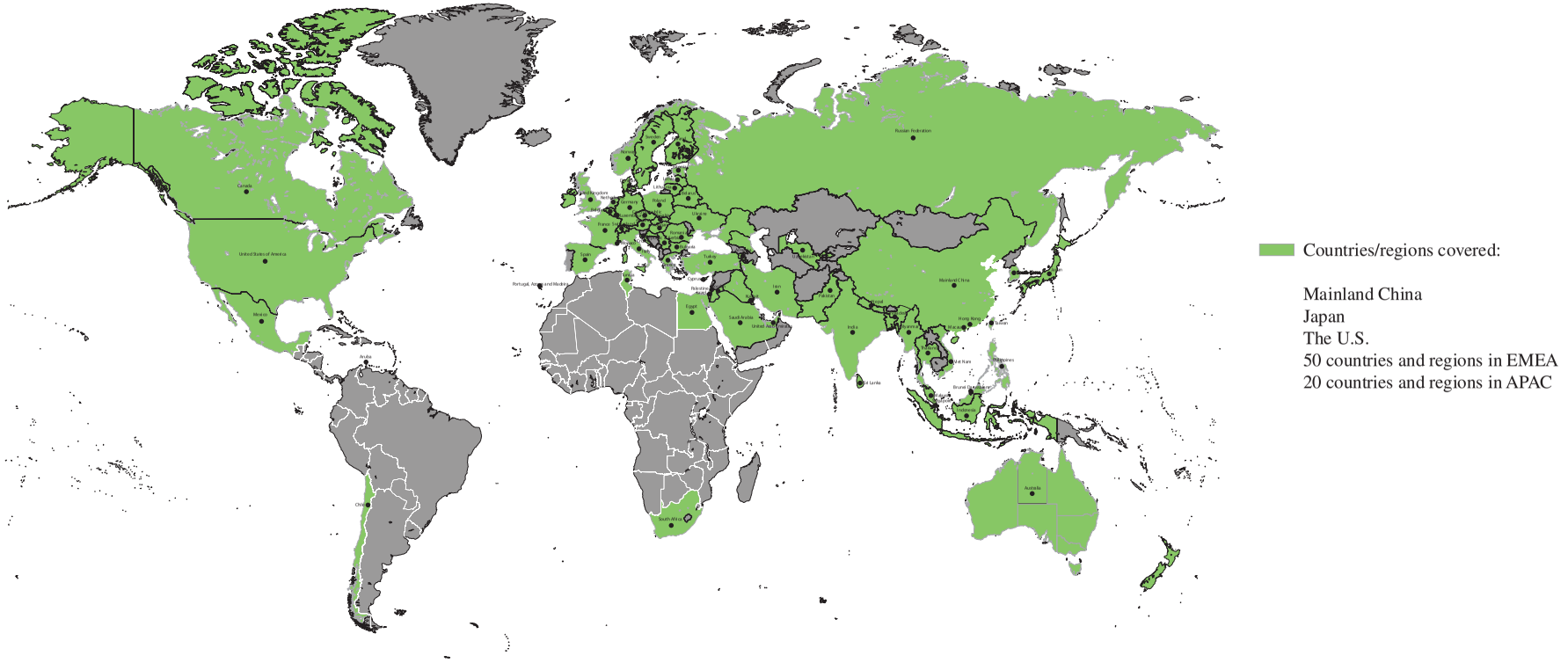
To the best knowledge of our Directors, there has been no material disruption of operations with our production facilities during the Track Record Period.

PRODUCT WARRANTY, RETURN, RECALL AND EXCHANGES

For our commercialized products, our internal policy is to assume responsibility as required by law if the competent regulatory authorities find that our products are defective. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any such finding. In line with the industry practice, our return and exchange policy generally does not allow any product return or exchange, except that in case of any product defect, we will consider returning or exchanging products by considering the specific scenario and our working relationship with our distributors. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material product return or exchange from customers. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, products returned by our customers amounted to approximately US$112,000, US$34,000, US$64,000, US$31,000 and US$2,000, respectively, representing approximately 0.12%, 0.04%, 0.05%, 0.05% and 0.003% of our revenue for relevant periods.

SALES, MARKETING AND DISTRIBUTION

As of June 30, 2022, our sales network covered over 70 countries and regions worldwide, among which we also built our direct sales force in the Mainland China, Hong Kong, Macau, Japan, Malaysia, Singapore, Germany, France, Switzerland and Spain. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our direct sales channel covered eight, nine, ten and ten countries and regions, respectively, and our distributorship channel covered 61, 59, 65 and 65 countries and regions, respectively. The map below sets forth countries and regions covered by our distribution and sales network as of June 30, 2022:



Our Sales and Marketing Teams

Our sales and marketing teams are primarily responsible for building brand image, broadening our brand recognition, and developing customer loyalty. Our marketing department will interact with different disciplines of our Group on a regular basis to conduct product positioning and form our market strategies, and assist with our research and development process. With our established sales and marketing teams and our experience in managing our comprehensive distribution network, we believe we are well prepared for the future launch of pipeline products. As of June 30, 2022, our sales and marketing team has an aggregate of 142 employees, of which nine focused on our marketing activities, and 133 employees focused on our sales activities.

Our Marketing Model

We adopt a diverse array of marketing strategies, including the following:

- *Ground-level and granular marketing*: our marketing team operates close to physicians, patients and healthcare professionals to understand their needs and challenges faced. Our marketing team also coordinates and analyses feedback in collaboration with our internal R&D function

- *Peer to Peer marketing*: we develop, and nurture endorsements and we engage our customers with other prospective customers regarding our products through various media such as workshops, seminars, and global events

- *Electronic marketing*: we have an active presence on social media, and operate on sites such as LinkedIn, Facebook and Twitter

- *Internal marketing*: we seek to ensure that all multidisciplinary teams across our global operations are constantly aware and informed of our marketing efforts and updates to market trends

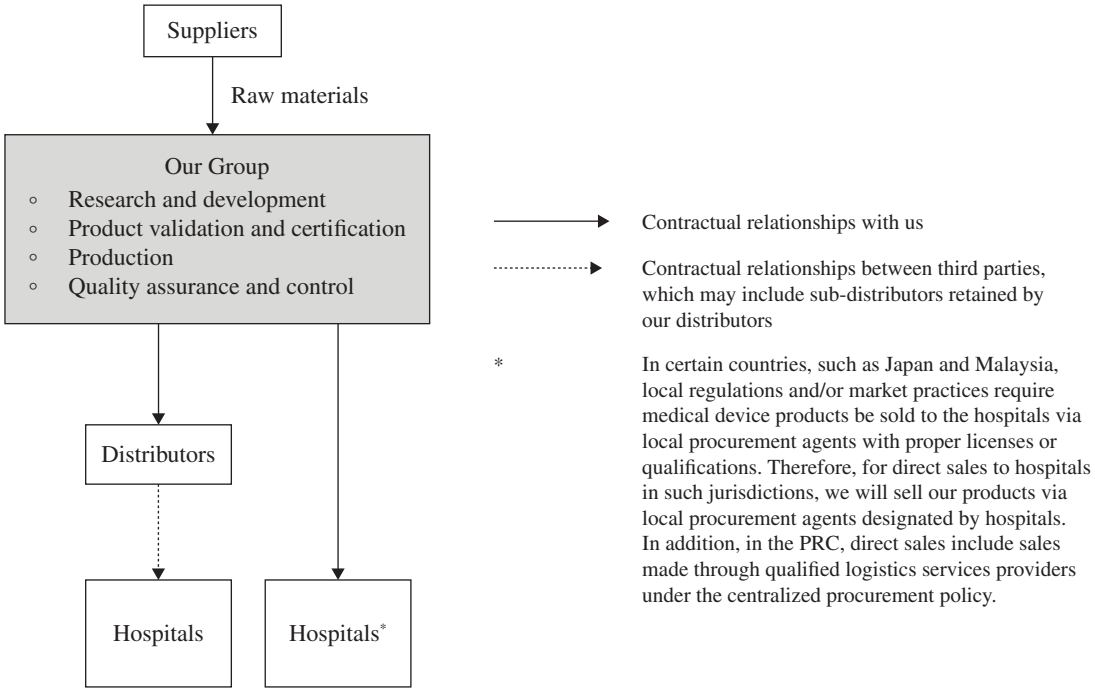
- *Distribution partners*: we work and communicate closely with the marketing departments of our distributors

We also take part in major symposiums around the world. During the Track Record Period, we have taken part in around 41 symposiums. In particular, we attend the annual Transcatheter Cardiovascular Therapeutics (TCT) conference held in the U.S., and the Paris Course for Revascularization (PCR), both are premier meetings for interventional cardiovascular medicine practitioners and physicians. These events give our engineers the opportunity to interact with cardiologists, KOLs and physicians across the world, discussing topics such as new product development concepts and challenges faced in laboratories. These events not only provide a platform for us to market our Company, but also allows us to evaluate or validate our existing product offerings, and evaluate our competitors. Knowledge and insights gathered from these conferences are transferred into our product development. We believe that through such frequent communications and training, we are able to maintain good working relationships with these KOLs and physicians, and help them gain familiarity with our products; and if these KOLs and physicians formed positive opinions of our products, it is likely that they will speak positively of our products in publications, at industry conferences, or when sharing experience with other physicians.

Our Sales Arrangements

In line with the industry practice, our sales transactions are conducted through two main channels: direct sales or through distributors. We believe the combination of distributorship and direct sales provides us with more flexible and effective sales strategies in our existing and new target markets. For certain countries/regions, we would opt to utilize a mixture of distribution and direct sales and adopt different sales tactics based on the local regulatory requirements, economic conditions and effectiveness considerations. Specifically, our sales strategy in a market (existing or new) depends on factors including the market size, fragmentation of the market, our product offering, local regulatory requirements, economic conditions, our internal knowledge of the market and set up cost for a direct sales team. For example, in well-established markets with long operating history, such as Japan, we adopted direct sales model; in new markets, such as U.S., we adopted distributorship model. In EMEA and APAC markets, a large number of countries or regions are involved. Different sales models were adopted after we take into account the aforementioned factors. For example, in the EMEA market, we adopted direct sales model in major developed European countries with relatively high sales volume, such as Germany, France, Spain and Switzerland while adopting distribution model in other countries with lower sales volume including Czech Republic, Slovakia, Italy, etc. In APAC, we adopted direct sales model in Hong Kong, Singapore and Malaysia taking into account the relatively high sales volume in those countries or regions while adopting distribution model in countries or regions including Taiwan, Indonesia, Vietnam, Thailand and India. In addition, for the PRC market, we have utilized a mixture of distribution and direct sales model since 2021. The utilization of such model in the PRC generally allowed us to capture the sales opportunities of products included under the centralized procurement policies by direct sales and products not included under the centralized procurement policies by distribution model. Please refer to "Sales, Marketing and

Distribution – Development of Our Sales Network in the PRC" in this section for more details of the sales arrangements for the PRC market. Going forward, we will continue to optimize our sales strategy after considering the aforementioned factors. The following chart sets out our two sales models:



Sales to Distributors

We had established an extensive and growing distribution network. As at June 30, 2022, we had a total of approximately 207 distributors, among which one, 59, 13 and 134 were located in the U.S., EMEA, APAC and the PRC. We sell our products to distributors as our customers, with an aim of leveraging their insight of local markets and to expand our sales network. We generally grant exclusivity for a specified country/region/hospital(s) to each distributor, and therefore we do not expect there are cannibalization issues between different distributors in their authorized territories. During the Track Record Period, we had only seven non-exclusive distributors, and all the others were exclusive distributors. We confirm that, to our best knowledge, after making reasonable enquiry, except for Customer A, all our distributors were Independent Third Parties to our Group. The following table sets forth the movement in the number of our distributors for 2019, 2020, 2021 and the six months ended June 30, 2022:

Number of distributors	2019	2020	2021	For the six months ended June 30, 2022
Opening balance	61	69	62	174
Increase	12	4	120	33
Decrease	(4)	(11)	(8)	–
Closing balance	69	62	174	207

We generally maintain long-term relationships with our distributors and review their performance on an annual basis in order to optimize our distribution network. For example, in 2020, we terminated five distributors and appointed one distributor in Italy to better manage of sale activities in the country, which led to a higher number of decrease in distributors in such year. Since 2021, we have adjusted our sales strategy for the PRC market in light of the changes in sales environment. Part of our products sold in the PRC market were brought into the scope of centralized procurement as a result of the strengthening of the centralized procurement system of high-value medical consumables. For details of the centralized procurement policies, please see the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Centralized Procurement of Medical Devices" in this document. With an aim to further expanding our sales network and hospital coverage, we ceased to cooperate with Customer A, being the former exclusive distributor of our products for the entire PRC market, and appointed over 100 new regional distributors in the PRC in 2021 to expand our sales network and hospital coverage. We have appointed over 100 new regional distributors in the PRC in 2021, each of which contributed to less than 1.0% of our revenue in 2021, with the largest distributor contributed to approximately 0.9%. Riding on the same strategy, we have further engaged 30 distributors in the PRC in the first six months of 2022 for further expansion of the PRC market. For more details, please refer to the paragraphs headed "Sales, Marketing and Distribution – Development of Our Sales Network in the PRC" in this section.

Selection and Management of Distributors

We select our distributors based primarily on their experience in the medical device industry and their working relationship with hospitals. Our distributors are typically reputable distributors in local markets with long operating history. Furthermore, they must hold the necessary business licenses and permits to sell medical devices in the country and/or regions where they conduct activities. Before we enter into an agreement with new distributors, we review their qualification documents to ensure that they have the appropriate license and background. In addition, we conduct a thorough assessment, including financial ability, creditworthiness and adequate territory and hospital coverage, before we accept a new distributor. In addition, we also assess relevant candidates' ability to achieve our targeted sales volume and to implement our pricing strategies for relevant territories, their number/qualifications of sales personnel, credibility of the founder/senior management (such as absence of criminal record, penalties and/or sanctions by local regulatory authorities). These criteria are subject to early discussions prior the initiation phase and apply to all our distributors. Save as otherwise disclosed in this document, to the knowledge of our Directors, all of our distributors during the Track Record Period and as of the Latest Practicable Date were Independent Third Parties to our Group.

Our distribution agreements typically have a term of one to three years and include an early termination right if the distributors do not meet sales targets, being the minimum purchase obligations in terms of number of units undertaken by the distributors under relevant distribution agreements which are usually renewed each year, or breach any of their undertakings in the agreement, thus ensuring that we can terminate our contractual relationships, if necessary. Annual sales targets are set by us and agreed by the distributors according to our projections of the market demand in relevant distributors' authorized territories. In addition, our distribution agreements typically require our distributors to covenant that they will comply with all applicable laws and regulations during their operations. During the Track Record Period, three of our distributors were unable to meet the minimum sales target without a valid reason and therefore we changed their exclusive distributor status to non-exclusive. In addition, during the Track Record Period and up to the Latest Practicable Date, none of our distributors was terminated by us due to failure to comply with applicable laws and regulations promulgated by regulatory authorities in applicable jurisdictions.

We proactively manage our network of distributors by conducting regular evaluation based on their performance. We review the distributors' sales performance, particularly whether they meet the target sales amount, and their authorized hospitals' feedback. Depending on our evaluation of their performance, we may grant rebates to our distributors, terminate our cooperation with them, or renegotiate the commercial terms in accordance with the distribution agreements. In 2019, 2020, 2021 and for the six months ended June 30, 2022, sales rebates to our distributors were approximately US$265,000, US$133,000, US$49,000 and nil, respectively, and the amounts of rebates were mainly determined by sales targets agreed between the distributors and us.

If the distributor breaches any material provision of the distribution agreement and fails to remedy such breach within a specified time, we may terminate the distribution agreement pursuant to relevant provisions in the distribution agreement. We lay great emphasis on our distributors' compliance with applicable laws and regulations, in particular the anti-bribery/corruption related laws and regulations. Each of our new distributors is required to provide information on its understanding of local anti-bribery legislation, and online anti-corruption training is made available by our Company to our distributors via an online training platform. Each of our distributors is also provided with a copy of our anti-corruption policy and code of business conduct and ethics and has undertaken to abide by those policies under the distributorship agreements. The distributorship agreement further provides an indemnity undertaking by distributor to hold the Company, its affiliates and others harmless from any loss arising out of any failure by any distributor representative and to follow the said policies or discharge the anti-bribery obligations stipulated under that agreement. Based on the above measures adopted by us and taking into account the fact that the Internal Control Consultant did not identify any further deficiencies on the formulation and implementation of such policies and measures established by our Group, our Directors are of the view, and the Joint Sponsors concur, that such measures are sufficient and effective in lowering and mitigating the risks of bribery and corruption by our distributors.

Market Demand

We believe that our sales to distributors during the Track Record Period reflected genuine market demand. We generally grant our distributors credit terms within 30 to 180 days. We recognize revenue from distributor sales when the products are dispatched from our storehouse for shipment to distributors, at which point the distributors take ownership of the products and assume the risk of loss. For more details of our revenue recognition policies, please refer to the paragraphs headed "Financial Information – Significant Factors Affecting Our Results of Operations and Financial Condition – Critical Accounting Policies – Revenue Recognition" in this document.

While we maintain regular communications with our distributors to understand their business plans and sales results, we do not track our distributors' inventory balance given that our relationship with the distributors are buyer and seller. In assessing our distributors' performance and creditworthiness, we take into account their respective sizes of local markets, sales budgets, order patterns and collection rates. Given that the shelf life of our products are only up to two years and the consumption of our products largely depends on the number of PCI/PTA procedures conducted by the hospitals covered by our distribution network, we believe that our distributors tend to only purchase products that they can reasonably sell and keep their inventory levels relatively low because, under the sales agreements, they are generally not able to return to us the products. We believe that our distributors would sell their inventory first before purchasing more products from us, which means that instead of purchasing a large amount of products each time, our distributors would purchase no more than what they need and make repeated purchases. Furthermore, we set annual sales targets for distributors which is in line with the industry practice. We set sales targets for each

distributor's territory according to our knowledge of the market potentials and our market share target, and the minimum sales prices of our products in each territory are separately negotiated and agreed by our distributors and us based on local market conditions.

We also communicate with distributors from time to time to gather relevant data in connection with sales potential and other information. We believe the above communication with our distributors as well as the relevant data and information we gather from them help us to set reasonable sales targets for distributors and adopt appropriate sales and pricing strategies.

Distribution Agreements

Our distributors are primarily Independent Third Parties to our Group and our relationship with our distributors is not that of a principal and an agent. As such, we have no ownership or management control over any of our distributors. However, the distributors are required to comply with the terms and conditions under our distribution agreement.

We enter into an agreement with each distributor, which contains appendices setting out tailored terms including minimum purchase obligation and designated distribution territory and/or hospitals. We generally renew our distribution agreements with our distributors in January every year after end of contract term. In addition, we generally do not prohibit our distributors from engaging sub-distributors in their respective authorized distribution territories, and we do not control or liaise with such subdistributors directly. The following table sets forth the salient terms of the standard agreement with our distributors.

Term	Generally one to three years.
Designated distribution territory or hospitals	The distributor may only sell our products in the designated distribution territory, or to the hospitals in the designated distribution territory as specified in the distribution agreement.
Relationship with distributor	Our relationship with them is not that of a principal and an agent, but that of a customer and a supplier with no obsolete stock arrangements.
Covenant not to sell competing products	The distributor is prohibited from selling competing products without our prior consent.
Exclusivity	In countries where we enter into exclusive distributorship, we do not appoint any other agent, representative or distributor in relevant distribution territories.

Minimum purchase obligation	If the distributor fails to meet the minimum purchase obligation set forth in the appendix to the relevant agreement, we can terminate the agreement.
Payment and credit terms	We generally grant our customers a credit term ranging from 30 days to 180 days depending on the sales volume and market practices. For some of our distributors in the PRC, we require them to make payment in full prior to shipping.
Product return/exchange	In line with the industry practice, we generally do not accept product returns or exchanges except for products with quality defects.
Transportation and delivery	We generally agree to deliver the products to locations specified by the distributors.
Warranty	We warrant that our products are free from defects in materials, workmanship and design for ordinary use.
Regulatory compliance	The distributor is required to comply with all applicable laws and regulations, including, among other things, those relating to anti-bribery and anti-kickbacks.
Termination	The agreement may be terminated by us when, among other things, the distributor fails to comply with relevant laws and regulations, fails to meet its minimum purchase obligation, or breaches any undertaking in the agreement and fails to remedy such breach within a specified period of time.

Direct Sales

In addition to our distribution network, we also maintain an experienced dedicated global sales team and conduct direct sales to hospitals in the Mainland China, Hong Kong, Macau, Japan, Malaysia, Singapore, Germany, France, Switzerland and Spain. Our highly trained sales team collaborates with our global marketing team to proactively identify market opportunities, design sales strategies, and provide product trainings to physicians. By working closely with the physicians, we in turn gain valuable insights into the operations of each local market and the physicians' needs. In countries and regions where we conduct direct sales to hospitals except for the PRC, we maintain a consignment system under which we stock consignment inventory at hospitals' warehouses to ensure product availability. By placing inventory in closer proximity of hospitals while retaining ownership of such inventory until hospitals ascertain the consumption and place orders, we are able to track the inventory level and handle consumption events at each consignment site, and replenish inventory on a timely manner, thereby significantly lowering write-offs for expired or damaged products. We typically replenish inventory within one week after receiving orders from hospitals. We are generally responsible for damaged products as well as for conducting regular checks on the inventory to assure quality and to replace products which have passed their expiry dates. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our direct sales amounted to US$50.5 million, US$49.1 million, US$63.9 million and US$33.6 million, respectively, representing 52.4%, 55.5%, 54.9% and 48.9% of our total revenue for the same periods, respectively. Among our direct sales in 2019, 2020, 2021 and for the six months ended June 30, 2022, US$29.1 million, US$27.5 million, US$38.8 million and US$20.0 million was to public hospitals, respectively, while US$21.4 million, US$21.6 million, US$25.1 million and US$13.6 million, was to private hospitals, respectively. Substantially all of our direct sales were conducted through the consignment sales arrangements with hospitals, which amounted to US$50.5 million, US$49.1 million, US$61.4 million and US$32.5 million respectively. In Japan and Malaysia, local regulations and/or market practices require that medical device products be sold to the hospitals via local procurement agent with proper licenses or qualifications designated by hospitals. While sales invoices are settled through the local procurement agents designated by the hospitals, sales are also conducted under consignment arrangements in the hospitals in such countries. These sales are regarded as under a direct sales model. In 2019, 2020, 2021 and for the six months ended June 30, 2022, among our direct sales through the consignment system, US$31.6 million, US$30.1 million, US$31.8 million and US$18.1 million was settled through local procurement agents designated by hospitals, respectively. In the PRC, direct sales include sales made through qualified logistics services providers under the centralized procurement policy.

We sell directly to hospital customers at retail prices determined primarily through the tender process, which are higher than the wholesale prices at which we sell to distributors, and therefore the gross profit margins for direct sales to hospitals are typically higher than those for sales to distributors. However, we may incur higher selling and marketing expenses for direct sales to hospitals. In line with the market practice, hospitals generally do not enter into framework or long-term sales agreements with us. We are responsible for arranging the delivery of products to our hospital customers and any loss or damage in transit.

The following table sets forth the movement in the number of our Group's direct sales customers during the Track Record Period:

	As of December 31,			As of June 30,
	2019	2020	2021	2022
Opening balance	466	523	532	598
Increase	82	69	118	71
Decrease	(25)	(60)	(52)	(58)
Closing balance	523	532	598	611

* In 2019, 2020, 2021 and for the six months ended June 30, 2022, our direct sales channel covered approximately 1,552, 1,541, 2,164 and 2,431 hospitals (including those that were settled through local procurement agents), respectively, of which approximately 857, 867, 1,468 and 1,692 were public hospitals and approximately 695, 674, 696 and 739 were private hospitals. In Japan and Malaysia markets, sales are settled through local procurement agents designated by hospitals under applicable local regulations and/or market practices. In the PRC, direct sales include sales made through qualified logistics services providers under the centralized procurement policy. The numbers of hospitals coverage were higher than the numbers of direct sales customers, primarily because a local procurement agent in Japan and Malaysia or a qualified logistics services provider in the PRC could cover more than one hospital.

The higher numbers in the decrease of direct sales customers in 2020, 2021 and the first six months of 2022 were primarily due to the decrease of direct sales customers (i.e., hospitals) in Germany during the corresponding periods as a result of the consolidation of hospitals by hospital groups during such periods.

In 2021, we adjusted our sales strategy for the PRC market in light of the changes in sales environment. Part of our products sold in the PRC market were brought into the scope of centralized procurement as a result of the strengthening of the centralized procurement system of high-value medical consumables. For details of the centralized procurement policies, please refer to the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Centralized Procurement of Medical Devices" in this document.

With an aim to further expanding our sales network and hospital coverage, we ceased to cooperate with Customer A, being the former exclusive distributor of our products in the entire PRC market, and actively participated in tender and won seven bids of centralized procurement to sell to the hospitals covering 23 provincial regions in the PRC in 2021. For more details, please refer to the paragraphs headed "Sales, Marketing and Distribution – Development of Our Sales Network in the PRC" in this section.

As advised by the Industry Consultant, based on surveys conducted by it and the interviews with relevant industry participants, each of (1) the two-pronged sales model adopted by us (i.e., direct sales and sales through distributors); (2) setting of annual sales targets for our distributors; (3) our lack of long-term sales/framework agreements with direct sales customers; and (4) return and exchange policy adopted by our Company are in line with industry practices.

New Market Entrance Arrangement

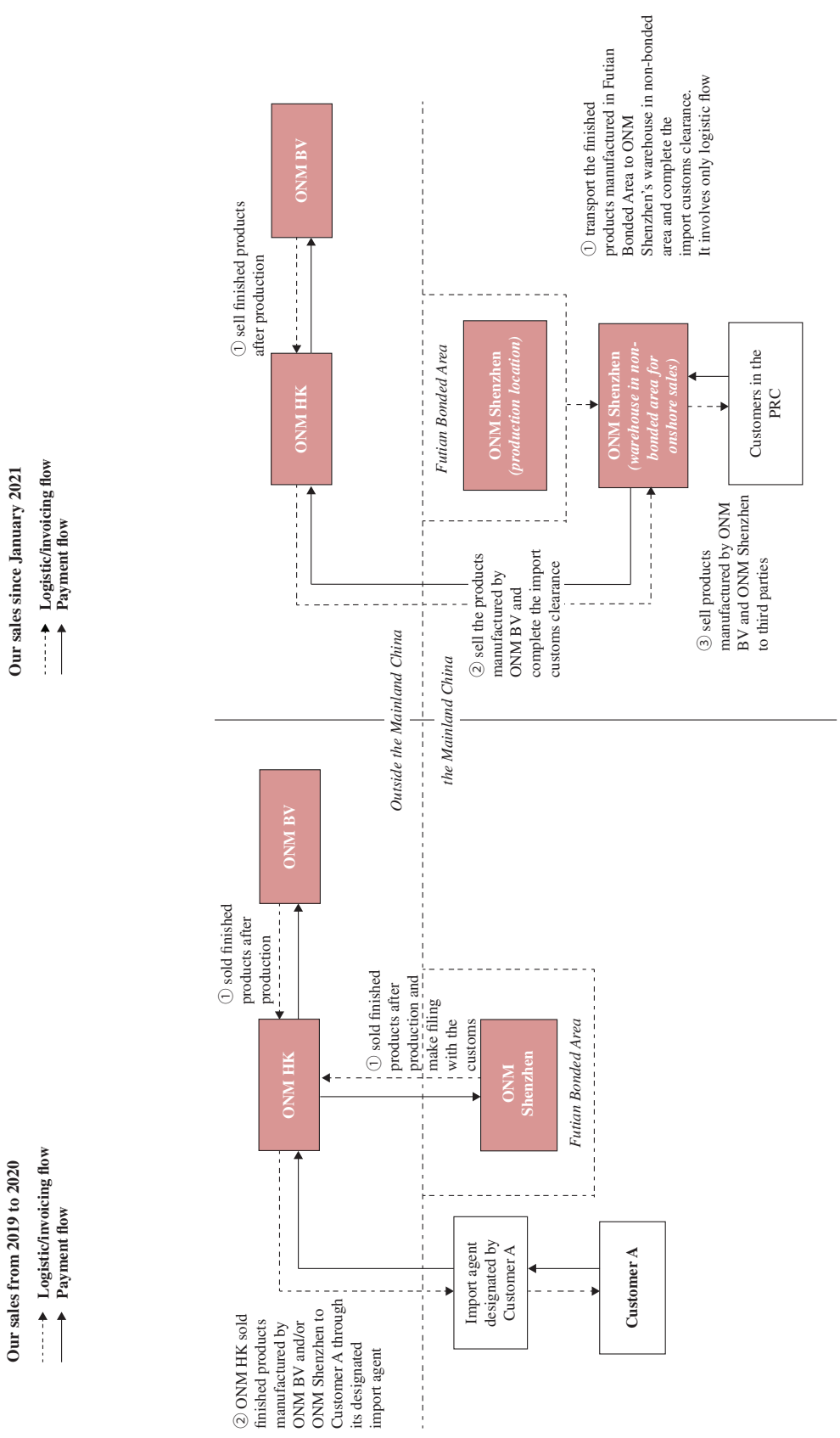
Before entering into a new market, we would research and analyse the products available on the market and assess the unmet market needs. After studying the market situation, we would usually first launch a product with unique features. For example, we launched our Sapphire II Pro which was the first 1.0mm diameter balloon cleared by the FDA when we first entered the U.S. market, and received positive market reception.

Since we may only possess limited market knowhow and offer limited products in new markets, we tend to enter new markets through distributors, which do not require us to set up a sales office in the new market immediately. Instead, our existing internal sales force will manage the distributors and provide necessary sales support. A territory head who is responsible for identifying and selecting potential distributor will conduct a preliminary assessment of the potential distributor to ensure that the essential basic requirements are met prior to furthering the process of introducing and approving a potential distributor. The assessments criteria on selecting new distributors include their financial ability, creditworthiness and adequate territory and hospital coverage. Distributors are then selected based primarily on their experience in the medical device industry and their working relationship with hospitals. The territory head will complete the new distributor approval form and submit it together with supporting documents to the department heads of sales, finance, legal, regulatory affairs, and logistics/supply chain for approval. After engaging the distributors, our internal sales force will be responsible for constantly managing the distributors' performance and provide them with necessary sales support and training. To this end, distributors need to submit periodic business review report to our relevant internal sales team. We also require the new distributor to confirm their understanding of local anti-bribery legislation, participate our online anti-corruption training and be provided with a copy of our anti-corruption policy and code of business conduct and ethics which the distributors have undertaken to abide by under the distributorship agreements.

Development of Our Sales Network in the PRC

During the Track Record Period and up to the Latest Practicable Date, our Group had two different sales arrangements for customers in the PRC market.

Sales to the PRC Market



Our Sales Network in the PRC from 2019 to 2020

From 2019 to 2020, ONM HK sold the products manufactured by ONM BV and/or ONM Shenzhen (as the case may be) to the PRC market first to the import agent designated by Customer A for the import customs clearance purposes. The import agent then sold our products to Customer A for further distribution. The involvement of the import agent in such sales arrangement was proposed by Customer A which, to our best knowledge, was mainly for the reason of improving efficiency in completing the import customs clearance.

Our Sales Network in the PRC since January 2021

Since January 2021, to expand our sales network and hospital coverage in the PRC, we have changed our distribution model in the PRC from the exclusive distributorship for the entire PRC market to a combination of direct sales and regional distributors. To this end, we have established our own direct sales team in the PRC, engaged new regional distributors and adjusted the sales arrangement to the PRC market since January 2021 as follows:

- In respect of the finished products manufactured by ONM Shenzhen, ONM Shenzhen sold the products directly to the various customers in the PRC after it completed the import customs clearance process when such products were transported from Futian Bonded Area to its warehouse located in non-bonded area in the PRC in accordance with the PRC customs regulations.

- In respect of the finished products manufactured by ONM BV, ONM HK sold such products to ONM Shenzhen and ONM Shenzhen transported such products to the warehouse located in non-bonded area for storage after it completed the import clearance process and then sold to the various customers in the PRC.

Our PRC legal advisors were of the view that the above sales arrangements to the PRC market during the Track Record Period did not violate the PRC customs laws and regulations in any material respects based on the followings including: (i) their understanding of the customs regulations of the PRC (including the Regulations on the Customs Supervision in Bonded Area (保税區海關監管辦法)), (ii) the confirmation letters issued by Fuzhong Customs (福中海關), being the competent authority responsible for issuing the confirmation letters regarding customs matters of ONM Shenzhen, and dated August 6, 2021, November 22, 2021, April 8, 2022 and July 22, 2022, respectively, which confirmed that ONM Shenzhen had no material non-compliance incidents at Shenzhen Customs District during the Track Record Period, and (iii) the results of the searches conducted by them on Credit Publicity Platform of Import and Export of Customs of the PRC (中國海關企業進出口信用信息公示平台) maintained by the General Administration of Customs of the PRC (中華人民共和國海關總署) and their review of the relevant documents provided by the Company, which indicated no records of material non-compliance incidents of ONM Shenzhen during the Track Record Period and up to the Latest Practicable Date.

Development of Our Relationship with Customer A in the PRC

We commenced our business relationship with Customer A as our former exclusive distributor for the PRC market since 2002. Incorporated in Shenzhen in November 2002, Customer A is a PRC private company engaged in the manufacturing and sales of medical devices with products selling over 20 provincial regions in the PRC. On January 1, 2020, ONM HK and Customer A entered into a distributorship agreement (the "**Distribution Agreement**"), pursuant to which ONM HK appointed Customer A as its exclusive distributor for some of our products in the entire PRC market with a term from January 1, 2020 to December 31, 2020 (the "**Distribution Period**") and Customer A purchased relevant products from us. Our sales arrangement with Customer A remained consistent in 2019 and 2020. We and Customer A did not renew the Distribution Agreement after the Distribution Period expired on December 31, 2020.

While we intended to continue the business relationship with Customer A, we were unable to agree on the commercial terms and renew the Distribution Agreement with Customer A primarily due to the following reasons:

(1) *Inclusion of part of our products in the scope of centralized procurement*: Part of our products sold in the PRC market were brought into the scope of centralized procurement as a result of the strengthening of the centralized procurement system of high-value medical consumables. For details of the centralized procurement policies, please refer to the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Centralized Procurement of Medical Devices" in this document. The inclusion of part of our products in the scope of centralized procurement had the following major implications on our sales activities in the PRC: (i) the end price of our products within the scope of centralized procurement is significantly lowered in order to maintain the competitiveness of our products in the bidding or tender process of centralized procurement, which may largely compress the profit margin of the intermediaries; (ii) according to the relevant policies and the tender documents of centralized procurement published by relevant provinces, the bidder in centralized procurement should be the manufacturer (including the deemed manufacturer, such as the general agent of the imported products) or the holder of the medical device registration certificate, and such requirement enables us, as the manufacturer and medical device registration certificate holder of our products, to directly participate in the bidding or tender process of centralized procurement. To the extent we win the bid, we are required to sell our products to the public medical institutions via qualified local logistics services providers. With an aim to further expanding our sales network and hospital coverage, we ceased to cooperate with Customer A, being the former exclusive distributor of our products in the entire PRC market.

(2) *Change of the PRC strategies of our Group*: Mr. David CHIEN assumed his position as our chief executive officer in 2016 and reshaped our business strategies in the PRC. Considering the high growth in the number of PCI procedures in the PRC especially in recent years, we intended to explore and have direct access to the PRC market which we believe to have high growth potential and strong market demand. As a result, we changed our sales model from exclusive distributorship to a combination of direct sales and regional distributors.

In view of our long term relationship with Customer A, we had entered into negotiations with Customer A since mid-2020 in respect of various aspects of the cooperation between Customer A and us. These negotiations fell through in around late 2020 to January 2021.

On September 13, 2021, we received an attorney's letter (the "**Attorney's Letter**") from the PRC attorney of Customer A, which (i) alleged the Group's termination of Customer A's exclusive distributorship constituted a breach of contract and our Group shall be liable for the compensation for losses arising from the breach; and (ii) demanded our Group to unconditionally repurchase Customer A's unsold inventory purchased from us at a reasonable price. As of the Latest Practicable Date, no claim, action or legal proceeding had been filed with any court against our Group in relation to the termination of distributorship with Customer A.

Our legal advisors as to PRC laws and Hong Kong laws on this matter, King & Wood Mallesons, having considered the nature and content of relevant documents, are of the view that the likelihood for our Group to be liable for compensation for losses arising from termination of the distributorship with Customer A (i.e. (i) the termination of the authorization letters with a term expired on December 31, 2021 which were issued by ONM Shenzhen and ONM BV to Customer A and (ii) the non-renewal of the Distribution Agreement with Customer A) is relatively low.

After taking into account (i) the views of our legal advisors as to PRC laws and Hong Kong laws on this matter, (ii) the fact that the potential dispute is at a very preliminary stage with no further legal actions taken, and (iii) the fact that we have repurchased the unsold inventory of US$0.4 million from Customer A in December 2021, and (iv) our estimate of the potential liabilities if Customer A brings a lawsuit against us before the PRC court, by considering the advice given by our PRC legal advisor on the PRC laws and the PRC judicial practice on compensation for losses arising from breach of contract, our Directors do not consider the potential dispute to be a material claim. In addition, the Directors are of the view that the amount of the potential dispute is not significant and would not have any material adverse impact on the operation and financial condition of the Group. Based on the views of our legal advisors as to PRC laws and Hong Kong laws and due diligence work conducted, the Joint Sponsors concurred with the views of our Directors on this matter.

In order to maintain our sales network in the PRC and achieve a continuing growth after our termination of distributorship with Customer A, we have adopted the following measures:

(a) We continue to apply for new product registrations in the PRC and increased the number of products approved for selling in the PRC market. During the Track Record Period, we obtained registration for five new products in the PRC.

(b) We believe the implementation of centralized procurement policies offered unique market access opportunities to us in further expansion of sales channels. The centralized procurement policies prompt the manufacturers to directly participate in the process of the centralized procurement and encourage the provincial governments to carry out the centralized procurement by means of collecting or combining the demand for high-value medical consumables from multiple medical institutions in one provincial region or even several provincial regions and then making volume-based negotiations with bidders for preferential price. We submitted bids directly in the centralized procurements organized by the provincial governments in the PRC after our products were brought into the scope of centralized procurement. To the extent we win the bid of the centralized procurement, our hospital coverage in the relevant provincial regions will be rapidly expanded, which will enable us to gain access to these hospitals and establish our reputation in respect of efficacy and quality, and to develop our network with the physicians in these hospitals to promote and market our products that are not yet included in the scope of centralized procurement, such as scoring balloons. In 2021, we actively participated in tender and won seven bids of centralized procurement covering 23 provincial regions to sell to the hospitals in these provincial regions in the PRC.

(c) We have been making public hospitals and distributors in PRC become more receptive to our products as they are now able to communicate directly with us as the manufacturer to obtain better technical support, product information and knowledge directly.

(d) In late 2020, in light of the likely failure of the aforesaid negotiations with Customer A, we began to build our own local sales and marketing team in the PRC through the lateral hiring of experienced sales and marketing experts and personnel to better capitalize the market potential of the PRC. Our PRC sales and marketing team continues to grow.

Pricing

Pricing policy for distributors

We sell products to our distributors at the price mutually agreed by the distributors and us. When determining the price of our products sold to distributors (whether the end customer is a private or public hospital), we deem it important to take into account factors such as our products' advantages, our costs, prices of competing products, and differences in features between our products and competing products.

Under the distribution model, a substantial majority of our products are sold by distributors to public hospitals through public tender processes. If our products win the bids, such products would be qualified for future procurement, and the bidding prices would generally be one of the important factors for us to determine the price we sell our products to the distributors. Depending on a number of factors such as the tender/retail prices, currency fluctuations, price of competing products, applicable tax rates, local salary level and marketing costs, we may grant a discount on the purchase prices to be paid by our distributors to us, which typically ranges from around 30% to 55%.

Pricing policy for direct sales

For direct sales to public hospitals involving tender process, our sales team will handle the entire process and prepare bidding materials for tender submission. Once the price is set and we are confirmed as the winning bidder, our product will be admitted into the hospital's qualified product pool for future procurement. Direct sales to private hospitals usually involves direct negotiation with the hospitals and rarely involves tender process.

For direct sales to hospitals (whether private or public), we also deem it important to take into account factors such as our products' advantages, our costs, prices of competing products, and differences in features between our products and competing products.

Our product pricing is also generally affected by local regulations and policies. For example, in the PRC, the governments implement the centralized procurement system which controls end prices of the high-value medical consumables if the products are included in the scope of the centralized procurement. For details of the centralized procurement policies, please refer to the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Centralized Procurement of Medical Devices" in this document.

In countries such as Japan, Spain and Switzerland where the government sets a cap for the reimbursement to hospitals, such cap would affect the prices of our products when we participate in tender held by or when we negotiate with hospitals (where applicable). Taking Japan market as an example, patients taking PCI procedures do not need to pay for the medical instruments used in such procedures and the hospitals are reimbursed by the government for relevant medical instruments subject to the reimbursement cap. As a result, hospitals are generally willing to purchase medical instruments with prices below the reimbursement cap set

by the government. As reimbursement price cap for medical instruments is typically revisited and adjusted every two years, medical device manufacturers (including our Company) often elect to launch new generations of products with a higher price to retain profitability in anticipation of reimbursement price cuts. In other countries like the U.S. where the majority population is covered by private insurance which is not government mandated and Germany where prices are driven by hospital chains/group purchasing organizations, government policies play a lesser role in our product pricing.

"Two-Invoice System" in the PRC

Compliance with "Two-Invoice System" in the PRC

In the PRC, some provinces and regions implement the "Two-Invoice System" in the procurement of the medical consumables by the public hospitals. To our best knowledge, during the Track Record Period and up to the Latest Practicable Date, insofar as the regions where we conducted the sales activities in the PRC, Shaanxi, Anhui and Fujian provinces compulsorily implemented the "Two-Invoice System" in practice and other regions which issued the policies regarding "Two-Invoice System" encouraged or recommended to implement rather than compulsorily implemented the "Two-Invoice System" in practice.

We adopted two different distribution models in the PRC during the Track Record Period and up to the Latest Practicable Date, i.e., (i) the exclusive distributorship for the entire PRC market for the years from 2019 to 2020, and (ii) the combination of direct sales and distributorship model for the period since January 2021.

Since January 2021, we retained only single-tier distributors or the qualified logistics services providers (配送商), which distributed or dispatched the products to the public hospitals directly in the areas where the "Two-Invoice System" was compulsorily implemented (such as Shaanxi, Anhui and Fujian provinces), and only two-tier value added tax invoices (as defined under the relevant "Two-Invoice System" policies) were issued when the Group's products were ultimately sold to the public hospitals in such areas. As advised by our PRC legal advisors, the foregoing sales arrangement was in compliance with the relevant policies of "Two-Invoice System".

From 2019 to 2020, we adopted the exclusive distributorship model for the entire PRC market without deep involvement in sales activities in PRC. Nevertheless, we believe that Customer A had complied with the "Two-Invoice System" in material respects from 2019 to 2020 in the course of its sales of our products in the areas where the "Two-Invoice System" was compulsorily implemented based on the followings: (i) as advised by our PRC legal advisors, according to the relevant local policies of the "Two-Invoice System" (such as the policies of Anhui and Shaanxi provinces), the public hospitals are generally responsible for verifying whether the requirements of the "Two-Invoice System" are satisfied before the products can be put in storage and used, and if the manufacturers or distributors fail to comply with such requirements, they will be included in the bad credit record list and may lose the qualifications in bidding or distribution of medical products to the public hospitals in such

areas; (ii) neither our Group nor, to the best of our knowledge, Customer A had been included in the bad credit record list or lost qualifications in bidding or distribution of our products to the public hospitals in the PRC due to violation of the "Two-Invoice System" in the course of sales of our products; (iii) after changing the distribution model in the PRC since January 2021, we have maintained normal business cooperation with the public hospitals in the areas where the "Two-Invoice System" are compulsorily implemented.

Impact of "Two-Invoice System" in the PRC on Our Business and Pricing Policy

The "Two-Invoice System" which is currently implemented in certain areas of the PRC had no material impact on our business or pricing policy during the Track Record Period and up to the Latest Practicable Date and our Directors consider it will not materially impact our business and pricing policy in the future unless the PRC governments will materially change the current policies of "Two-Invoice System".

The pricing policy of our products sold in the PRC largely depend on whether such products are included in the scope of centralized procurement.

The prices of our products that are in the scope of centralized procurement are determined based on the bidding or tender process and the competitive negotiation between us and the purchaser (such as the alliance/representative of multiple public hospitals) in the course of the centralized procurement we participate in, without taking into account the impact of "Two-Invoice System". If we win the bid in such centralized procurement, we will sell our products to the hospital via the local logistics services providers. The flows of our products under the centralized procurement are generally in compliance with "Two-Invoice System", both of which are in the common purpose and effect of reducing the intermediate links of the products from the manufacturers to the hospitals.

The prices of our products that are not yet included in the scope of centralized procurement scope are set by the mutual agreement between us and our PRC distributors by taking into account various factors such as our products' advantages or features, our costs, prices of competing products and purchase volume of the distributor. We do not adjust our prices of the products to be sold to the PRC distributors by taking into account the impact of "Two-Invoice System" based on the following reasons:

(i) "Two-Invoice System" is only compulsorily implemented in several regions in the PRC and we would not price the products differently only because some regions of the PRC compulsorily implement the "Two-Invoice System" while others do not;

(ii) from 2019 to 2020, we implemented the exclusive distributorship model in the entire PRC market and, based on the relevant policies of "Two-Invoice System" and to best of our knowledge, the value-added tax invoices issued by our former exclusive distributor in the entire PRC market to its customers would be generally deemed as the first-tier value-added tax invoice under "Two-Invoice System", which would not affect our sales to our former exclusive distributor in any material respect; and

(iii) the "Two-Invoice System" had been implemented in several years before we started to directly participate in the sales activities in the PRC in 2021 and, based on our understanding of the immaterial impact of "Two-Invoice System" on our business historically, we did not change our pricing policy only due to "Two-Invoice System" when we changed our distribution model in the PRC. However, we retained only single-tier distributors or the qualified logistics services providers (配送商) to distribute or dispatch our products to the public hospitals in the areas where the "Two-Invoice System" is compulsorily implemented, in order to comply with the relevant requirements of "Two-Invoice System" in such areas.

OUR CUSTOMERS

Our customers are mainly (i) hospitals (including sales to hospitals and through local procurement agents designated by hospitals), which are our direct customers, and (ii) distributors who further sell our products to hospitals.

In 2019, 2020, 2021 and for the six months ended June 30, 2022, sales to our largest 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, representing 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 five largest customers in each year/period of the Track Record Period amounted to US$20.7 million, US$18.4 million, US$18.2 million and US$13.6 million, respectively, representing 21.5%, 20.8%, 15.5% and 19.8% of our total revenue for the same periods, respectively.

In 2019, 2020, 2021 and for the six months ended June 30, 2022, sales to Customer A, one of our top five customers in 2019 and 2020, amounted to US$8.3 million, US$5.0 million, US$0.9 million and nil, respectively, representing 8.6%, 5.7%, 0.8% and nil of our total revenue for the same periods, respectively. We ceased the exclusive distributorship with Customer A in the PRC since January 2021.

To the best knowledge of our Directors, each of our five largest customers in each year/period of the Track Record Period (other than Customer A) was an Independent Third Party. Except for Customer A, one of our customers which is 50% owned by a cousin of Mr. David CHIEN, our chairman, executive Director, chief executive officer and one of our controlling shareholders, none of our Directors or any of their respective close associates and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, had any interest in any of our five largest customers in each year/period of the Track Record Period. In addition, save for (i) Customer A*; (ii) an existing distributor in Korea which is owned by a former employee who left our Group in 2016 to set up such distributor; and (iii) ON AG, which was acquired and has become a wholly-owned subsidiary of our Group since 2020, there is no past or present relationships or dealings (including family, business, employment, trust, fund flow, financing or otherwise) between our Group and our customers, their respective shareholders, directors or senior management, or any of their respective associates. Please refer to the sections headed "History, Development and Corporate Structure – Key Development Milestones" and "History, Development and Corporate Structure – Acquisition During the Track Record Period" for the details of the acquisition of ON AG.

* Based on public information, from January 2015 to December 2017, Customer A was (a) 55% owned by a cousin of Mr. David CHIEN (our chairman, executive Director, chief executive officer and one of our Controlling Shareholders), and (b) 45% owned by a person who (i) acted as a non-executive director of ONM BVI from January 2010 to May 2013 principally for his advice and insights for the product development for the PRC market and (ii) was a former shareholder of ONM BVI holding no more than 0.01% of the issued share capital of ONM BVI prior to the redemption and cancellation of his shares in ONM BVI in July 2020. Since December 2017 and up to the Latest Practicable Date, each of the above individual shareholders has owned 50% of Customer A. As of the Latest Practicable Date, Customer A had four directors, including the above two individual shareholders and the spouse of the cousin of Mr. David CHIEN.

Distributor Customers

The table below sets forth certain information of our top five distributor customers during the periods indicated.

		For the Year Ended December 31, 2019					
Customer	**Products sold**	**Sale amount** *(US$'000)*	**Percentage of total revenue** *(%)*	**Credit terms granted**	**Distribution territory**	**Customer's business profile**	**Years of business relationship as at June 30, 2022**
Customer A[(1)]	Coronary balloon	8,269	8.6	120 days	Mainland China	Privately owned medical device trader	19
Customer B[(2)]	Coronary balloon, peripheral balloon and other medical accessories	3,326	3.4	60 days	The United States	Medical device trader listed in the U.S.	4
Customer C[(3)]	Coronary balloon and coronary stent	3,111	3.2	60 days	Taiwan	Privately owned medical device trader	15
Customer D[(4)]	Coronary balloon and coronary stent	3,071	3.2	60 days	India, Pakistan, Bangladesh	Privately owned medical device trader	4
Customer E[(5)]	Coronary balloon, peripheral balloon and coronary stent	2,966	3.1	90 days (balloon)/ 180 days (stent)	Vietnam	Privately owned medical device trader	12
Total		20,743	21.5				

		For the Year Ended December 31, 2020					
Customer	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer B	Coronary balloon, peripheral balloon and other medical accessories	6,220	7.0	60 days	The United States	Medical device trader listed in the U.S.	4
Customer A[(1)]	Coronary balloon	5,012	5.7	120 days	Mainland China	Privately owned medical device trader	19
Customer F[(6)]	Coronary balloon and coronary stent	2,627	3.0	60 days	Russia	Privately owned medical device trader	3
Customer E	Coronary balloon, peripheral balloon and coronary stent	2,402	2.7	90 days (balloon)/ 180 days (stent)	Vietnam	Privately owned medical device trader	12
Customer C	Coronary balloon and coronary stent	2,150	2.4	60 days	Taiwan	Privately owned medical device trader	15
Total		18,411	20.8				

		For the Year Ended December 31, 2021					
Customer	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer B	Coronary balloon, peripheral balloon and other medical accessories	7,230	6.2	60 days	The United States	Medical device trader listed in the U.S.	4
Customer D	Coronary balloon and coronary stent	3,411	2.9	60 days	India, Pakistan, Bangladesh	Privately owned medical device trader	4
Customer G[7]	Coronary balloon	2,917	2.5	40 days	Iran	Privately owned medical device trader	3
Customer H[8]	Coronary balloon, peripheral balloon, coronary stent and other medical accessories	2,366	2.0	150 days	Indonesia	Privately owned medical device trader	12
Customer C	Coronary balloon and coronary stent	2,224	1.9	60 days	Taiwan	Privately owned medical device trader	15
Total		18,148	15.5				

		For the six months ended June 30, 2022					
Customer	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer B	Coronary balloon, peripheral balloon and other medical accessories	7,007	10.2	60 days	The United States	Medical device trader listed in the U.S.	4
Customer D	Coronary balloon, peripheral balloon, coronary stent and other medical accessories	2,164	3.1	60 days	India, Pakistan, Bangladesh	Privately owned medical device trader	4
Customer H	Coronary balloon, peripheral balloon, coronary stent and other medical accessories	1,661	2.4	150 days	Indonesia	Privately owned medical device trader	12
Customer C	Coronary balloon and coronary stent	1,568	2.3	60 days	Taiwan	Privately owned medical device trader	15
Customer Q[(9)]	Coronary balloon	1,246	1.8	cash on delivery	Mainland China	Privately owned medical device trader	1
Total		13,646	19.8				

Notes:

(1) Sales to Customer A were transacted through an agent designated by Customer A which is specialized in customs clearance and logistics arrangements. We ceased to renew the distributorship with Customer A in 2021. Based on public information, Customer A, established in 2002, is a PRC private company engaged in the manufacturing and sales of medical devices with products selling over 20 provincial regions in the PRC.

(2) Based on public information, Customer B is a US-listed headquartered company which develops and produces medical devices. It offers a medical device that removes hardened plaque and calcuium from arteries.

(3) Based on public information, Customer C, established in 1996, is a Taiwan private company engaged in the sales of medical devices in Taiwan.

(4) Based on public information, Customer D, established in 1978, is a Hong Kong private company engaged in distribution of medical devices across Hong Kong, Macau and other Asian countries. It is a subsidiary of a global conglomerate.

(5) Based on public information, Customer E, established in 2009, is a Vietnam private company engaged in the sales of medical devices in Vietnam.

(6) Based on public information, Customer F, established in 2019, is an Austria private company engaged in the sales of medical devices in Russia.

(7) Based on public information, Customer G, established in 2003, is an Iran private company engaged in the sales of medical devices in Iran.

(8) Based on public information, Customer H, established in 2010, is an Indonesia private company engaged in the sales of medical devices in Indonesia.

(9) Based on public information, Customer Q, established in 2018, is a Chinese private company engaged in the sales of medical devices in Mainland China.

Direct Customers

Our direct customers were primarily hospitals. In certain countries, such as Japan and Malaysia, sales are settled through local procurement agents designated by hospitals under applicable local regulations and/or market practices.

The table below sets forth certain information of our top five direct customers during the periods indicated.

	For the Year Ended December 31, 2019						
Customer*	**Products sold**	**Sale amount** *(US$'000)*	**Percentage of total revenue** *(%)*	**Credit terms granted**	**Distribution territory**	**Customer's business profile**	**Years of business relationship as at June 30, 2022**
Customer I[(1)]	Coronary balloon, peripheral balloon and other medical accessories	2,958	3.1	140 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Customer J[(2)]	Coronary balloon, peripheral balloon, third party product and other medical accessories	1,545	1.6	90 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices and consumables	18
Customer K[(3)]	Coronary balloon, peripheral balloon, coronary stent, third party products and other medical accessories	1,423	1.5	60 days	Singapore	Hospital with specialty of treating cardiovascular diseases	12

		For the Year Ended December 31, 2019					
Customer*	**Products sold**	**Sale amount** *(US$'000)*	**Percentage of total revenue** *(%)*	**Credit terms granted**	**Distribution territory**	**Customer's business profile**	**Years of business relationship as at June 30, 2022**
Customer L[4]	Coronary balloon, peripheral balloon, coronary stent, third party products and other medical accessories	1,350	1.4	90 days	Malaysia	Privately owned company engaged in procurement and logistic services of medical instruments and accessories, laboratory equipment and accessories and hospital disposables	11
Customer M[5]	Coronary balloon, peripheral balloon and third party products	1,153	1.2	60 days	Hong Kong	Regional acute hospital	15
Total		8,429	8.8				

		For the Year Ended December 31, 2020					
Customer*	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer I	Coronary balloon, peripheral balloon and other medical accessories	2,025	2.3	140 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Customer N[(6)]	Coronary balloon, peripheral balloon, coronary stent, third party product and other medical accessories	1,510	1.7	80 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	18
Customer J	Coronary balloon, peripheral balloon, third party product and other medical accessories	1,428	1.6	90 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices and consumables	18
Customer L	Coronary balloon, peripheral balloon, coronary stent, third party products and other medical accessories	1,267	1.4	90 days	Malaysia	Privately owned company engaged in procurement and logistic services of medical instruments and accessories, laboratory equipment and accessories and hospital disposables	11

		For the Year Ended December 31, 2020					
Customer*	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer O[7]	Coronary balloon, peripheral balloon, coronary stent and other medical accessories	1,162	1.3	100 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices and consumables	19
Total		7,392	8.3				

		For the Year Ended December 31, 2021					
Customer*	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer I	Coronary balloon, peripheral balloon and other medical accessories	2,226	1.9	140 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Customer M	Coronary balloon, peripheral balloon and third party products	1,461	1.3	60 days	Hong Kong	Regional acute hospital	15
Customer N	Coronary balloon, peripheral balloon, coronary stent, third party product and other medical accessories	1,455	1.2	80 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	18
Customer P[(8)]	Coronary balloon, peripheral balloon, coronary stent and other medical accessories	1,448	1.2	30 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Customer J	Coronary balloon, peripheral balloon, third party product and other medical accessories	1,447	1.2	90 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices and consumables	18
Total		8,037	6.8				

		For the six months ended June 30, 2022					
Customer*	Products sold	Sale amount *(US$'000)*	Percentage of total revenue *(%)*	Credit terms granted	Distribution territory	Customer's business profile	Years of business relationship as at June 30, 2022
Customer R[9]	Coronary balloon, peripheral balloon, coronary stent, third party product, other medical accessories	1,035	1.5	90 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	less than 1
Customer I	Coronary balloon, peripheral balloon and other medical accessories	1,000	1.5	140 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Customer P	Coronary balloon, peripheral balloon, coronary stent and other medical accessories	816	1.2	30 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Customer N	Coronary balloon, peripheral balloon, coronary stent, third party product and other medical accessories	773	1.1	80 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	18
Customer S[10]	Coronary balloon, peripheral balloon, coronary stent, third party product, other medical accessories	683	1.0	90 days	Japan	Privately owned company engaged in procurement and logistic services of medical devices	19
Total		4,307	6.3				

Notes:

* In certain countries, such as Japan and Malaysia, local regulations and/or market practices require medical device products be sold to the hospitals via local procurement agents with proper licenses or qualifications. Therefore, for direct sales to hospitals in such jurisdictions, we will sell our products via local procurement agents designated by hospitals.

(1) Based on public information, Customer I, established in 1983, is a Japan private company engaged in distribution of medical devices in Japan. It is the subsidiary of a company listed on the Tokyo Stock Exchange.

(2) Based on public information, Customer J, established in 1992, is a Japan private company engaged in distribution of medical devices and consumables in Japan.

(3) Based on public information, Customer K, established in 1998, is a hospital with specialty of treating cardiovascular diseases in Singapore.

(4) Based on public information, Customer L, established in 1997, is a Malaysia private company engaged in the sales of medical instruments and accessories, laboratory equipment and accessories and hospital disposables in Malaysia.

(5) Based on public information, Customer M, established in 1984, is one of the largest regional acute hospitals in Hong Kong.

(6) Based on public information, Customer N, established in 2001, is a Japan private company engaged in distribution of medical devices in Japan.

(7) Based on public information, Customer O, established in 1987, is a Japan private company engaged in distribution of medical devices and consumables in Japan.

(8) Based on public information, Customer P, established in 1976, is a Japan private company engaged in distribution of medical devices in Japan.

(9) Based on public information, Customer R, established in 2001, is a Japan private company engaged in distribution of medical devices in Japan. It is the subsidiary of a company listed on the Tokyo Stock Exchange.

(10) Based on public information, Customer S, established in 1992, is a Japan private company engaged in distribution of medical devices in Japan.

As a result of the recent Russo-Ukrainian conflict, certain international sanctions have been imposed by several countries, including the U.S., the U.K. and Australia, and the European Union, in relation to Russia, certain regions of Ukraine, and Belarus since February 24, 2022 (the "**Newly Imposed Sanctions**"). Based on the analysis conducted by our International Sanctions Legal Advisors, we are of the view that the Newly Imposed Sanctions do not result in a material increase of our Group's sanctions risk primarily due to, among others, (i) our Group's products are limited to certain medical devices/equipment that would likely be designated as EAR99 or characterized "No License Required" if any given product were subject to U.S. export control, and, to the knowledge of our Company, end-users of our Company's products are mostly hospitals and private individuals and none of the products are intended for "military end use" or "military end users", and no "military end user" is a party to any transaction in relation to the products, *e.g.*, as a "purchaser," "intermediate consignee," "ultimate consignee," or "end-user"; (ii) we do not conduct business in Crimea nor Ukraine at present, and neither the distributors used by our Group for sales in Russia, Ukraine and Belarus nor their respective owners/directors have been named in the SDN List issued by the OFAC;

and (iii) none of the payments received by our Group from the distributors are received into accounts held by Russian banks subject to U.S. sanctions, and all payments from our Group's sales in Russia are received in Euros. In addition, taking into account that the aggregated sales to Russia, Ukraine and Belarus contributed to only 3.2%, 3.1%, 1.6% and 0.4% of our Group's annual revenues for 2019, 2020, 2021 and for the six months ended June 30, 2022, respectively, our Directors are of the view that the potential impact of the Newly Imposed Sanctions on our Group's business operations and financial performance is not material.

Customer Complaint Handling Procedures

We have adopted internal policies and procedures to handle customer complaints and communicate with both our hospital customers and distributors to resolve potential issues or complaints, if any.

Our general complaint handling procedures are as follows:

- *Complaint notification*. We are notified of a complaint when we receive the complaint from a variety of sources, which is usually from our end-customers and distributors. We forward all complaints received from different locations to our complaint handling team in Shenzhen, the PRC.

- *Review and evaluation*. Our complaint handling team reviews all available information to determine if additional investigation is required, and if so it will gather further information and document the investigation thoroughly in the investigation report.

- *Conclusion and complaint closure*. After reviewing and taking into account all available information, including clinical information, product analysis, lot history and complaint history, our complaint handling team will reach a conclusion and document it in the complaint investigation report. Once the complaint investigation report is finalized, a final letter is sent to the end-customers or distributors to explain the results.

- *Trend analysis on past complaints*. We perform trend analysis periodically during management review meetings on past complaints.

During the Track Record Period and up to the Latest Practicable Date, we had not received any material complaints from our customers and our products had not been subject to any material claim, litigation or investigation. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material product return or exchange.

BUSINESS ACTIVITIES WITH CUSTOMERS IN RELATION TO COUNTRIES/REGIONS SUBJECT TO INTERNATIONAL SANCTIONS

Certain countries or organizations, including the U.S., the European Union, the United Nations and Australia, maintain economic sanctions and trade restrictions targeting certain industries or sectors within countries/regions subject to International Sanctions.

During the Track Record Period, our Group sold balloon catheters and stent products to distributors located in the Relevant Regions, including Iran, the Syria Arab Republic, Russian Federation, Belarus and Ukraine. 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. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our revenue generated from sales to distributors in Iran and Syria 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; 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 as (1) none of our subsidiaries in the U.S. nor 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 nor sanctions laws of other Relevant Jurisdictions. Consequently, we were 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 (the "SDN Lists") 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. Furthermore, our sales do not involve industries or sectors that are currently subject to specific sanctions imposed by the U.S., the European Union, the United Nations, the United Kingdom, and Australia. Consequently, we were advised by International Sanctions Legal Advisors that our secondary sanctions exposure is low.

Our Directors confirmed that, as of the Latest Practicable Date, 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 may continue to have the dealings with existing distributors that present low sanctions risks as mentioned above. In addition, we have implemented, and will continue to enhance, internal control and risk management measures which we believe enable us to better monitor and evaluate our business and to address economic sanctions risks. For more details, please refer to the paragraph headed "Internal Control over Business Operations – Internal Control" in this section. 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**], [**REDACTED**] and clearing of our Shares (including the Stock Exchange, its [**REDACTED**] and related group companies) is low.

Our undertakings to the Stock Exchange

We undertake to the Stock Exchange that:

- we will not use the net [**REDACTED**] from the [**REDACTED**], as well as any other funds raised through the Stock Exchange, whether directly or indirectly, to finance or facilitate any illegal or sanctioned activities, or businesses with any country, government, individual or entity sanctioned by the U.S., the European Union, Australia or the United Nations;

- we will not undertake any future business that would cause us, the Stock Exchange, HKSCC, HKSCC Nominees, our Shareholders or potential investors to violate any sanctions laws of the U.S., the European Union, Australia or the United Nations;

- we will make timely disclosure on the website of the Stock Exchange and our website if we believe that any of our business activities would put our Group or our Shareholders and investors at risks of being in breach of the sanctions imposed by the U.S., the European Union, Australia or the United Nations; and

- we will also include such disclosures in our annual reports and the discussion of our efforts on monitoring our business exposure to sanctions risk, the status of our future business (if any) in any country subject to sanctions imposed by the U.S., the European Union, Australia and the United Nations, and our business intention relating to customers from any such country.

TRANSFER PRICING ARRANGEMENTS

During the Track Record Period, our operations were mainly in Hong Kong, the Mainland China, the Netherlands and Japan, and we had conducted business with customers worldwide. Production of our Group's endovascular interventional instrument products was carried out by ONM Shenzhen in Shenzhen, the PRC and by ONM BV in Hoevelaken, the Netherlands.

ONM HK is our Group's headquarters which (i) makes major business decisions for our Group's other subsidiaries to execute; (ii) manages the cash flow of the supply chain; and (iii) centralizes our Group's procurement, warehousing and logistics managements. Taking into account (i) the economic policy of free trade; (ii) the rule of law; (iii) a sophisticated commercial infrastructure; and (iv) a variety of financial alternatives available, our Directors decided to set our internal trading hub in Hong Kong to support our distribution in overseas markets.

The following transactions were our major intra-group transactions relating to our transfer pricing arrangement during the Track Record Period:

Netherlands originated products

- Semi-finished products manufactured by ONM Shenzhen were sold to ONM HK (as an intermediate trading company) and further to ONM BV for ONM BV to manufacture and finish our Netherlands originated balloon/stent products.

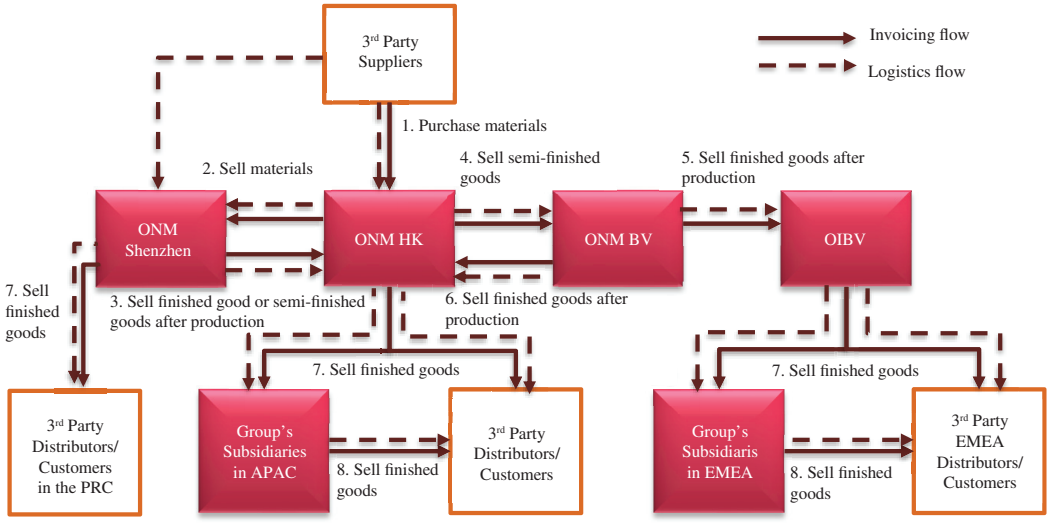
- Finished balloon/stent products by ONM BV were sold to OIBV for distribution of our Netherlands originated products to our distribution subsidiaries in Europe and third-party distributors.

- Finished balloon/stent products by ONM BV were also sold to ONM HK for distribution of our Netherlands originated products to our distribution subsidiaries in APAC and third-party distributors.

The PRC originated products

- Finished balloon products manufactured by ONM Shenzhen (as the PRC originated balloon products) were sold to third-party distributors in the PRC directly and to ONM HK for distribution of our PRC originated products to our distribution subsidiaries and third-party distributors outside the PRC.

The following chart illustrates the business and logistics flow of the buy-sell arrangements within our Group during the Track Record Period:



During the Track Record Period, ONM HK as our Group's entrepreneur carried out all the key business activities and significantly contributed to the value creation of our Group's valuable intangible assets, e.g., trademarks, logos, reputation and client relationships, while the other group entities assumed limited or routine functions (i.e., ONM Shenzhen acted as a manufacturer carrying out R&D activities, ONM Japan and ONM Singapore were the routine distributor assuming local market risk, while the remaining operating entities assumed limited-risk roles with respect to manufacturing, distribution, or R&D activities).

Our Group has engaged an independent transfer pricing tax consultant, PricewaterhouseCoopers Limited, to conduct a transfer pricing review and to evaluate the transfer pricing arrangement within our Group during the Track Record Period.

Evaluation of the buy-sell intercompany transactions

Based upon the functional profiles of ONM HK and other group entities, resales price method ("RPM") and transactional net margin method ("TNMM") are selected as the most appropriate transfer pricing methods to evaluate the buy-sell intercompany arrangement

between ONM HK and other group entities for the period from January 1, 2019 to June 30, 2022. Both the RPM and TNMM are commonly accepted in the OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations and stipulated in the relevant transfer pricing regulations.

The benchmarking studies were conducted by selecting independent companies that are comparable to our Group entities which conducted buy-sell transactions with ONM HK. The table below shows our group entities with their applicable profit level indicator.

Tested Party	**Profit Level Indicator***
ONM Shenzhen	FCMU
ONM BV	FCMU
ONM Japan	GM
ONM Singapore	GM
OIBV	ROS
ONM Spain	ROS
ONM Germany	ROS
ON AG	ROS
ONM Malaysia	ROS

Note: The calculation of the profit level indicators are as follows:

- *Gross Margin ("GM") = Gross Profit/Sales*
- *Return on sales ("ROS") = Operating profit/Sales*
- *Full cost mark-up ("FCMU") = Operating profit/Total operating costs*

During the period from January 1, 2019 to June 30, 2022, the above group entities all achieved the profitability within or slightly above the arm's length profit ranges derived from the relevant sets of comparable companies. ONM HK as our Group's entrepreneur, was entitled to the residual profits or losses along our Group's supply chain.

Accordingly, our Directors, with the support of the transfer pricing tax consultant, are of the view that the benchmarking studies conducted are appropriate for assessing the Group's buy-sell intercompany transactions, and these arrangements were in line with the arm's length principle from the transfer pricing perspectives.

Evaluation of the contract R&D services transactions

Apart from the buy-sell intercompany transactions, our Group had the intercompany contract R&D services rendered by OrbusNeich Medical Trading Inc. ("ONM US") to ONM HK, starting from January 1, 2019. The total intercompany R&D services payments from ONM HK to ONM US for the period from January 1, 2019 to June 30, 2022 is approximately US$9.2 million.

Based upon the functional profiles of ONM US, comparable profit method ("CPM") is selected as the most appropriate transfer pricing method to evaluate the contract R&D services rendered by ONM US to ONM HK during the period from January 1, 2019 to June 30, 2022. CPM is commonly accepted in the international transfer pricing practices and stipulated in the US transfer pricing regulations.

A benchmarking study was conducted by selecting independent companies providing contract R&D services which are comparable to those performed by ONM US to ONM HK. The comparable companies exhibit the arm's length range of the latest three-year weighted average FCMU ratios from 4.62% to 18.00%, with a median of 11.58%. Based on the management account of ONM US, the weighted average FCMU ratio of ONM US during the period from January 1, 2019 to June 30, 2022 is 14.17%, which falls within the arm's length range of the independent comparable companies.

Conclusion

Based on the transfer pricing review, both the buy-sell intercompany transactions and the contract R&D services transactions were generally within the profit range that was considered an appropriate range for arm's length transactions during the Track Record Period.

In addition, our Group has prepared transfer pricing master file for each year/period of the Track Record Period and relevant group entities have prepared transfer pricing local files to fulfil the applicable transfer pricing documentation compliance requirements.

On this basis, our Directors, together with our transfer pricing tax consultant, are of the view that the above-mentioned intecompany transactions of the Group were in line with the arm's length principle and our Group has been in compliance with the relevant transfer pricing laws and regulations during the Track Record Period.

In order to ensure our ongoing compliance with the applicable transfer pricing laws and regulations, we have adopted or are in the process of adopting the following measures:

(i) we will engage an external tax consultant on transfer pricing matters annually to conduct analysis on our transfer pricing method and profit level indicator selected, and plan our transfer pricing policy of the transactions through financial budgeting according to the result of the analysis;

(ii) we will provide trainings to our finance team relating to updates on relevant transfer pricing laws and regulations in the relevant jurisdictions;

(iii) our financial controller will review all reporting forms before submitting to the relevant tax authority;

(iv) we will optimize the supporting of functional profile for the main operating business;

(v) our financial controller will ensure the profit arrangement is aligned with each entity's value contribution; and

(vi) our financial controller will document and file relevant supporting documents of value contribution of each entity for risk management purposes, including but not limited to responsibilities planning, correspondences, performance and outcome assessment of relevant work, etc.

Our Directors (after consultation with our tax advisor, one of the Big Four accounting firms globally) are of the view that our Group has observed and is in compliance with the applicable transfer pricing laws and regulations. To the knowledge of our Directors, our Group's transfer pricing arrangements have not been challenged by relevant tax authorities in Hong Kong, the Mainland China, the Netherlands and Japan during the Track Record Period and up to the Latest Practicable Date.

Our management had been and will continue to closely monitor our Group's transfer pricing arrangements including reviewing the reasonableness of the pricing policy of our intra-group transactions from time to time. However, we cannot assure that our transfer pricing arrangements will not be subject to review and possible challenge by any relevant tax authorities in future, even though we believe we have reasonable grounds to defend ourselves against such possible challenge. Please refer to the section headed "Risk Factors – Risks Relating to Doing Business in Countries where we have Operations – Our Global Transfer Pricing model may subject to challenges raised by tax authorities in different jurisdictions" in this document for further details.

OUR SUPPLIERS

Suppliers

During the Track Record Period, the suppliers for our products mainly included suppliers of raw materials, and institutions that provided stent coating, testing or clinical trial related services and machinery for production. In 2019, 2020, 2021 and for the six months ended June 30, 2022, purchases from our five largest suppliers in each year/period of the Track Record Period amounted to US$12.9 million, US$13.3 million, US$11.7 million and US$7.5 million, respectively, representing 58.2%, 59.8%, 51.1% and 51.6% of our total purchases for the same periods, respectively. In 2019, 2020, 2021 and the six months ended June 30, 2022, purchases from our largest supplier in each year/period of the Track Record Period amounted to US$5.2 million, US$5.8 million, US$4.5 million and US$2.8 million, respectively, representing 23.3%, 26.0%, 19.5% and 19.4% of our total purchases for the same periods, respectively.

The table below sets forth certain information with respect to our five largest suppliers in each year/period of the Track Record Period:

	For the Year Ended December 31, 2019					
Suppliers	**Goods and services provided**	**Purchase amount** *(US$'000)*	**Percentage of total purchase** *(%)*	**Supplier's location**	**Supplier's business profile**	**Years of business relationship as at June 30, 2022**
Supplier A[(1)]	Hypotube, mandrels, distal wire, shrink tube	5,183	23.3	Ireland, The United States, Hong Kong	Supplier A is a provider of technologies and services to medical companies, specializing in minimally invasive delivery and access devices	21
Supplier B[(2)]	Stent coating	3,279	14.7	The Netherlands	Supplier B concentrates its business on surface modification (coating), ready-to-use substrates and sensors, and polymers for surface modification	16
Supplier C[(3)]	Orbital atherectomy system, atherectomy guide wire, saline infusion pump	2,579	11.6	The United States	Supplier C is a medical device trader listed in the U.S.	3
Supplier D[(4)]	Stainless steel stent frame	1,022	4.6	Germany	Supplier D is a global ISO-certified contract manufacturer specialized in laser material processing (e.g., laser cutting of stents)	19
Supplier E[(5)]	Coil	882	4.0	Japan	Supplier E is a manufacturer and distributor of medical disposables	11
Total		12,945	58.2			

		For the Year Ended December 31, 2020				
Suppliers	**Goods and services provided**	**Purchase amount** *(US$'000)*	**Percentage of total purchase** *(%)*	**Supplier's location**	**Supplier's business profile**	**Years of business relationship as at June 30, 2022**
Supplier A	Hypotube, mandrels, distal wire, shrink tube	5,768	26.0	Ireland, The United States, Hong Kong	Supplier A is a provider of technologies and services to medical companies, specializing in minimally invasive delivery and access devices	21
Supplier B	Stent coating	4,407	19.8	The Netherlands	Supplier B concentrates its business on surface modification (coating), ready-to-use substrates and sensors, and polymers for surface modification	16
Supplier C	Orbital atherectomy system, atherectomy guide wire, saline infusion pump	1,269	5.7	The United States	Supplier C is a medical device trader listed in the U.S.	3
Supplier D	Stainless steel stent frame	1,042	4.7	Germany	Supplier D is a global ISO-certified contract manufacturer specialized in laser material processing (e.g., laser cutting of stents)	19
Supplier F[(6)]	Marker band	801	3.6	The United States, Malaysia	Supplier F develops and manufactures medical equipment and devices and serves customers in the medical industry worldwide	20
Total		13,287	59.8			

		For the Year Ended December 31, 2021				
Suppliers	**Goods and services provided**	**Purchase amount** *(US$'000)*	**Percentage of total purchase** *(%)*	**Supplier's location**	**Supplier's business profile**	**Years of business relationship as at June 30, 2022**
Supplier A	Hypotube, mandrels, distal wire, shrink tube	4,458	19.5	Ireland, The United States, Hong Kong	Supplier A is a provider of technologies and services to medical companies, specializing in minimally invasive delivery and access devices	21
Supplier B	Stent coating	3,143	13.7	The Netherlands	Supplier B concentrates its business on surface modification (coating), ready-to-use substrates and sensors, and polymers for surface modification	16
Supplier C	Orbital atherectomy system, atherectomy guide wire, saline infusion pump	2,353	10.3	The United States	Supplier C is a medical device trader listed in the U.S.	3
Supplier G[(7)]	Mandrel	885	3.9	Mainland China	Supplier G is a private company based in Mainland China	7
Supplier F	Marker band	843	3.7	The United States, Malaysia	Supplier F develops and manufactures medical equipment and devices and serves customers in the medical industry worldwide	20
Total		11,682	51.1			

		For the six months ended June 30, 2022				
Suppliers	**Goods and services provided**	**Purchase amount** *(US$'000)*	**Percentage of total purchase** *(%)*	**Supplier's location**	**Supplier's business profile**	**Years of business relationship as at June 30, 2022**
Supplier A	Hypotube, mandrels, distal wire, shrink tube	2,810	19.4	Ireland, The United States, Hong Kong	Supplier A is a provider of technologies and services to medical companies, specializing in minimally invasive delivery and access devices	21
Supplier C	Orbital atherectomy system, atherectomy guide wire, saline infusion pump	1,524	10.5	The United States	Supplier C is a medical device trader listed in the U.S.	3
Supplier H[(8)]	Drug eluting balloon	1,349	9.3	Switzerland	Supplier H is a privately-owned medical technology company which develops drug-eluting balloons for patients suffering from coronary and peripheral arterial disease.	3
Supplier B	Stent coating	1,347	9.3	The Netherlands	Supplier B concentrates its business on surface modification (coating), ready-to-use substrates and sensors, and polymers for surface modification	16
Supplier I[(9)]	Pouch	443	3.1	The United States, Mainland China	Supplier I provides medical packaging to healthcare industries	16
Total		7,473	51.6			

Notes:

(1) Based on public information, Supplier A is an American Swiss-domiciled technology company listed in the U.S..

(2) Based on public information, Supplier B, established in 2001, is a Dutch private company.

(3) Based on public information, Supplier C is a U.S.-listed and headquartered company which develops and produces medical devices. It offers a piece of medical device that removes hardened plaque and calcuium from arteries.

(4) Based on public information, Supplier D, established in 1991, is a German private company.

(5) Based on public information, Supplier E, established in 1986, is a manufacturer and distributor of medical disposables.

(6) Based on public information, Supplier F is subsidiary of a company listed in the U.S..

(7) Based on public information, Supplier G, established in 2013, is a Hong Kong private company.

(8) Based on public information, Supplier H, established in 2008, is a Swiss private company.

(9) Based on public information, Supplier I is a U.S.-headquartered private company specializing in pharmaceutical product packaging.

To the best knowledge of our Directors, each of our five largest suppliers in each year/period of the Track Record Period was an Independent Third Party. None of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our five largest suppliers in each year/period of the Track Record Period.

Overlapping Customers and Suppliers

A medical device developer and manufacturer in the United States, labelled as Customer B and Supplier C, was one of our five largest customers and one of our five largest suppliers, respectively, in each year/period of the Track Record Period. A medical technology company in Switzerland, labeled as Supplier H, was one of our customers during the Track Record Period and one of our five largest suppliers for the six months ended June 30, 2022. Customer B/Supplier C and Supplier H are collectively referred to as "**Overlapping Customers-Suppliers**."

Our Group purchases and distributes atherectomy medical device products manufactured by Customer B/Supplier C and purchases and distributes drug eluting balloons manufactured by Supplier H through our well-established global sales network. Our purchase with Customer B/Supplier C amounted to US$2.6 million, US$1.3 million, US$2.4 million and US$1.5 million in 2019, 2020, 2021 and for the six months ended June 30, 2022, respectively, representing 11.6%, 5.7%, 10.3% and 10.5% of our total purchase amount in relevant periods, respectively. Our purchase with Supplier H amounted to US$1.3 million for the six months ended June 30, 2022, representing 9.3% of our total purchase amount in such period.

Customer B/Supplier C purchases and distributes our balloon products and other medical accessories in the United States and Supplier H purchases our balloon catheters for its manufacturing of drug eluting balloons. Our sales to the Customer B/Supplier C amounted to US$3.3 million, US$6.2 million, US$7.2 million and US$7.0 million, representing 3.4%, 7.0%, 6.2% and 10.2% of the total sale amount in 2019, 2020, 2021 and for the six months ended June

30, 2022, respectively. Our sales to Supplier H amounted to US$1.0 million, US$1.1 million, US$0.3 million and US$5,550, representing 1.0%, 1.2%, 0.2% and 0.01% of the total sale amount in 2019, 2020, 2021 and for the six months ended June 30, 2022, respectively.

Our directors confirmed that our purchase and/or distribution of the Overlapping Customers-Suppliers' products and the Overlapping Customers-Suppliers' purchase and/or distribution of our products were conducted in the ordinary course of business under normal commercial terms. The agreements that we entered into with our Overlapping Customers-Suppliers were on normal commercial terms as the key terms of which were similar with the agreements we entered into with our other customers/suppliers, including the rights and obligations of both parties with respect to the promotion and marketing of products, obtaining regulatory approvals and registration, and territorial exclusivity. As advised by the Industry Consultant, as some manufacturers in the medical device industry will cooperate to distribute the products among different regions leveraging their respective advantages in distribution networks, it is not uncommon for them to purchase and/or distribute products from each other and it is not uncommon to have overlapping customers/suppliers in the medical device industry.

To the best knowledge of our Directors, each of the Overlapping Customers-Suppliers was an Independent Third Party. There is no past or present relationships between the Overlapping Customers-Suppliers and the Company, its subsidiaries, the Directors and/or the Controlling Shareholders.

PROCUREMENT MANAGEMENT

Raw materials

For our balloon and stent products, we primarily use raw materials including medical grade stainless steel stent frame, polyester and nylon in our manufacturing process. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our expenses of raw materials and consumables used under research and development expenses and cost of sales amounted to US$16.0 million, US$16.2 million, US$16.6 million and US$10.0 million, respectively.

We select our raw material suppliers based on a number of factors, including the quality of raw materials, after-sales service and price. For our principal raw materials, we primarily use suppliers from Ireland, the Netherlands, Germany, Japan, the PRC and the United States, as well as suppliers from certain other countries. Based on the current market conditions, we intend to maintain stable working relationships with our major suppliers of raw materials. We have more than two years of business relationship with each of our top five suppliers.

To ensure the quality of our principal raw materials, we will only procure from selected suppliers that can satisfy our raw material requirements. While a substantial portion of our raw materials during the Track Record Period were procured from a limited number of suppliers, considering that there are also other qualified suppliers in the PRC and overseas that may satisfy our stringent quality requirements, we believe we are able to source medical grade stainless steel frame, polyester and nylon and from other suppliers if our relationship with the current suppliers is materially adversely affected.

We seek to manage the impact of fluctuations in price of raw materials through various measures, such as acquiring raw materials locally to minimize transport costs, managing our stock levels and continuing to diversify and expand our supplier pool. We maintain a pool of qualified suppliers for internal purposes, which is reviewed annually. As of June 30, 2022, we had a pool of over 300 qualified suppliers. We inspect raw material candidates from qualified suppliers in such pool and makes necessary purchases according to inventory risks and costs associated with the raw materials and components needed.

Procurement Arrangements with Suppliers

We place purchase orders with our suppliers for our raw material procurements. The terms of our typical procurement arrangements with our suppliers are generally similar. The principal terms of our typical purchase orders primarily include: (i) quantity and product/service specifications of raw materials/services to be purchased, (ii) unit prices and aggregate purchase price of relevant raw materials/services, which is privately negotiated between our suppliers and us, (iii) expected delivery schedule and (iv) payment terms. Our supplier are required to confirm the delivery schedule according to delivery due date stated in 5-10 working days after receipt of the purchase order. Our relationships with suppliers are buyer and seller relationship and not that of a principal and an agent.

During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulties in procuring our major raw materials, and had not experienced significant fluctuations in the prices of our supplies. To the best knowledge of our Directors, there has been no material breach of terms of purchase orders with our suppliers during the Track Record Period and up to the Latest Practicable Date. Our Directors believe, after taking into consideration the impact of the recent outbreak of COVID-19, that we would not experience any material difficulties in procuring our major raw materials.

INVENTORY MANAGEMENT

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.

To maintain an appropriate level of inventories, we have established a set of Standard Operating Policies and Work Instructions to govern the purchase, processing, monitoring and recording of inventories. Before a raw material purchase request was initiated, the operation team would take reference to a rolling production plan to determine the type and quantity of raw materials required.

To ensure a stable supply of raw material at relatively low unit costs, certain raw materials are ordered in large quantities which can support production for up to 2 years. The useful lives of these raw materials are relatively long with no definite expiry dates.

For finished goods, we generally offer hospitals under consignment sales arrangement a full range of products with different sizes to ensure our customers' needs are satisfied. Our coronary and peripheral interventional products generally have shelf lives ranging from approximately 1.5 to 2 years. To ensure there is no excessive write off due to expiry, we regularly perform stock take and review the condition of our products.

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.

We currently store our finished goods primarily at our warehouses in Hong Kong, Shenzhen, Japan and the Netherlands. We store our work in progress and raw materials in our production facilities in Shenzhen and Netherlands. As at December 31, 2019, 2020, 2021 and for the six months ended 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.

QUALITY ASSURANCE

Our quality assurance and regulatory teams are involved in every aspect of our daily operations to ensure the quality assurance of our products. Quality assurance for both the Shenzhen and Netherlands facilities utilize the same quality management systems to manage and track problems in a timely manner. Per the applicable regulatory requirements, we have a quality manual documenting our Quality Management System and its implementation. As of June 30, 2022, our quality assurance and regulatory team had 107 employees dedicated to the quality control of our products.

We have established an internal control protocol for the design and development of new medical devices, with reference to the globally recognized Medical Device specific ISO 13485:2016 Quality Management System Standard and globally recognized Risk Management Standard, ISO 14971:2019. Please refer to the section headed "Business – Research and Development – Product Development" in this document for details of our product design processes.

We also have ISO 13485:2016 certifications for our manufacturing sites, which demonstrates international certification for our quality management system in terms of manufacturing. Our quality control system is established in accordance with the applicable regulations. We implement quality control measures throughout our manufacturing process, including raw material control and inspection, process control, product inspection and environmental control. Our quality control procedures in the manufacturing process primarily consist of the following:

- **Raw material control and inspection**: we conduct assessment on our suppliers and only purchase our raw materials from suppliers who observe our internal supplier management policies. We also inspect samples and/or request certification for each batch of raw materials to help assure conformance to specification, and to ensure there are no quality or other issues;

- **Process control**: we plan the production process based on quality plan developed for each product type and monitor the entire production process, particularly certain key steps of the production process;

- **Product inspection**: we compile our product inspection working instruction based on our product specifications, and inspect our products in accordance with our product inspection working instruction, including testing the capability and measurement of our products, verifying the product labels and Instructions For Use as well as confirming that the products are properly packaged and sterilized; and

- **Environment control**: we establish our environmental control procedure for our clean rooms, labs and production facilities and monitor the implementation of the procedure.

We have successfully completed our external quality management system inspections and have passed all of the inspections up to the Latest Practicable Date. During the Track Record Period and up to the Latest Practicable Date, our products had not been subject to any regulatory or governmental material claim, litigation or investigation. In addition, during the Track Record Period and up to the Latest Practicable Date, we did not experience any material product return or exchange.

To ensure the quality of products provided by third parties, we have designed an approved supplier list from which we select and procure our key raw materials. We also evaluate our suppliers' quality, cost, delivery rate, and other aspects, and conduct on-sit audits of key suppliers.

COMPETITION

The competitive landscapes of global PCI/PTA balloon markets are relatively stable and are dominated by several key manufacturers. Aside from such key players in the market, the rest of the PCI/PTA balloon manufacturers mostly focus on and specialize in specific type/category of products, such as PTA balloons or neuro-interventional devices, while we cover a broader scope of product offering when compared to our peers.

According to the CIC Report, the following table sets forth the number of key market players and their aggregate market shares in terms of sales volume in 2021, respectively, in each of the following geographical markets:

	PCI Balloon Market		PTA Balloon Market	
	Number of Key Market Players*	Aggregate Market Shares of Key Market Players	Number of Key Market Players	Aggregate Market Shares of Key Market Players
Japan	4	88%	7	83%
Europe	6	97%	5	97%
PRC	9	80%	5	94%
The U.S.	5	95%	7	80%

* "Key Market Players" refer to those market players whose market share accounted for more than 5% in relevant geographical market in terms of sales volume in 2021

We believe our commitment and long-term investment in developing high quality medical products will continue to build our brand recognition and enable us to effectively compete with the top players in each of our key geographical markets. In particular, we plan to leverage our strong research and development capabilities and proprietary know-how accumulated throughout the years to constantly develop novel new products and address different market demands. We also collaborate and maintain good relationship with physicians and key opinion leaders who can help us better identify and understand the unmet clinical needs and provide us constructive feedbacks on prototypes of our pipeline products, thereby enabling us to effectively develop and upgrade our products.

For information of competition in the markets we serve, please refer to the paragraphs headed "Industry Overview – Overview of Percutaneous Coronary Intervention Procedural Instrument Market – Competitive landscape" and "Industry Overview – Overview of Percutaneous Transluminal Angioplasty Procedural Instrument Market – Competitive landscape" in this document.

INTELLECTUAL PROPERTY RIGHTS

We have built a comprehensive intellectual property portfolio in the PRC, Japan, the U.S., and the EU to protect our technologies, inventions and know-how and ensure our future success with commercializing our product portfolios. As of the Latest Practicable Date, we had an aggregate of 82 registered invention patents and 47 published invention patents in the key jurisdictions where we have operations. In addition, as of the Latest Practicable Date, we had an aggregate of 114 registered trademarks and 62 pending trademark applications in relevant jurisdictions. For further details of our intellectual property rights, 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.

The term of an individual patent may vary based on the jurisdictions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular jurisdiction/country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will be granted with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned, licensed or issued patents or any such patents that may be issued in the future will be commercially useful in protecting our existing and pipeline products and methods of manufacturing the same.

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, pursuant to which intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. We also have established an internal policy governing the confidentiality of all company information. Despite the measures we have taken to protect our intellectual property, our proprietary information may be obtained by unauthorized parties.

We also own a number of registered trademarks and pending trademark applications. As of the Latest Practicable Date, we had registered trademarks and pending trademark applications for our Company name "ORBUSNEICH" or "OrbusNeich" (including in combination with our corporate logo) in Hong Kong, the Mainland China, Taiwan, Switzerland, Germany, Japan, the U.S. and the EU and "業聚"/"业聚" in Hong Kong, the Mainland China, Singapore and Malaysia. We seek trademark protection for our Company and our corporate logo in the jurisdictions where available and appropriate.

During the Track Record Period and up to the Latest Practicable Date, we are not involved in any pending material proceedings in respect of intellectual property right infringement claims against us or initiated by us. However, there are risks if we fail to protect our intellectual property rights in the future. For details, please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Intellectual Property Rights" in this document.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE ("ESG") MATTERS

Board Oversight of ESG Matters

We actively take into account and incorporate sustainable development in our daily business operation decisions. We are subject to various health, safety, social and environmental laws and regulations in countries where we have operations, in particular in the PRC where our major manufacturing facilities are located, and our operations are regularly inspected by local government authorities. Our Board is responsible for establishing, adopting and reviewing our ESG policies, vision and goals to evaluate, determine and address our ESG-related risks once a year. We plan to adopt more ESG policies relating to social responsibility and internal governance as our Board deems fit. Our Board takes full responsibility to our ESG strategy and reporting.

Our quality control and regulatory team is primarily responsible for ensuring our compliance with applicable environmental rules and regulations, coordinating the management and reporting of our ESG matters with our Board's authorization and guidance, and ensuring that we have talents with appropriate skills, policies and measures to follow up and manage our ESG matters and reporting regularly to our Board regarding the effectiveness of our ESG strategies and relevant measures.

Furthermore, our Board may assess or engage independent third party(ies) to evaluate the ESG risks and review our existing strategy, target and internal controls. Necessary improvements will then be implemented to mitigate the risks. At the same time, each of our business unit is responsible for promoting and implementing various sustainable development measures and providing disclosure information relevant to sustainable development measures.

To further enhance our ESG management, we will implement an ESG Management Policy which governs the ESG management and sets out overall strategy, approaches and key ESG principles of our Group. We also plan to establish an ESG Working Group upon [**REDACTED**]. The ESG Working Group will assist our Board in fulfilling its responsibilities relating to promotion, development and implementation of ESG initiatives, policies, plans, goals and targets of our Group in accordance with all applicable laws, regulations and rules.

The ESG Working Group will comprise at least one executive Director and the Chairman of the ESG Working Group must be an executive Director of our Company. Our ESG Working Group shall at least annually report to the Board on their findings, decisions and recommendations. The duties of our ESG Working Group primarily include:

- identifying, evaluating, prioritizing and managing the material ESG-related issues of our Group (including risks to our business) (the "ESG-related Issues");

- making recommendation to the Board to approve (i) the process to identify and the criteria for the selection of the material ESG-related issues; and (ii) the ESG-related goals and targets in order to align with the goal of long-term business development and the materiality analysis of the important investors and stakeholders of our Group;

- developing and implementing the ESG-related strategies, frameworks and policies of our Group in order to attain the ESG-related goals and targets and report to the Board on the progress and effectiveness of the development and implementation; and

- reviewing and making recommendation to the Board for approval on the preparation and disclosures of the ESG report of our Company in accordance with all applicable laws, rules and regulations.

Material ESG Topics

The vision of our Group is to become a global leading medical device developer and manufacturer that offers a variety of endovascular and structural heart interventional solutions to effectively improve patients' quality of life. Achieving this goal relies on the support from various stakeholders including governments, physicians, patients, suppliers, business partners, employees, investors and the society. Hence, we have established various channels and regularly communicate with the various stakeholders of our Company by various means such as employee newsletters and customer site visits, symposiums, audits, inspections, regular work meetings, and industry exchanges. Through these channels, the feedbacks are consolidated and reflected to the management, so that the management is able to incorporate their feedback into the materiality assessment and our corporate strategy where applicable.

Our Group upholds the core value of "Integrity, Passion, Innovation and Performance", and is also aware of the increasing concern on environment related issues, such as carbon emission amid the decarbonisation initiatives worldwide. With reference to ESG Industry Materiality Map by MSCI for Health Care Equipment sub-sector under Health Care sector, we have identified the following material ESG issues:

ESG topics	Materiality	Potential Risks, Opportunities and Impacts
Product responsibilities – Product safety and quality – Innovation	Most Critical	The product responsibility reflects our capacity to produce quality medical instruments that integrate the patients' health and safety, integrity and data privacy. Our dedication to developing innovative products and our responsible R&D processes may help us to achieve greater satisfaction of our customers/physicians and promote the health of patients/end-users of our products. Please refer to the sections headed "Business – Research and Development" and "Business – Quality Assurance" in this document for details of our product design and quality control processes.
Well-being and development of talents – Operational health and safety – Benefits – Training and development	Critical	The productivity of employees may be affected if no proper health and safety policy is implemented. Meanwhile, strong human capital development may lead to a stronger employee base and a lower turnover rate.
Corporate governance and business ethics – Code of ethics and anti-corruption – Board and senior management diversity – Pay for performance	Critical	Regulatory risks in failing to maintain good business ethics may cause compliance-based impacts. However, outstanding business ethics may help us yield a positive business image.
Environmental protection – Toxic emissions and waste – Carbon emissions and climate change	Important	The health and safety of employees and company assets may be put at risk due to environmental-related issues, such as increasingly frequent extreme weather conditions and failure to control toxic emission at the production site. Whereas good practice of environmental protection can enhance corporate image and lower costs through reduced consumption of resources and green financing.

Awards and Accolades

We have regular participation in community events, such as sporting events, charitable donations, blood drives or other involvement in local organizations. During the COVID-19 outbreak, we donated personal protection equipment to local communities. In recognition of our efforts and emphasis on ESG matters, ONM HK has been awarded by the Hong Kong Council of Social Service as a "Caring Company" from 2011 to 2021, and has been recognized by the Environmental Campaign Committee of Hong Kong as a "Green Organization" with excellent level in waste reduction.

Product Responsibility

Product Safety and Quality

Product safety and quality has also been the top priority of our Group, hence we have established a comprehensive quality system to ensure the safety and quality of our products. Quality assurance for both the Shenzhen and Netherlands facilities utilize the same quality management systems to manage and track problems in a timely manner. Per the applicable regulatory requirements, we have a quality manual documenting our Quality Management System (QMS) and its implementation. Leveraging our strict and well-established QMS, our production facilities have passed the audits and inspections by regulatory bodies like the NMPA, FDA, PMDA and NB to certify our QMS. For instance, the recent FDA inspection to OrbusNeich was a pre-PMA inspection at the end of December of 2020 with the result of NAI. In addition, our production facilities in the PRC have passed audits from NB in 2020 and 2021 and audits from NMPA in 2021. Our production facilities in the Netherlands are subject to annual audits from NB and have passed such audits in 2020, 2021 and 2022, and have passed inspection from PMDA in 2019.

Our manufacturing sites have obtained ISO 13485:2016 certifications. Our quality control system is established in accordance with the applicable regulations. We implement quality control measures product inspection and environmental control. Our quality control procedures in the manufacturing process primarily consist of the following:

- raw material control and inspection: we conduct assessment on our suppliers and only purchase our raw materials from suppliers who observe our internal supplier management policies. We also inspect samples and/or request certification for each batch of raw materials to help assure conformance to specification, and to ensure there are no quality or other issues;

- process control: we plan the production process based on quality plan developed for each product type and monitor the entire production process, particularly certain key steps of the production process;

- product inspection: we compile our product inspection working instruction based on our product specifications, and inspect our products in accordance with our product inspection working instruction, including testing the capability and measurement of our products, verifying the product labels and Instructions For Use as well as confirming that the products are properly packaged and sterilized; and

- environment control: we establish our environmental control procedure for our clean rooms, labs and production facilities and monitor the implementation of the procedure.

In line with the industry practice, our return and exchange policy generally does not allow any product return or exchange, except in case of any product defect. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material product return or exchange from customers. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, products returned by our customers amounted to approximately US$112,000, US$34,000, US$64,000, US$31,000 and US$2,000, respectively, representing approximately 0.12%, 0.04%, 0.05%, 0.05% and 0.003% of our revenue for relevant periods.

Innovation

We believe innovation and R&D capabilities solidify our market position and to maintain long-term growth. Our strong in-house R&D capabilities with over twenty years of accumulated product development experience and continued investment in R&D activities empowered us with abundant proprietary knowhow in product design, material treatment, manufacturing processes, and enabled us to successfully develop various proprietary technologies. As of the Latest Practicable Date, we own more than 100 granted patents globally across key jurisdictions, including 32 and 45 granted patents in the U.S. and in the PRC, respectively. The comprehensive intellectual property portfolio in the PRC, Japan, the U.S., and the EU enables us to protect our technologies, inventions and know-how and ensure our future success with commercializing our product portfolios.

In addition to granted patents and published patents application, we rely, in some circumstances, on 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, pursuant to which intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. We also have established an internal policy governing the confidentiality of all company information.

Well-being and Development of Talent

Diversified Workforce

We embrace diversity and comply with local labor law requirements to prevent any gender, age, nationality, religious belief, or social status-based discriminations. As of June 30, 2022, among the 880 full-time employees of our Group, 347 were male and 533 were female.

Employee Benefits

We have a generous set of employee benefits for health, dental and life insurance, retirement funding. We offer flexible working hours, annual leave, marriage leave, maternity leave, paternity leave, compassionate leave, sick leave and compensation leave to enable our employees to better achieve work-life balance. To better align our interests with the interest of our employees, we also adopted employee stock option plans (ESOP). We also offer education grants to our employee to encourage their continuous learning.

Development of Employees

We also attaches great importance in training of staff. Therefore, we provide required resources for training and ensure the employees to accept suitable training. The departments compile the training needs, formulate, and implement annual training plans which should be filed in Human Resource department. Trainings can be delivered through classroom training or onsite training internally or employees can participate external training or education. For instance, we conduct site-wide workforce training in a number of topics including sexual and non-sexual harassment, safety, emergency action plan and diversity.

- on-boarding training – On-boarding training is a mandatory training that all the employees receive at the beginning of the position and provides employee with information regarding the company culture and policies including quality policies and environment control.

- competency-based training – Competency-based training is carried out prior to performing the job in order to ensure every employee is equipped with the specific skills and abilities and able to perform his/her work efficiently, safety and independently. Relevant trainings including but not limited to regulatory, basic theory knowledge and operational skills, process quality control skills, quality inspection skills and etc. should be provided to the personnel who perform the job which affects production quality.

- continuing training – Besides the on-boarding training and competency-based training, further training is designed to strengthen and improve employee's skills and performance, and maintain our competitiveness. For instance, we provide

trainings covering design control, development of products, technical knowledge etc. to our engineers. We also coordinate with external organisations to provide product training to sales and marketing team.

- common skills promotion training – We also design and conduct common skills promotion training based on relevant questionnaire survey. The training will involve personnel skills, common management and technical skills, such as communication skills, team building, data analysis and etc.

Health and Safety

We regard occupational health and safety as an important social responsibility. We implemented measures to (i) promulgate safety operation procedures relating to various aspects of production, such as the use and storage of chemicals and operation of equipment, (ii) conduct safety training for all employees, (iii) conduct regular safety and compliance inspections of our facilities, (iv) coordinate third-party occupational health assessments and third-party fire safety inspections and (v) oversee the safety of experiments through approvals of experiment plans and regular monitoring throughout the experiments. Specifically, we focus on the following:

– health and safety – Employee and visitor health and safety check is conducted in our production facility through safety officers responsible and held accountable for the health and well-being of people on our business premises. Strict procedures (including COVID-19 detection and prevention) have been implemented. In response to the COVID-19 pandemic, we provided COVID-19 tests for our staff and adopted flexible working hours and work-from-home arrangements. We conduct training for accident prevention and safety inspections on our facilities. We also provide free annual health check-ups for the staff in our Shenzhen facilities; and

– working conditions – We handle chemicals during our manufacturing process and therefore we lay great emphasis on and monitor our employees' potential exposure to toxic fumes. We have a policy of removing pregnant woman from operations. We provide private rooms for mothers who are nursing.

Governance

We have instituted important governance policy and procedures that encompass a range of best practices including:

Code of Ethics and Anti-Corruption

- adopting a Code of Ethics and believing our pursuit of high ethical standard has enabled us to attract top tier investors and collaboration partners. We have also implemented a whistleblower system, data integrity detection and training, and fraud prevention in the banking system;

- requiring all our employees to undertake to comply with the Employee Handbook that outlines prohibited behavior related to bribery, corruption, kick-backs, and other improper behaviors. These policies will be reviewed for compliance on a regular basis;

- setting up a whistle-blowing channel to encourage all employees, directors and executive officers to report any suspected violations promptly and intends to thoroughly investigate any good faith reports of violations. We will adopt a more detailed and comprehensive whistle-blowing policy upon [**REDACTED**], which will align the whistleblowing mechanism with our corporate governance structure upon [**REDACTED**] such that all whistleblowing reports will be directed to the Risk Management Committee, being a sub-committee of our Audit Committee;

Board and Senior Management Diversity

- selecting candidates on merits. We will have two women out of eight Board members upon [**REDACTED**]. The Board composition at the present time demonstrates diversity and inclusion. Please refer to the section headed "Directors and Senior Management – Corporate Governance – Board Diversity" for details of measures to develop a pipeline of potential female candidates; and

Pay for Performance

- advocating that our remuneration structure shall be linked to a KPI system.

Environment Protection

We manufactures medical devices in Shenzhen, the PRC and Hoevelaken, the Netherlands. Our operations and facilities are subject to certain environmental protection laws and regulations in both the Netherlands and the PRC, which govern, among other things, the generation, storage, handling, use and transportation of hazardous materials, flammable chemical materials and the handling and disposal of hazardous and biohazardous waste generated at our facilities. These laws and regulations also require us to obtain permits from governmental authorities for certain operations. Please refer to the section headed "Regulatory Overview" in this document for more details.

In order to protect the environment, prevent pollution, and comply with the relevant laws and regulations, we have established detailed internal rules regarding environmental protection. For example, our production facilities in Shenzhen formed Environment, Health and Safety Committee and formulated various policies such as the Environmental Protection Administration and Control Procedure (《環境保護管理控制程序》) and Hazardous Wastes Administrative System (《危險廢物管理制度》). During the Track Record Period and up to the Latest Practicable Date, we did not incur material cost of compliance with relevant

environmental protection laws and regulations. In 2019, 2020, 2021 and for the six months ended June 30, 2022, we spent approximately US$9,400, US$6,200, US$32,000 and US$16,000, respectively, with respect to environmental protection.

Exhaust Gas Emission and Waste Management

Our quality control and regulatory team has implemented measures and procedures to ensure our compliance with the applicable environmental protection laws and regulations, such as conducting solid waste sorting in our existing facilities and engaging professional waste-disposal companies to manage the disposal of hazardous and biohazardous waste. We contract with qualified third parties for the disposal of hazardous materials and wastes. According to our ESG policies, we have established a comprehensive set of key performance indicators to evaluate and guide our business operations. In 2019, 2020 and 2021, the amounts of hazardous and non-hazardous waste disposed by our Shenzhen facility are set out below:

	2019	**2020**	**2021**
Hazardous waste (kg)	6,938	3,390	5,960
Non-hazardous waste (kg)	3,880	6,515	4,932
Total waste (kg)	10,818	9,905	10,892

Our quality control and regulatory team also monitors and tests our sewage discharge on a daily basis, by testing the concentration of various substances in effluent water to ensure compliance with applicable effluent standards.

As for exhaust gas management, our production facilities generate non-methane hydrocarbon due to stent processing, injection and extrusion process, sterilisation and laboratory testing. We have installed certain exhaust gas treatment equipment, such as two-stage activated carbon equipment and acid spraying equipment to reduce the relevant emissions in the production plants. In 2019, 2020 and 2021, our exhaust gas discharge (non-methane hydrocarbons) was 3.1 mg/m^3, 1.5 mg/m^3 and 3.8 mg/m^3, respectively, way lower than the permitted cap of 120 mg/m^3 imposed by the Local Standard of Guangdong Province Emission Limits of Air Pollutants (廣東省地方標準大氣污染物排放限值) (DB44/27–2001).

Resources Consumption and Carbon Emission

Our major energy consumption is the purchased electricity from electricity grid, which is also the major source of carbon emission of our Group. Hence, we are committed to improve energy efficiency with an aim to reduce carbon emission. During the Track Record Period, we invested in upgrading our facilities to reduce energy consumption as part of our efforts and contribution to lower the overall greenhouse gas emissions, such as replacing with LED lightings, energy saving cooling tower. Meanwhile, the electricity provider of the facility in the Netherlands generates electricity with green and renewable sources such as solar and wind and does not have carbon emissions for the electricity used in our facility in the Netherlands. Our unit power consumption for products manufactured shows a decreasing trend which evidences our enhanced energy consumption efficiency.

Apart from electricity, we also consume other kinds of energy and water. The total amount and the intensity of consumption of various resources in 2019, 2020 and 2021 are set out below:

	2019	**2020**	**2021**
Water consumption (m^3)	22,000	28,000	30,000
Water consumption intensity (m^3/unit produced)	0.02	0.03	0.03
Electricity consumption (Kwh)	5,471,000	5,231,000	5,557,000
Electricity consumption intensity (Kwh/unit produced)	6.0	5.9	4.9
Gasoline consumption (kg)	17,000	12,000	16,000
Gasoline consumption intensity (kg/unit produced)	0.02	0.01	0.01
Natural gas consumption (m^3)	10,100	8,500	9,200
Natural gas consumption intensity (m^3/units produced)	0.011	0.009	0.008

The table below sets out the direct emission, indirect emission and total greenhouse gas emission of our facilities in Shenzhen and the Netherlands in 2019, 2020 and 2021:

	2019 CO_2 equivalent	**2020 CO_2 equivalent**	**2021 CO_2 equivalent**
Direct emission (ton)	69	52	65
Indirect emission (ton)	5,000	4,800	5,100
Total greenhouse gas emission (ton)	5,100	4,900	5,200
Total greenhouse gas emission intensity (kg/units produced)	5.6	5.4	4.6

We will implement measures to control the consumption intensity of resources and energy in our daily operations. We strive to control the power consumption and greenhouse gas emissions and aim to maintain the consumption and emission intensity level at 90% to 110% of those of 2021 for each year over the next three years. In addition, for the construction of our recent expansions in the PRC, we have endeavoured to use energy efficient fixtures and materials to the extent possible. Examples include windows, roofing materials, cooling towers, emission gas handling units, air conditioning units and lighting.

As advised by the Industry Consultant, our ESG performance is in line with industry practice, as our waste disposal, resources consumption and greenhouse gas emission are within the range of other leading industry players with reference to the data disclosed in their respective public annual reports.

Climate Change

We acknowledges that climate change is a universal problem and that a business cannot stay unaffected. To ensure our long-term resilience to climate risks, we are committed to strengthen the ability to adapt and withstand climate change and mitigate the negative effects of such risks. We make reference to the TCFD recommendations to disclose our Group's management of climate change according to governance, strategy, risk management, metrics and targets. The following tables set forth our actions in relation to climate change-related issues:

	Our actions
Governance	The Board is responsible for management of ESG issues including climate-related issues, while ESG Working Group will be responsible for assisting the Board in managing climate change matters and report to the Board at least once a year. For further details, please refer to the paragraphs headed "– Board Oversight of ESG."
Strategy	To understand the risks and opportunities brought by climate change to our business, we identify and assess the risks and opportunities brought by climate change based on the potential financial impact and the likelihood of occurrence. And we do not consider climate-related risks as major risks relating to our operations. For the descriptions of relatively significant risks and opportunities, please refer to the paragraphs headed "– Climate Change Risks and Opportunities."

	Our actions
Risk management	We regularly communicate with various stakeholder groups through different channels. Hence, the Board is able to identify and assess various potential ESG risks and opportunities, including climate-related risks and opportunities, that have a relatively more significant impact on the business. We incorporate the feedbacks from various stakeholders into the formulation of long-term strategy and implement response measure.
Metrics and targets	We measure and monitor energy-related metrics to monitor the climate change management performance, including: – Energy consumption – Energy consumption intensity per units produced We will continue to monitor and measure our activity and report with full transparency our emission statistics annually to investors as appropriate after the [**REDACTED**].

Climate Change Risks and Opportunities

The following tables set forth our climate-related risks and opportunities and our actions to address them:

Climate related risks	**Possible financial impacts**	**Mitigation measures**
Increased severity and frequency of extreme weather events such as cyclones and floods	Decreased revenues due to interruption of production	– Formulated emergency plans to reduce the damages to the production facilities due to adverse weather
Potential electricity curb due to rigorous decarbonisation policy	Decreased revenues due to interruption of production	– Explore the possibilities of applying renewable or clean energy in offices and production facilities – Continue to improve the energy efficiency by investing and upgrading the production facilities

Climate related risks	Possible financial impacts	Mitigation measures
Increased investor concern on ESG issues, including but not limited to, carbon emission	Decreased access to capital	– Set up ESG working group to assist the board to oversee ESG issues and disclose ESG reports upon [**REDACTED**]

Climate related opportunities	Possible financial impacts	Current response measures
– More low-emission energy sources available	– Decrease in cost of energy	– Explore the possibilities of applying renewable or clean energy in offices and production facilities
– Emerging green finance opportunities	– Decreased cost of finance	– Implement carbon reduction measures
		– Set up ESG working group to assist the board to oversee ESG issues and disclose ESG reports upon [**REDACTED**]

Environmental Impact

Our operation may impact the environment especially when there are capacity expansion projects. Therefore, when a new construction project is proposed, our quality control and regulatory team will carry out environmental feasibility study in the early stage of the construction of our new facilities. We also conduct comprehensive analysis and testing on the environmental issues involved in the manufacturing processes. All our property, plant and equipment owned or operated meet the standards required for compliance with applicable environmental rules and regulations, and we believe we have maintained good relationship with the communities surrounding our production facilities. Our production facilities have also established Emergency Response Plan to minimise the impacts on the environment when emergency incidents happen.

EMPLOYEES

Our Employees

As of June 30, 2022, we employed 880 full-time employees, among which 608 were based in the PRC, 52 were based in Hong Kong, 112 were based in Japan, 8 were based in the U.S., 17 were based in Malaysia, 8 were based in Singapore, and 51 were based in Netherlands. The following table sets forth the number of our full-time employees by function as of June 30, 2022.

Function	Number of employees	Percentage
Operations (Manufacturing/Logistics)	468	53.2%
Sales and Marketing	142	16.1%
Quality Assurance	78	8.9%
Research and Development	68	7.7%
Senior Management and Administrative	51	5.8%
Finance	28	3.2%
Regulatory Affairs	29	3.3%
Information Technology	16	1.8%
Total	880	100.0%

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We invest in continuing education and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development.

In compliance with the relevant labor laws in countries where we have operations, we enter into individual employment contracts with our employees covering matters such as terms, wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. In addition, we are required under PRC laws to make contributions to statutory social insurance (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and childbirth insurance) and housing provident fund for our employees in the PRC at a certain percentage of our employees' salaries, subject to further adjustment in the event that the employees' salaries are less than the minimum standard of or more than the maximum standard of the contribution base specified by the local government. During the Track Record Period and up to the Latest Practicable Date, we have made full contributions to the statutory social insurance and housing provident fund for our employees in the PRC in accordance with the applicable laws and regulations.

We are also subject to safety laws and regulations of the PRC. For a description of these laws and regulations, please refer to the paragraphs headed "Regulatory Overview – PRC Regulatory Overview" in this document. We have implemented various internal occupational health and safety procedures to maintain a safe work environment, including adopting protective measures at our production facilities, inspecting our equipment and facilities regularly to identify and address safety hazards, and providing regular training to our employees on safety awareness. We do not have an established labor union.

We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with occupational health and safety laws or regulations, and had not experienced any strikes, labor disputes or industrial actions which have had a material effect on our business.

PROPERTIES

Owned Properties

As of June 30, 2022, we own the land use right of one parcel of land located in Futian Bonded Area, Shenzhen, Guangdong province, the PRC, with a total site area of 9,999.51 sq.m. On this parcel of land, we constructed and owned buildings with an aggregate gross floor area of 8,912.46 sq.m which are mainly used as our production facility, laboratories, warehouse and offices. We obtained the real estate certificate indicating (i) our land use right of the above parcel of land with a term of 50 years expiring on March 23, 2050 and (ii) our ownership of the above-mentioned buildings. As of June 30, 2022, those properties were in compliance with the uses prescribed in the real estate certificate and free of any mortgages. Our PRC legal advisors are of the view that we have valid legal title to the land use right and the buildings and we are entitled to legally occupy, use, benefit from, lease, mortgage or otherwise dispose of them. These properties are used for non-property activities as defined under Rule 5.01(2) of the Listing Rules. They are mainly used as our production facility, laboratories and offices.

Leased Properties

As of June 30, 2022, we also leased properties in nine countries and regions, with an aggregate gross floor area of approximately 23,000 sq.m. As of June 30, 2022, we entered into 77 lease agreements (as lessee), all of which were entered into with Independent Third Parties. We primarily use leased properties as our office, production facilities, staff quarter and storage, as well as for car parking purposes.

Defects in the leased properties

As advised by our PRC legal advisors, during the Track Record Period, two of our leased properties located in the PRC for warehouse and dormitory purposes had title defects or restrictions on renting out under the relevant PRC regulations. As a result, we may need to find another property to replace such warehouse and dormitory if our landlord terminates relevant

lease agreement or if relevant property is demolished or confiscated by the government during our lease terms. During the Track Record Period and up to the Latest Practicable Date, we had not received any demand for return or demolition of such properties. As advised by our PRC legal advisors, we, being the tenants, would not be subject to any penalties by reason only of the lease of such properties with title defects or restrictions on renting out since the applicable PRC regulations mainly regulate the activities of the owner or the administrator of such properties and impose no penalties on their tenants. Our Directors are of the view that such title defects or restrictions would not have any material adverse impact on our business operations and financial conditions based on the followings: (i) relevant properties are only used for the temporary storage of our finished products which generally accounted for less than 5% of the total value of our finished products, (ii) it is relatively easy for us to find an alternative property with valid titles, and (iii) the potential increase in rent and the relocation costs are not material.

Non-registration of certain lease agreements in the PRC

According to Administrative Measures for Commodity House Leasing (商品房屋租賃管理辦法) promulgated by Ministry of Housing and Urban-Rural Development on February 1, 2010, the lease agreements shall be registered with the competent local authority within 30 days after the execution by the parties. As of the Latest Practicable Date, we had not completed the relevant registrations for three of our lease agreements in the PRC. As advised by our PRC legal advisors, the failure to complete such registration would not affect the validity of the relevant lease agreements, and a maximum penalty of RMB10,000 may be imposed for the non-registration of each lease agreement.

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising from the non-registration of our lease agreements, and had not experienced any dispute arising out of, or in relation to, our leased properties.

Remedial actions

We entered into a new lease agreement for an alternative property with valid titles to replace the defective leased property for dormitory purpose on November 15, 2021 and we completed the relocation prior to December 14, 2021, being the expiry date of the old lease agreement. In respect of the other defective leased property used for temporary storage of a small portion of our finished products, prior to the expiry of the existing lease agreement (i.e. January 2023), we will relocate to the properties with valid titles we lease pursuant to the lease agreements dated October 1, 2022.

Our Group has engaged an external PRC legal advisor to provide the legal services of daily business operation and training on the relevant PRC regulations from time to time to ensure future compliance with relevant PRC legal and regulatory requirements, including the legal requirements of the properties permitted for rent and the registration of lease agreements.

According to section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all our interests in land or buildings, for the reason that, as of the date of the most recent audited consolidated balance sheet of our Group, none of the properties owned and leased by us had a carrying amount of 15% or more of our consolidated total assets.

INSURANCE

We maintain certain insurance policies as of the Latest Practicable Date. For example, we maintain insurance policies that cover losses arising from accidents and natural calamities in respect of our machinery, equipment, inventories and other fixed assets in our research and manufacturing facilities, and we have purchased product liability insurance policies for our products. We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period and up to the Latest Practicable Date, we had not made, or been the subject of, any material insurance claims. Based on the due diligence conducted and having considered (i) the terms of the product liability insurance policies of the Group, (ii) the Industry Consultant's view that the coverage by such policies is in line with industry norm, and (iii) the absence of any material product liability claim during the Track Record Period and up to the Latest Practicable Date, nothing has come to the attention of the Joint Sponsors that may cause them to cast doubt on the adequacy of the product liability policies maintained by the Group for the Group's present operations in any material aspect.

PERMITS AND LICENSES

We are required to obtain various permits, licenses, approvals and certifications from government authorities as required under applicable laws and regulations of jurisdictions where we have operations. During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, permits and certifications that are material for our operations, and such licenses, permits and certifications all remain in full effect. As of June 30, 2022, we had obtained one medical device production permits and 15 medical device registration certificates from the NMPA, and 288 medical device registration certificates from FDA, EMA, PMDA and the regulatory authorities of global markets. For more details regarding the applicable laws and regulations to which we are subject in our major markets, please refer to the section headed "Regulatory Overview" in this document.

The following table sets forth the key licenses and permits related to our major products as of the Latest Practicable Date.

License/Permit	License/Permit No.	Validity Period	Authority
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20153030603	2025/3/31	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20173034163	2027/7/20	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20153030920	2025/2/16	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20193030403	2024/6/23	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20193030330	2024/5/22	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20223030742	2027/6/12	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20223030841	2027/6/30	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Zhun (國械註准) 20173033337	2027/9/28	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20153031726	2025/4/15	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20173030456	2027/2/22	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20173030457	2027/2/22	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20203130390	2025/8/17	NMPA

License/Permit	License/Permit No.	Validity Period	Authority
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20163030725	2026/1/25	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20163031295	2026/1/25	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20213030205	2026/6/14	NMPA
Registration Certificate for Medical Device (醫療器械註冊證)	Guo Xie Zhu Jin (國械註進) 20193030566	2024/11/18	NMPA
510(K) Clearance Letter	K103657	Indefinite	FDA
510(K) Clearance Letter	K103808	Indefinite	FDA
510(K) Clearance Letter	K162209	Indefinite	FDA
510(K) Clearance Letter	K192344	Indefinite	FDA
510(K) Clearance Letter	K173894	Indefinite	FDA
510(K) Clearance Letter	K182713	Indefinite	FDA
510(K) Clearance Letter	K200269	Indefinite	FDA
510(K) Clearance Letter	K180921	Indefinite	FDA
510(K) Clearance Letter	K182360	Indefinite	FDA
510(K) Clearance Letter	K201794	Indefinite	FDA
510(K) Clearance Letter	K202231	Indefinite	FDA
510(K) Clearance Letter	K211807	Indefinite	FDA
510(K) Clearance Letter	P200041	Indefinite	FDA
EC-Design Examination Certificate	CE 649480	2023/6/15	NB
EC-Design Examination Certificate	CE 649479	2023/5/26	NB
EC-Design Examination Certificate	CE 649487	2024/5/26	NB
EC-Design Examination Certificate	CE 649488	2024/5/26	NB
EC-Design Examination Certificate	CE 649483	2024/2/19	NB
EC-Design Examination Certificate	CE 649484	2024/2/19	NB
EC-Design Examination Certificate	CE 619994	2024/5/26	NB
EC-Design Examination Certificate	CE 620000	2024/5/26	NB
EC-Design Examination Certificate	CE 649477	2023/5/23	NB
EC-Design Examination Certificate	CE 649589	2024/5/26	NB
EC-Design Examination Certificate	CE 646778	2024/5/26	NB
EC-Design Examination Certificate	CE 646780	2024/5/26	NB
EC-Design Examination Certificate	CE 673072	2023/3/5[1]	NB
EC-Design Examination Certificate	CE 673071	2023/3/5[1]	NB
EC-Design Examination Certificate	CE 706141	2024/5/26	NB
EC-Design Examination Certificate	CE 706144	2024/5/26	NB

License/Permit	License/Permit No.	Validity Period	Authority
EC-Design Examination Certificate	CE 712118	2024/5/26	NB
EC-Design Examination Certificate	CE 712825	2024/5/26	NB
EC Certificate – Full Quality Assurance System	CE 619995	2023/4/21	NB
EC Certificate – Full Quality Assurance System	CE 619995	2023/4/21	NB
EC Certificate – Full Quality Assurance System	CE 619984	2023/4/20	NB
EC Certificate – Full Quality Assurance System	CE 619984	2023/4/20	NB
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	21900BZX00740000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22000BZX00741000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22000BZX01056000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22000BZX01058000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22300BZX00178000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22400BZX00246000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22500BZX00132000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22200BZX00666000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22500BZX00133000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22600BZX00247000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22900BZX00381000	Indefinite	PMDA

License/Permit	License/Permit No.	Validity Period	Authority
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)[2]	22600BZX00398000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)[3]	22600BZX00398000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22300BZX00400000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22600BZX00369000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22800BZX00226000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	30100BZX00150000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22900BZX00167000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22900BZX00161000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	22900BZX00165000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	23000BZX00347000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	23100BZX00005000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	30200BZX00107000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	30300BZX00163000	Indefinite	PMDA
Medical Device Manufacturing and Sales Approval (醫療機器製造販賣承認書)	30300BZX00219000	Indefinite	PMDA

License/Permit	License/Permit No.	Validity Period	Authority
Medical Device Licence	105506	Indefinite	Health Canada
Medical Device Licence	105218	Indefinite	Health Canada
Medical Device Licence	105219	Indefinite	Health Canada
Medical Device Licence	105905	Indefinite	Health Canada
Medical Device Licence	105220	Indefinite	Health Canada
Medical Device Licence	104693	Indefinite	Health Canada

Notes:

1 Our renewal application for the certificate has been submitted.

2 Denotes approval received on September 25, 2014.

3 Denotes approval received on May 8, 2015.

During the Track Record Period and up to the Latest Practicable Date, we have obtained all requisite licenses, permits and certifications that are material for our operations. We intend to apply for renewal for the licenses with validity period prior to their respective expiry dates. The successful renewal of our existing licenses, permits and certifications will be subject to our fulfilment of relevant requirements. We will also apply for registration certificates once our pipeline products are ready to be marketed.

We intend to initiate the renewal process pursuant to the mandatory submission timeframe set by each regulatory authority. Our Directors are not aware of any reason that would cause or lead to the refusal or delay to the renewal of the licenses, permits and certificates which are material to our business operations.

LEGAL COMPLIANCE AND PROCEEDINGS

We may become a party to legal, arbitral or administrative proceedings arising in the ordinary course of our business. Our Directors confirmed that, as of the Latest Practicable Date, none of the legal, arbitral or administrative proceedings to which we were a party, individually or in aggregate, would have a material and adverse effect on our business, financial condition or results of operations, and they are not aware of any potential or threatened legal, arbitral or administrative proceedings to which we will be named as a party that would have a material adverse impact on our business. Our Directors further confirm that none of our Directors or senior management personnel was personally involved in any of these legal, arbitral or administrative proceedings.

During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance incidents which our Directors believe would, individually or in aggregate, have a material legal, operational or financial impact on our Group as a whole.

The following sets forth incidents which our Company considers to be immaterial or do not constitute material or systematic non-compliances.

Investigation of OIBV conducted by the Dutch Public Prosecution Service

Background

Facts and circumstances

On June 3, 2021, OIBV, one of our Material Subsidiaries incorporated in the Netherlands, accepted an out-of-court settlement agreement (the "**Settlement Agreement**") offered by the Dutch Public Prosecution Service ("**DPPS**") in relation to a criminal investigation (the "**Investigation**") conducted by the Fiscal Intelligence and Investigation Service of the Netherlands ("**Fiod**") and the DPPS since February 2018. The Investigation relates to certain unusual transactions prompted by the then auditor of OIBV (the "**Auditor**") to the Financial Intelligence Unit in 2014 regarding a suspicion of OIBV having given gifts to Belgian cardiologists (the "**Alleged Unusual Transactions**") between 2011 and 2015 (the "**Relevant Period**"), by which OIBV allegedly gained a more favorable position concerning the supply of medical products to six hospitals in Belgium where these cardiologists worked. The hospitals concerned were not aware of such arrangements. The Alleged Unusual Transactions involved five employees of OIBV responsible for the sales and marketing activities to the relevant hospitals and/or the finance function of OIBV at the time of the Alleged Unusual Transactions (the "**Relevant Persons**"). Amongst the five Relevant Persons, four of them left our Group between 2016 and 2019 upon their resignation, retirement and/or dismissal by the Group and the remaining Relevant Person has been placed on administrative leave since November 2018. None of the Relevant Persons is or has been a Director or member of senior management of the Company.

OIBV was made aware of the Alleged Unusual Transactions when the Auditor raised queries in the context of their audit on OIBV in August 2014 in relation to the Alleged Unusual Transactions, and the Group conducted internal investigations on the matter shortly thereafter.

DPPS claimed that the Alleged Unusual Transactions were conducted by concealing the arrangements from OIBV's financial records through (i) billing the hospitals at the official invoice price; (ii) receiving sales proceeds from the hospitals; (iii) drawing up credit notes addressed to the hospitals without actual issuance of the same; (iv) paying the amounts underlying the credit notes to the cardiologists upon their requests; and (v) using consultancy agreements to facilitate payments to cardiologists. The annual transaction amount with the six hospitals were approximately EUR88,000 (US$124,000), EUR100,000 (US$130,000), EUR130,000 (US$172,000), EUR238,000 (US$317,000) and EUR361,000 (US$402,000), respectively, representing 0.2%, 0.2%, 0.3%, 0.5% and 0.6% of our Group's revenue in 2011, 2012, 2013, 2014 and 2015. Among the Relevant Persons, three of them were responsible for the sales and marketing activities of OIBV, and two of them were responsible for the finance functions and internal administrations of OIBV, ONM BV (which had no external sales) and ON GmBH (an indirect wholly-owned subsidiary of our Company incorporated in Germany engaged in the trading, sales and marketing of medical devices instruments). The annual revenue generated by OIBV and ON GmBH together was approximately EUR13.3 million (US$18.6 million), EUR12.1 million (US$15.7 million), EUR13.2 million (US$17.6 million), EUR13.4 million (US$17.9 million) and EUR17.2 million (US$19.2 million), respectively, representing approximately 31.7%, 26.6%, 28.6%, 28.1% and 27.6% of our Group's revenue in 2011, 2012, 2013, 2014 and 2015. The annual revenue generated by OIBV itself was approximately EUR12.0 million (US$16.7 million), EUR11.0 million (US$14.2 million), EUR12.0 million (US$16.0 million), EUR12.1 million (US$16.1 million) and EUR15.5 million (US$17.3 million), respectively, representing approximately 28.6%, 24.1%, 26.0%, 25.3% and 25.0% of our Group's revenue in 2011, 2012, 2013, 2014 and 2015. The annual revenue generated by OIBV for the years ended December 31, 2019, 2020 and 2021 were approximately US$21.1 million, US$17.5 million and US$21.5 million, respectively, representing approximately 21.8%, 19.8% and 18.4% of our Group's revenue. During the Relevant Period, there were 15 to 22 employees working under OIBV.

Subsequent to the Investigation and up to the Latest Practicable Date, three out of the six relevant hospitals have continued to purchase products from our Group through our distributors.

Underlying causes

The internal investigations conducted by the Group (as detailed below) revealed that the arrangements underlying the Alleged Unusual Transactions were initially proposed to the Relevant Persons by the cardiologists. The internal investigations found that the then employees of OIBV believed that such arrangements were common practice in Belgium at the

relevant time, and did not indicate that any of the Relevant Persons had received any personal kick-backs from the Alleged Unusual Transactions. It is likely that the Relevant Persons were not aware that such arrangements were not strictly in compliance with the relevant laws and regulations.

During the Relevant Period, unlike the way the Group is currently operating and managed, the payment arrangements in OIBV involved issuing invoices, drawing up credit notes and/or entering into consultancy agreements that were within the scope of authority of the Relevant Persons during the Relevant Period, and therefore, the then directors and senior management team of the Group were not aware of the underlying arrangements until the Auditor raised queries in the context of their audit on OIBV in August 2014 in relation to the Alleged Unusual Transactions.

Internal investigations

First round of internal investigations

The Group first engaged an independent international law firm (the "**First Law Firm**") in September 2014 to look into the legitimacy and regulatory aspects of the payments made to the cardiologists under the Alleged Unusual Transactions and to provide legal advice on agreements that medical device companies were allowed to enter into with hospitals or healthcare professionals and the relevant legal requirements applicable to such agreements.

The internal investigations conducted by the First Law Firm revealed an overview of the actual course of events regarding the payments made to the cardiologists under the Alleged Unusual Transactions. After conducting investigation, the First Law Firm had not discovered any evidence suggesting that the senior management of the Group had any influence over the Alleged Unusual Transactions, and therefore, the Company believes that the Relevant Persons did not act at the directions of more senior personnel in executing the Alleged Unusual Transactions. It also provided a form of a consultancy agreement which they recommended to document the actual consultancy arrangements between the Group and cardiologists.

Second round of internal investigations

After finalization of the first internal investigation in May 2015, the Auditor raised additional questions about the financial reporting issues involved in the Alleged Unusual Transactions and in response to such questions, the Group engaged another independent international law firm (the "**Second Law Firm**") in June 2015 to:

- expand the scope of investigation in particular financial reporting issues and accounting treatment of Alleged Unusual Transactions;
- understand the sales practice of the Group in the EU;
- identify the employees involved; and

- investigate any indications of similar arrangements in other EU countries.

The Second Law Firm conducted email review, documentary review and investigatory interview with employees. To assist them with their investigation, the Second Law Firm also engaged an independent forensic accounting firm (the "**Forensic Auditor**") mainly to:

- conduct a comprehensive review of, and conducted data analytics on, financial records of OIBV, ONM BV and ON GmBH (being the only companies in the Group operating in Europe at the time), and

- investigate anomalies via review of additional information provided by employees.

The internal investigations conducted by the Second Law Firm and the Forensic Auditor revealed more extensive factual details regarding the Alleged Unusual Transactions, including approval and payment procedures involved, the employees involved in the arrangements, as well as the underlying accounting treatment of the Alleged Unusual Transactions. They also concluded that no senior management of our Group at that time was aware of the arrangement, and no similar arrangement took place in European countries other than Belgium. Based on the results of such investigations, the Company considered that the regulatory risk of the sales and transactions (other than the Alleged Unusual Transactions) conducted by the Relevant Persons in Europe was remote in practice.

Outcome of the Investigation

In addition to the abovementioned internal investigations conducted and the implementation of a series of enhanced internal control measures as detailed below, our Group also fully cooperated with the DPPS throughout the Investigation after the DPPS reached out to OIBV's office in the Netherlands for the Investigation.

In July 2020, the Fiod issued a report (the "**Investigation Report**"). Based on the general summary of the Investigation Report, it was revealed that (i) Fiod and DPPS did not identify any member of our Group (other than OIBV) as a suspect after the Investigation; (ii) the then employees of our Group involved in the communication, payment and approval of the Alleged Unusual Transactions were members of the sales team, accounting and finance team of OIBV; (iii) the Fiod and DPPS did not find any of the Directors and senior management of our Company as having been involved in, and/or approved the payments, credit notes or agreements in respect of, the Alleged Unusual Transactions. Stibbe, our legal advisors as to Dutch laws which acted for the Group in relation to the Investigation (the "**Dutch Investigation Counsel**"), confirms this conclusion on the basis of the Investigation Report. It was also noted that the conclusion was generally consistent with the findings of the internal investigations as outlined above.

In September 2020, the DPPS informed the Dutch Investigation Counsel that consultations could be held to reach an out-of-court settlement. After a series of substantive discussions on the settlement, OIBV has accepted the offer of the Settlement Agreement.

Pursuant to the Settlement Agreement, (i) OIBV shall pay to the government of the Netherlands a settlement sum of EUR174,000 and the alleged illegally obtained benefit of EUR174,000 (collectively the "**Settlement Amount**"), and (ii) upon full payment of the Settlement Amount, the DPPS shall have no outstanding claim against OIBV and the DPPS's right to prosecute OIBV for the Alleged Unusual Transactions shall expire. The DPPS is of the view that the Settlement Agreement is an appropriate disposal of the matter and the Settlement Amount has taken into account OIBV's cooperative attitude and the fact that our Group conducted internal investigations on its own initiative, which also led to a stricter and more comprehensive compliance policy for our Group.

According to the Dutch Investigation Counsel, directly interested parties may seek to challenge the Settlement Agreement within three months after the DPPS' press release about the Settlement Agreement dated July 7, 2021, and such three-month period had lapsed on October 6, 2021. As of the Latest Practicable Date, we had not received any complaint in relation to the Settlement Agreement.

We are not aware of any recurrence of incidents of a nature similar to the Alleged Unusual Transactions after the Relevant Period.

Enhanced Internal Control Measures

We conducted internal investigations in relation to the Alleged Unusual Transactions. Based on the results of the internal investigations, we believed that the Alleged Unusual Transactions were conducted due to (i) the lack of legal knowledge by the employees, (ii) the lack of education on the legal requirements and training on anti-corruption measures, and (iii) the then decentralized management of our EU operations and the lack of sufficient internal control in place to allow the then directors and senior management team of our Group to have the opportunity to identify any potential irregularities or non-compliances.

To address these underlying reasons and to strengthen our internal control system, we adopted the following enhanced internal control measures across our Group, and have not identified any recurrence of similar incidents after the Relevant Period:

(i) **Adoption of internal control policies**.

(a) In 2016, our Group adopted an internal anti-corruption policy, which, among others, (1) requires supporting documents should be provided to support payment request for consulting services to avoid unauthorized or improper payments, and (2) formalizes the review and approval procedures for such written agreements with external consultants.

(b) In 2019, our Group imposed stricter procedures regulating business-related expenses, which sets out, among others, (1) clearer limits and stricter rules on reimbursements for business related expenses, including expenses arising from

business meetings, meals and entertainments etc. with business partners and stakeholders, (2) expense reimbursement guidelines, and (3) procedure for submission of business-related expense reports for internal review and approval.

(c) Our Group will adopt a more detailed and comprehensive whistle-blowing policy upon [**REDACTED**], which provides for an internal mechanism for employees in our Group to report any suspected improprieties on an anonymous or non-anonymous basis and will align the whistleblowing mechanism with the corporate governance structure of the Company upon [**REDACTED**] such that all whistleblowing reports will be directed to the risk management committee, being a sub-committee of our audit committee.

(ii) **Regular staff training**. After the adoption of the anti-corruption policy in 2016, in May 2017, our Group reinforced implementation of the anti-corruption policy by conducting a staff training on the same across our Group. In May 2019, our Group updated the anti-corruption policy and launched an online platform through which our employees from different locations were provided with trainings on the anti-corruption policy. Since 2019, each of our Group's employees is required to undertake annual online training on the anti-corruption policy. Our training materials include the anti-corruption policy, the relevant laws, and examples of case studies, prohibited behaviors and business scenarios. The training materials are periodically reviewed and updated by the legal department of our Group.

(iii) **Centralized and enhanced contract approval process**. From 2018 to 2019, our Group underwent a series of internal control enhancement measures to put in place a more centralized management for our Company's subsidiaries and an enhanced internal approval process for entering into contracts, including:

(a) In April 2018, we formalized and institutionalized contract review process at the headquarters level for all contracts. Such review process is undertaken by our Contracts Review Committee ("**CRC**"), which comprises our chief operation officer, chief financial officer and general counsel, who possess relevant professional knowledge and experience.

(b) In May 2018, we amended the articles of association of our subsidiaries in the Netherlands, including OIBV, to clarify that the company could be represented by two directors acting jointly only, instead of solely by any single director. In 2017 and 2018, Mr. David CHIEN and Mr. Wing Shing CHEN, the senior management in the headquarters of our Group, were appointed as directors of OIBV, respectively. In August 2018, our Group realigned the reporting lines and the financial controller in the Netherlands has since then been reporting directly to the chief financial officer of our Group, Mr. Wing Shing CHEN. In addition, payment controls at OIBV were strengthened in that bank payment authorizations require the signatures of any two of the following: (i) the

finance head in the Netherlands; (ii) Senior Director, Corporate Finance in the headquarters; and (iii) chief financial officer in the headquarters. The more centralized management structure strengthens accountability and governance of our Netherlands subsidiaries.

(c) In October 2019, we issued additional CRC submission procedures to all offices, which requires all contracts and/or payment commitments exceeding certain monetary threshold to be entered into by our Group, including the contracts with the external consultants, advisors or business partners together with relevant approval form (the "**Submission Package**") should be submitted to CRC/designee for review and approval. The specific monetary thresholds are stated in the relevant policy, and vary according to the office location and the type of contracts. For example, for our Netherlands offices, the following types of contracts require CRC's review and approval: (1) for any purchase of services of value above EUR10,000 (except for the renewal of contracts with existing suppliers with a price increase not exceeding 10% and are based on terms substantially similar to prior arrangements); and (2) for any purchase of machinery, if the value exceeds EUR12,500.

(iv) **Anti-corruption policy and training for business partners**. In May 2019, our Group adopted an anti-corruption policy for business partners (including distributors and suppliers), which requires, among others, the distributors to ensure compliance with all applicable anti-corruption laws and regulations and provide their staff with training on the same. Such anti-corruption policy also prohibits our Group and our business partners from providing any gifts to healthcare professionals except where the items are of modest value, and are not given for the purpose of inducing such healthcare professionals to perform their duties disloyally or otherwise improperly. Anti-corruption training was provided to our business partners via our online platform.

In connection with the [**REDACTED**], the Company engaged an independent internal control consultant (the "**Internal Control Consultant**") to perform an assessment on our Group's internal control measures, which includes the review of the anti-corruption policy, trainings for staff and business partners, and centralized and enhanced contract approval process of our Group. Other than recommending a more detailed and comprehensive whistleblowing mechanism as outlined under sub-paragraph (c) of (i) adoption of internal control policies above, the Internal Control Consultant noted that the enhanced internal control measures abovementioned (including centralized and enhanced contract approval process) were in place and did not identify any further deficiencies on the formulation and implementation of such policies and measures established by our Group. Noting the reinforcement of awareness training among staff and business partners in relation to the anti-corruption compliance measures and tightening of the previously decentralized control of payment and contracting activities at the subsidiary level by the headquarters in Hong Kong, the Internal Control Consultant is not aware of any reasons to disagree with our Directors' view

that our Group's current enhanced internal controls are sufficient and effective to prevent a recurrence of incidents such as the Alleged Unusual Transactions should we continue to properly maintain and implement such enhanced internal controls.

On the bases of the following, our Directors are of the view, and the Joint Sponsors have no reasons to doubt the view of the Directors that the enhanced internal control measures are effective and sufficient in preventing the recurrence of the Alleged Unusual Transactions:

(i) **Enhanced internal control measures.** Our Group has adopted the enhanced internal control measures as detailed above. Specifically, (a) the adoption of certain internal control procedures, including an internal anticorruption policy adopted by our Group in 2016 to prevent unauthorized or improper payments, and stricter procedures regulating contract approval process and business-related expenses imposed by our Group in 2019 and (b) the implementation of anti-corruption policy by conducting regular training for staff as well as business partners may prevent the recurrence of bribery incidents.

(ii) **Internal control review by the Internal Control Consultant.** In connection with the [**REDACTED**], the Internal Control Consultant conducted an internal control review and did not identify any further deficiencies on the formulation and implementation of the internal control policies established by our Group and the Internal Control Consultant is not aware of any reasons to disagree with our Directors' view that our Group's current enhanced internal controls are sufficient and effective to prevent a recurrence of incidents similar to the Alleged Unusual Transactions should we continue to properly maintain and implement such enhanced internal controls.

(iii) **Ongoing training.** Our Group has regularly reviewed and updated training materials and conducted annual training for our Group's employees on the anti-corruption policy, the relevant laws, and examples of case studies, prohibited behaviors and business scenarios.

(iv) **Appointment of our chief operating officer and chief financial officer.** Our chief operating officer, Ms. Kwai Ching Denise LAU, is a qualified solicitor in England and Wales and in Hong Kong. Our chief financial officer, Mr. Wing Shing CHEN, is a certified public accountant in Hong Kong, the State of Washington and the State of Delaware of the United States. Given their professional experience and direct participation in the contract review and payment authorization process under the enhanced internal control measures, with the assistance by a team of qualified legal and accounting professionals at the headquarters, our Directors believe that they will guide our Company to comply with the relevant rules and regulations when performing their duties.

(v) **Enhanced corporate governance structure.** In preparation for the [**REDACTED**], we have also enhanced our corporate governance structure to strengthen its reporting and review structure. Our Company has established an Audit Committee comprising three independent non-executive Directors, in compliance with Rule 3.21 of the Listing Rules. Our Audit Committee is responsible for reviewing and supervising the effectiveness of the financial reporting process, internal control and risk management systems of our Group.

(vi) **External review.** We have engaged Rainbow Capital (HK) Limited as our compliance advisor in accordance with Rule 3A.19 of the Listing Rules upon the [**REDACTED**]. Our Company will also engage external counsel to assist the Company with ongoing compliance and regulatory obligations after [**REDACTED**].

Indemnity given by the Controlling Shareholders

Pursuant to the Deed of Indemnity dated [●], our Controlling Shareholders have undertaken to fully indemnify us against, amongst other things, any and all liabilities arising from the Alleged Unusual Transactions and/or the Investigation.

Impact on our Group and our Directors

Based on the advice of Stibbe, our Dutch Investigation Counsel, we understand that:

(i) the DPPS is the only authority in the Netherlands empowered to prosecute suspects of criminal behaviour;

(ii) OIBV is the only entity in our Group that the DPPS concluded as a suspect of the Alleged Unusual Transactions after the Investigation. The Investigation did not identify any other subsidiaries of our Company to be a suspect and did not reveal that any of the Directors or members of senior management of our Company was involved in the Alleged Unusual Transactions; and

(iii) the Settlement Agreement grants full and final discharge to OIBV of consequences arising from the facts and circumstances revealed from the DPPS' criminal investigation into the Alleged Unusual Transactions and all ensuing consequences yet to arise to OIBV, of whatever nature; and all criminal liability related to the Alleged Unusual Transactions is settled.

In addition to the investigation of the DPPS and the abovementioned understanding based on the advice of Stibbe, the internal investigations also concluded that no similar practice to the Alleged Unusual Transactions took place in any European countries other than Belgium. Therefore, our Directors are of the view, and the Joint Sponsors concur, that none of our Company's other subsidiaries was involved in the Alleged Unusual Transactions.

Our Directors confirm that, after taking into account the advice of the Dutch Investigation Counsel, (a) the risk of criminal proceedings against the relevant members of the Group and/or their respective directors is low because from Dutch and European law perspective, it would be difficult for foreign authorities to prosecute the acts which have been settled in the Netherlands as the Dutch and European law protect citizens from being prosecuted twice for the same conduct; (b) although interested parties could initiate civil proceedings against former suspects or persons or entities involved in the Alleged Unusual Transactions on the basis of unlawful act or breach of contract within a limitation period of five years from the day following the day on which such interested parties become aware of both the damage and the person liable, the risk of civil proceedings against the Group and/or its directors is low given that (i) the Investigation did not show that the parties had suffered financial damage as a result of the Alleged Unusual Transactions; and (ii) the Settlement Agreement was publicized and no challenge has been received from any directly interested party so far; and (c) the risk of a regulatory action against the Group and/or its directors is low given the Company understands that the conduct under the Alleged Unusual Transactions is not within the jurisdiction of the industry-specific regulatory authorities having jurisdiction over the Group's principal businesses in the EU and in any event, the fact that the DPPS has already investigated into the Alleged Unusual Transactions and reached the Settlement Agreement makes it difficult for any regulatory authorities to investigate into the same subject matter again in the spirit against double jeopardy, i.e. a person cannot be tried twice for the same conduct. Our Directors further confirm that as of the Latest Practicable Date, no notices or demands relating to any actual, potential or threatened criminal or civil proceedings or regulatory action has been received by the Group and/or its Directors. As a result of the foregoing, the Company believes that the risk of any criminal or civil proceedings being taken against the Group in connection with the Alleged Unusual Transactions in other European jurisdictions (other than the Netherlands) is remote.

Based on the following:

(i) the advice of our Dutch Investigation Counsel as summarised above;

(ii) our Company or Directors had not received any complaint in relation to the Settlement Agreement which might potentially invalidate the Settlement Agreement;

(iii) the amount of the Settlement Sum involved, being EUR348,000, was fully settled and does not have any material adverse impact on the financial position of the Group. Further, the annual transaction amount with the six hospitals involved was immaterial as it represented 0.2% to 0.6% of the consolidated annual revenue of our Group in each relevant year during the Relevant Period;

(iv) there was no bribery-related qualifications in any of the auditor's reports which had been issued on the financial statements of the companies comprising the Group for each of the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2022;

(v) no arrangement similar to the Alleged Unusual Transactions was discovered in ONM BV and ON GmBH (together with OIBV, being the only companies in the Group in operation in Europe at the time) during the internal investigations;

(vi) the fact that none of the Alleged Unusual Transactions, payments, credit notes or agreements was found to have been approved by the Directors and senior management team of the Company;

(vii) the Internal Control Consultant has not identified any further deficiencies in relation to the formulation and implementation of the anti-corruption policy and internal approval measures established by our Group;

(viii) the foregoing internal control policies adopted across our Group, which our Directors consider to be sufficient and effective in preventing the recurrence of the Alleged Unusual Transactions;

(ix) our Group has not identified any recurrence of incidents of a nature similar to the Alleged Unusual Transactions after the Relevant Period;

(x) the indemnity given by the Controlling Shareholders; and

(xi) although certain Directors and members of the senior management (namely, Mr. David CHIEN, Mr. Ching Chung John CHOW, Mr. Alain Djamel KHAIR and Mr. Robert John COTTONE JR) were in our Group's employment during the Relevant Period, none of them was a director of OIBV, nor were they involved in the daily operations of OIBV during the Relevant Period, or had any knowledge of the Alleged Unusual Transactions at the time. Although Alain Djamel KHAIR was the director of clinical marketing of OIBV from July 2014 to July 2016, he was responsible for the clinical marketing activities of OIBV in Middle East only and he was not in the position to approve any of the Alleged Unusual Transactions,

our Directors are of the view, and the Joint Sponsors concur, that the Alleged Unusual Transactions and the Investigation have no material impact on (i) the legal affairs, operations and financial condition of our Group, (ii) the suitability of our Directors under Rules 3.08 and 3.09 of the Listing Rules, or (iii) our suitability for [**REDACTED**] under Rule 8.04 of the Listing Rules.

Our Company is of the view that the impact on our Group's business or damage to our reputation as a result of the Alleged Unusual Transactions was limited. Although the press release about the Settlement Agreement in July 2021 might have caused a mild degree of reputational impact, the DPPS expressly mentioned in the press release about our Company's cooperative attitude and the fact that we carried out an internal investigation that resulted in a stricter compliance policy. Overall, there was no decrease in the sales amount and volume of the Group in Europe and other major markets after the press release was issued.

RISK MANAGEMENT

We are exposed to various risks for our operations, so risk management is important for our business. For details of the various operational risks we face, please refer to the section headed "Risk Factors" in this document. In addition, we are also exposed to various financial risks, such as credit, liquidity and foreign exchange risks that arise in the normal course of our business. For details, please refer to the paragraphs headed "Financial Information – Qualitative and Quantitative Disclosure About Market Risk" in this document.

We have designed and adopted a consolidated set of risk management policies in compliance with Rule 3.21 of the Listing Rules, and the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Our audit committee, and ultimately our Board supervises the implementation of our risk management policies. Risks identified by senior management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Company and reported to our Board.

Our senior management implements the risk management policies, strategies and plans set by our Board. Our senior management is responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant teams in our Company and supervising the implementation of our risk management policy by the relevant departments; and (iii) reporting to our audit committee on our material risks.

Each functional team in our Company, including the finance and investment teams, monitors and evaluates the implementation of risk management and internal control policies and procedures on a day-to-day basis. In order to formalize risk management across our Company and set a common level of transparency and risk management performance, the relevant teams will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report bi-annually for our chief executive officer's review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

With respect to urgent matters which arise between scheduled Board meetings, the Board secretary may also seek Board approval via telephone conference call or written Board consent. Before each Board meeting, an agenda is prepared with input from Directors, as well as from senior management and other vice presidents. At Board meetings, depending on the agenda, different team heads will gather information relating to their functions and report to the Board on the relevant agenda items, as necessary. The Board secretary attends all Board meetings to ensure that there is no gap in communication between the two bodies. During Board meetings,

the Board will on occasion further review and/or analyze particular issue and report their findings at the next Board meeting. Our Board believe that our corporate structure provides an appropriate system of checks and balances to improve our risk management procedures.

Our audit committee also reviews and approves our risk management policy to ensure that it is consistent with our corporate objectives, reviews and approves our corporate risk tolerance, monitors the most significant risks associated with our business operation and our management's handling of such risks, reviews our corporate risk in light of our corporate risk tolerance, and monitors and ensures the appropriate application of our risk management framework across our Company.

INTERNAL CONTROL OVER BUSINESS OPERATIONS

Internal Control

We have implemented various risk management policies and measures to identify, assess and manage risks arising from our operations. Details on risk categories identified by our management, internal and external reporting mechanism, remedial measures and contingency management have been codified in our policies. For details of the potential risks associated with our business, please refer to the section entitled "Risk Factors" in this document. To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will adopt, among other things, the following risk management and internal control measures:

- the establishment of an audit committee responsible for overseeing our financial records, internal control procedures and risk management systems. Please refer to the paragraphs titled "Directors and Senior Management – Board Committees – Audit Committee" in this document for the qualifications and experience of these committee members as well as a detailed description of the responsibility of our audit committee;

- the appointment of Mr. Wing Shing CHEN as our company secretary to ensure the compliance of our operation with relevant laws and regulations. For their biographical details, please refer to the section entitled "Directors and Senior Management" in this document;

- the appointment of Rainbow Capital (HK) Limited as our compliance advisor upon the [**REDACTED**] to advise us on compliance with the Listing Rules; and

- the engagement of external legal advisors to advise us on compliance with the Listing Rules and to ensure our compliance with relevant regulatory requirements and applicable laws, where necessary.

The following internal control and risk management measures have been implemented as at the Latest Practicable Date to address sanctions risks of our Group:

- to further enhance our existing internal risk management functions, the Company [has established] a risk management committee which will oversee its risk management and internal control system, including sanctions risk exposure;

- we have put in place an enhanced sanctions policy and control system which provides for processes and control measures to identify and manage potential sanctions risk taking a risk based approach. These include the following:

  - o checking the Group counterparties, including distributors, suppliers and customers against relevant sanctions lists;

  - o obtaining ultimate beneficial owner information or negative confirmation from the Group counterparties that no sanctioned person is a material owner such that the entity could be 50% owned or controlled by the sanctioned person; and

  - o including standard terms of sale in the Group distributor agreements which prohibit resale to persons or entities on relevant sanctions lists.

- we have retained reputable external international legal counsel with necessary expertise in International Sanctions to provide regular updates with regard to sanctions developments relating to countries subject to International Sanctions in which the Group conducts business; and

- our risk management committee will, with the assistance of our legal department, periodically review our internal control policies and procedures with respect to sanctions matters taking a risk based approach. As and when necessary, we will retain reputable external international legal counsel with necessary expertise in International Sanctions matters for recommendations and advice.

Our International Sanctions Legal Advisors have reviewed and evaluated these internal control measures and are of the view that these measures are consistent with guidance published by OFAC regarding sanctions compliance programs, and these measures appear adequate and effective for our Group based on our products and risk assessment, to comply with applicable international sanctions laws and address sanctions risks.

Finally, we have adopted or will adopt before the [**REDACTED**], various internal regulations against corrupt and fraudulent activities, which include measures against receiving bribes and kickbacks, and misuse of company assets. Major measures and procedures to implement such regulations include:

- authorizing our audit and supervision department to assume responsibility for oversight of our anti-corruption and anti-fraud measures, including handling complaints, ensuring protection for the whistle-blower and conducting internal investigations;

- providing anti-corruption compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations, and including relevant policies and express prohibitions against non-compliance in staff handbooks; and

- undertaking rectification measures with respect to any identified corrupt or fraudulent activities, evaluating the identified corrupt or fraudulent activities and proposing and establishing preventative measures to avoid future non-compliance.

Our Directors are of the view that such controls and measures are sufficient and effective to avoid the occurrence of corruption, bribery, or other improper conduct of our employees. During the Track Record Period and up to the Latest Practicable Date, save for the Investigation, we were not subject to any government investigation or litigation with respect to claims or allegations of monetary and non-monetary bribery activities, and to the best knowledge of our Directors, none of our employees were involved in any bribery or kickback arrangements.

We have designated responsible personnel to monitor our ongoing compliance with relevant laws and regulations that govern our business operations, and to oversee the implementation of any necessary measures. Meanwhile, we plan to provide our Directors, senior management and relevant employees with continuing training programs and updates regarding the relevant laws and regulations on a regular basis, with a view to proactively identifying any concerns or issues relating to any potential non-compliance. We believe that we have established adequate internal procedures, systems and controls in relation to anti-corruption and anti-bribery law compliance.