Application Proof of

OrbusNeich Medical Group Holdings Limited
業聚醫療集團控股有限公司

(Incorporated in the Cayman Islands with limited liability)

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OrbusNeich 業聚醫療

OrbusNeich Medical Group Holdings Limited
業聚醫療集團控股有限公司

(Incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under the [REDACTED]	**:**	**[REDACTED] Shares**
Number of [REDACTED]	**:**	**[REDACTED] Shares (subject to reallocation)**
Number of [REDACTED]	**:**	**[REDACTED] Shares (subject to reallocation)**
Maximum [REDACTED]	**:**	**HK$[REDACTED] per Share plus brokerage of 1.0%, SFC transaction levy of 0.0027%, AFRC transaction levy of 0.00015% and the Hong Kong Stock Exchange trading fee of 0.005% (payable in full on application, subject to refund)**
Nominal value	**:**	**US$0.0005 per Share**
Stock code	**:**	**[●]**

Joint Sponsors, **[REDACTED], [REDACTED], [REDACTED]** ***and*** **[REDACTED]**

CICC 中金公司　　建银国际 CCB International

[REDACTED], [REDACTED], [REDACTED] ***and*** **[REDACTED]**

[Logo(s) to be inserted]

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IMPORTANT

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[**REDACTED**]

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***This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to invest in the* [REDACTED].**

***There are risks associated with any investment. Some of the particular risks in investing in the* [REDACTED] *are set out in the section headed "Risk Factors" in this document. You should read that section carefully before you decide to invest in the* [REDACTED].**

OVERVIEW

We are a major global medical device manufacturer specialized in interventional instruments for percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (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 which traces back to 2000, 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.

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 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. With a focus on the entire development lifecycle of our products, we maintain a comprehensive team from research and development to commercialization. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, our research and development expenses was US$9.6 million, US$12.6 million, US$12.1 mllion, US$5.8 million and US$6.7 million, respectively, accounting for 10.0%, 14.2%, 10.4%, 10.2% and 9.8% of our total revenue for the same periods. We also collaborate with clinical trial institutions to conduct clinical trials where such institutions will generally assist us in 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.

Headquartered in Hong Kong, we maintain an established global sales network which consists of both direct sales and distributorship. 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. 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.

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 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.

OUR PRODUCTS AND PRODUCT PIPELINE

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, 22 products with CE Mark, 14 FDA cleared or approved products and 15 NMPA approved products, respectively, which were widely adopted by hospitals in over 70 countries and regions around the world as of June 30, 2022.

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

- 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 with relatively high procedural success rate in smaller diameter vessels that are not ideal for stenting;
- 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; and
- 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.

As of June 30, 2022, we had a robust product pipeline consisting 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 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. Specifically, 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, and a Jade II series PTA balloon for our next generation Jade series products.

In addition, 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, an ECMO left ventricle assist device which is currently at preclinical stage, and a new generation drug eluting balloon product (DEB) for various clinical indications.

Horizontally, we intend to leverage our technical expertise in the PCI/PTA instrument field and expand our product offerings to include structural heart intervention products and neuro intervention products. In the structural heart disease intervention arena, we intend to develop certain catheter-based medical devices used for structural heart interventional procedures such as valvuloplasty balloon catheter, and we are also working closely with ON P&F to develop 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-eluting balloons. Having a variety of neuro intervention products will enable us to effectively penetrate and compete in the neuro intervention market.

SUMMARY FINANCIAL INFORMATION

The following tables summarize our consolidated financial results during the Track Record Period and should be read in conjunction with the section headed "Financial Information" in this document and the Accountant's Report set out in Appendix I to this document, together with the respective accompanying notes.

Summary of Consolidated Statements of Profit or Loss

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Revenue	96,342	88,472	116,462	57,339	68,851
Cost of sales	(30,895)	(30,452)	(35,290)	(16,790)	(21,137)
Gross profit	65,447	58,020	81,172	40,549	47,714
Profit/(loss) before income tax	7,507	7,255	(1,318)	4,979	9,689
Profit/(loss) for the year/period attributable to owners of the Company	6,958	7,071	(4,444)	3,321	8,037

Non-HKFRS Measures

To supplement our consolidated results, which are prepared and presented in accordance with HKFRS, we use certain additional financial measures which are not required by or presented in accordance with HKFRS. Such measures include adjusted profit for the year/period (non-HKFRS measure) and adjusted net profit margin (non-HKFRS measure). Our adjusted profit for the year (non-HKFRS measure) are not calculated in accordance with HKFRS, and they are considered non-HKFRS measures. We believe that adjusted profit for the year/period (non-HKFRS measure) are useful for investors in comparing our performance, and they allow investors to consider metrics used by our management in evaluating our performance.

We define adjusted profit for the year/period (non-HKFRS measure) as profit/(loss) for the year/period by adding back: (i) unwinding of interests on convertible redeemable preferred shares, (ii) share-based compensation expenses, (iii) fair value losses of convertible redeemable preferred shares, (iv) loss on derecognition of financial liability in relation to convertible redeemable preferred shares, (v) [**REDACTED**], and (vi) fair value loss of a Commodity Linked Fixed Rate Note. We also define adjusted net profit margin (non-HKFRS measure) as adjusted profit for the year/period (non-HKFRS measure) divided by total revenue. We elected to add back these items for the non-HKFRS measure primarily because (i) all outstanding Series A and Series A-2 Preferred Shares of our Company have been or will be reclassified to equity upon fulfillment of conditions attached in the relevant agreement and no later than the completion of the [**REDACTED**], and therefore, we will no longer incur any unwinding of interests, fair value losses or losses on derecognition of financial liability, in relation to the convertible redeemable preferred shares. In addition, unwinding of interests, fair value losses and losses on derecognition of financial liability in relation to the convertible redeemable preferred shares were non-cash items, (ii) our share-based compensation expenses were non-cash in nature, (iii) we incurred [**REDACTED**] in relation to the [**REDACTED**], and (iv) we will hold the Commodity Linked Fixed Rate Note till maturity and receive its face values plus predetermined coupon rate of 2.8% in December 2023, and the fair value loss was non-cash item and there will be fair value gain in subsequent period till maturity to completely offset the current fair value loss.

Our adjusted profit for the year (non-HKFRS measure) increased by 201.4% from US$7.1 million in 2020 to US$21.4 million in 2021, and our adjusted net profit margin (non-HKFRS measure) increased from 8.0% in 2020 to 18.3% in 2021, primarily due to the increase in gross profit as a result of increase in revenue, and our relatively stable expenses (excluding reconciling items under non-HKRFS measure) in 2021 as compared to 2020.

Our adjusted profit for the period (non-HKFRS measure) increased by 23.6% from US$11.0 million for the six months ended June 30, 2021 to US$13.6 million for the six months ended June 30, 2022, and our adjusted net profit margin increased from 19.2% for the six months ended June 30, 2021 to 19.8% for the six months ended June 30, 2022, primarily due to the increase in gross profit as a result of increase in revenue, and our relatively stable expenses (excluding reconciling items under non-HKRFS measure) for the six months ended of June 30, 2022 as compared to the same period in 2021.

Our Directors believe that the presentation of non-HKFRS measures when shown in conjunction with the corresponding HKFRS measures provide useful information to investors and management regarding financial and business trends relating to its financial condition and results of operations, by eliminating potential impact of certain items.

The use of non-HKFRS measures has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for or superior to analysis of, our results of operations or financial conditions as reported under HKFRS. In addition, non-HKFRS measures used in this document may be defined differently from similar terms used by other companies.

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Non-HKFRS Measures					
Profit/(loss) for the year/period	6,958	7,071	(4,444)	3,321	8,037
Add:					
Unwinding of interests on convertible redeemable preferred shares	–	–	4,853	476	1,336
Share-based compensation expenses	–	–	1,339	670	368
Fair value loss of the Commodity Linked Fixed Rate Note	–	–	–	–	1,266
Fair value losses of convertible redeemable preferred shares	–	–	14,397	6,030	–
Loss on derecognition of financial liability in relation to convertible redeemable preferred shares	–	–	559	–	–
[**REDACTED**]	–	–	[REDACTED]	[REDACTED]	[REDACTED]
Adjusted profit for the year/period (non-HKFRS measure)	6,958	7,071	21,352	10,989	13,606

Revenue and Gross Profit

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.

Our revenue and gross profit decreased from 2019 to 2020, primarily due to (i) the impact of the COVID-19 pandemic, which led to a lower number of PCI surgeries performed and reduced the consumption of our products as patients generally do not take relevant procedures unless necessary, and (ii) a decrease in the average selling prices of our products reflecting the product mix sold and the contribution by different markets in relevant periods, partially offset by our launch of COMBO Plus products in Japan, which had a higher average selling price.

Our revenue increased by US$28.0 million from US$88.5 million in 2020 to US$116.5 million in 2021, which was primarily attributable to increases in sales volume of both direct sales and distributor sales as a result of the resumption of business activities in various markets as COVID-19 pandemic became stabilized. In particular, (i) revenue from our EMEA market increased by US$9.7 million in 2021 due to the increases in average selling price and sales volume; (ii) the introduction of our new Jade OTW series in the U.S. market in 2021 brought in an increase in revenue from PTA balloons of US$4.2 million; and (iii) due to the change in sales model from exclusive distributorship to a combination of direct sales and regional distributors in the PRC as well as our additional marketing efforts for certain products not subject to the centralized procurement policy, we were able to increase our revenue by US$12.0 million in the PRC market in 2021. In addition, our gross profit margin increased slightly to 69.7% in 2021 and thus with the increased revenue, our gross profit has increased by US$23.2 million from US$58.0 million in 2020 to US$81.2 million in 2021.

Our revenue increased by US$11.6 million from US$57.3 million in the first six months of 2021 to US$68.9 million in the first six months of 2022, which was primarily attributable to increases in sales volume of both direct sales and distributor sales. In particular, (i) revenue from our U.S. market increased by US$2.9 million in the first six months of 2022 due to the increases in sales volume of our coronary balloons as a result of the introduction of our Scoreflex NC series in the U.S. market upon product approval by the FDA in late 2021; (ii) the increase in sales volume of our Scoreflex Trio series in the Japan market, which has the higher average selling price among our scoring balloons, brought in an increase in revenue of US$2.4 million in the first six months of 2022; and (iii) revenue in the PRC market increased by US$6.4 million in the first six months of 2022, primarily due to the increase in volume and average selling price for our Scoreflex series as a result of the expansion of our sales networks and change in sales model in the PRC as well as our additional marketing efforts for certain products not subject to the centralized procurement policy. With the increased revenue, our gross profit has increased by US$7.2 million from US$40.5 million in the first six months of 2021 to US$47.7 million in the first six months of 2022.

Government Grant

The government grant received by our subsidiary in the PRC increased from US$1.0 million in 2019 to US$1.9 million in 2020, and decreased to US$0.8 million in 2021. The government grant received by our subsidiary in the PRC decreased from US$0.3 million in the first six months of 2021 to US$0.2 million in the first six months of 2022.

The government grants received by our subsidiary in the PRC in 2020 and 2021 were mainly related to the government's support on (i) product registration when entering into a new market, (ii) obtaining medical devices production license for the production of Class III medical devices and (iii) employment in relation to the COVID-19 pandemic, which were non-recurring in nature. The higher amount of government grant in 2020 was primarily due to the support from the PRC government in relation to obtaining approval from the PMDA for the sales of our Sapphire NC 24, Teleport and Jade PTA series in the Japan market.

Selling and Distribution Expenses

Our selling and distribution expenses decreased by 17.3% from US$32.3 million in 2019 to US$26.7 million in 2020, primarily due to the slowdown of business activities and decreased sales volume in 2020 as affected by the COVID-19 pandemic, which led to less marketing activities, lower royalty and travel and entertainment expenses in 2020.

Our selling and distribution expenses increased by 12.7% from US$26.7 million in 2020 to US$30.1 million in 2021, which was primarily due to the setup of our own PRC sales and marketing team.

Our selling and distribution expenses increased by 12.2% from US$14.7 million in the first six months of 2021 to US$16.5 million in the first six months of 2022, primarily due to the increase in marketing expenses as a result of the resumption of marketing activities such as medical congresses and trade shows.

General and Administrative Expenses

Our general and administrative expenses decreased by 8.9% from US$15.7 million in 2019 to US$14.3 million in 2020, primarily due to a decrease in employee benefit expenses due to the departure of certain former senior management, a decrease in headcount of our U.S. office which has a higher average salary and reduction of bonuses paid to our employees as a result of decreased revenue due to the COVID-19 pandemic, partially offset by an increase in legal and professional fees in connection with our acquisition of ON AG.

Our general and administrative expenses increased by 39.9% from US$14.3 million in 2020 to US$20.0 million in 2021, primarily due to the increase in employee benefit expenses as a result of our increased headcount and the overall salary increment.

Our general and administrative expenses increased by 30.5% from US$8.2 million in the first six months of 2021 to US$10.7 million in the first six months of 2022, primarily due to the increase in [**REDACTED**] in the first six months of 2022.

Research and Development Expenses

Our research and development expenses increased by 31.3% from US$9.6 million in 2019 to US$12.6 million in 2020, primarily due to the increase in clinical trial expenses from a net reversal of US$2.6 million in 2019 to an expense of US$1.2 million in 2020.

Our research and development expenses remained relatively stable in 2020 and 2021, and we recorded research and development expenses of US$12.1 million in 2021.

Our research and development expenses increased by 15.5% from US$5.8 million in the first six months of 2021 to US$6.7 million in the first six months of 2022, primarily due to the increase in employee benefit expenses as a result of the overall salary increment and the increase in our outsourced R&D service fees in relation to the consultation services for our pipeline products, which were provided to us by individual experts in universities and hospitals as well as professional medical research institutes and consulting companies. Such consultation services included advising on our clinical study design and trial protocol, performing tests and trials of our pipeline products, providing feedback and clinical evaluation of our pipeline products and assisting with respect to our regulatory strategies and/or submissions.

Net Profit/(Loss)

Our profit was US$7.0 million in 2019 as compared to US$7.1 million in 2020, and our net profit margin increased from 7.2% in 2019 to 8.0% in 2020.

Our profit decreased from US$7.1 million in 2020 to a net loss of US$4.4 million in 2021, mainly attributable to the unwinding of interests on convertible redeemable preferred shares amounting to US$4.9 million, share-based compensation expenses of US$1.3 million, fair value losses and loss on derecognition of convertible redeemable preferred shares amounting to US$14.4 million and US$0.6 million respectively, and [**REDACTED**] of US$[**REDACTED**] in 2021. Our adjusted profit for the year (non-HKFRS measure) increased by 201.4% from US$7.1 million in 2020 to US$21.4 million in 2021, and our adjusted net profit margin (non-HKFRS measure) increased from 8.0% in 2020 to 18.3% in 2021, primarily due to increase in gross profit as a result of increase in revenue, and our relatively stable expenses (excluding reconciling items under non-HKRFS measure) in 2021 as compared to 2020.

Our profit increased from US$3.3 million in the first six months of 2021 to a US$8.0 million in the first six months of 2022, mainly attributable to the increase in gross profit of US$7.2 million as a result of the increase in revenue, and we did not incur fair value losses of convertible redeemable preferred shares upon the reclassification to equity in 2022, as compared to US$6.0 million of such losses in the first six months of 2021, partially offset by the fair value loss of the Commodity Linked Fixed Rate Note of US$1.3 million, increase in selling and distribution expenses of US$1.8 million, increase in general and administrative expenses of US$2.6 million and increase in research and development expenses of US$0.9 million. Our adjusted profit for the period (non-HKFRS measure) increased by 23.6% from

US$11.0 million in the first six months of 2021 to US$13.6 million in the first six months of 2022, and our adjusted net profit margin (non-HKFRS measure) increased from 19.2% in the first six months of 2021 to 19.8% in the first six months of 2022, primarily due to the increase in gross profit of US$7.2 million as a result of the increase in revenue, partially offset by the increase in selling and distribution expenses of US$1.8 million, increase in general and administrative expenses of US$2.6 million and increase in research and development expenses of US$0.9 million.

We believe that our following strategies since 2021 enabled us to achieve a substantial improvement in our financial performance compared to previous years: (i) in the established markets where we have already achieved a high hospital coverage, including Japan, certain countries or regions in EMEA and APAC such as Hong Kong, Malaysia, Singapore and Spain, we strove to sustain market share for our existing products by introducing new generations of existing products of higher performance than both our previous generation of products and other existing products in the market. For instance, the latest generation of Sapphire balloon series, Sapphire 3 and Sapphire NC 24 were launched in 2021, each with a higher selling price than its previous generation. These new generations of products enabled us to sustain growths in revenue, gross profits and gross profit margin in these established markets; (ii) in fast-growing markets (such as the U.S. and Mainland China) where we have a lower hospital coverage, we strove to launch the products with good functionality, quality, and performance in order to rapidly increase the hospital coverage and market share. For instance, we successfully launched Jade OTW series and Scoreflex NC series in the U.S. in 2021 and 2022 respectively and received market reception; (iii) on the cost side, we managed to control the increase in costs at a mild pace. Our selling and distribution expenses only increased by 12.7% from 2020 to 2021, and 12.2% from the first six months of 2021 to the first six months in 2022. Our general and administrative expenses (excluding share-based compensation and [**REDACTED**]) decreased by 2.3% from 2020 to 2021 and increased by 10.6% from the first six months of 2021 to the first six months of 2022. Our research and development expenses decreased by 3.4% from 2020 to 2021 and increased by 15.5% from the first six months of 2021 to the first six months of 2022. The growth of our expenses for the first six months of 2022 were less than the revenue growth. The relatively stable expenses were attributable to the well-established global sales network which did not incur significant increase in costs despite expansion in product offerings. We will continue to pursue such strategies of market expansion and cost control in order to improve our profitability.

The following table sets forth our revenue by product categories, in absolute amount and as a percentage of our total revenue, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Coronary interventional medical devices										
Balloon										
Semi-compliant	30,125	31.3%	25,875	29.2%	27,427	23.6%	14,153	24.7%	13,993	20.3%
Non-compliant	23,842	24.7%	20,670	23.4%	25,948	22.3%	12,826	22.4%	13,176	19.1%
Scoring	16,402	17.0%	14,352	16.2%	29,383	25.2%	12,154	21.2%	24,700	35.9%
Stent										
Dual therapy stents	11,619	12.1%	12,879	14.5%	13,591	11.7%	7,240	12.6%	6,259	9.1%
Bare metal stents	229	0.2%	71	0.1%	47	0.0%	23	0.0%	2	0.0%
Subtotal	82,217	85.3%	73,847	83.4%	96,396	82.8%	46,396	80.9%	58,130	84.4%
Peripheral interventional medical devices										
Balloon	6,963	7.2%	7,476	8.5%	11,683	10.0%	6,703	11.7%	5,581	8.1%
Other medical accessories	5,065	5.3%	4,810	5.4%	3,689	3.2%	1,469	2.6%	2,486	3.6%
Third party products	2,097	2.2%	2,339	2.7%	4,694	4.0%	2,771	4.8%	2,654	3.9%
Total	96,342	100.0%	88,472	100.0%	116,462	100.0%	57,339	100.0%	68,851	100.0%

The decrease in revenue from 2019 to 2020 in most product categories was mainly due to a lower number of PCI surgeries performed and thus a lower demand for our products, as a result of the COVID-19 pandemic. We managed to maintain a slight growth in dual therapy stents and peripheral balloons due to the introduction of our COMBO Plus series in Japan and Jade OTW series in the U.S. market.

Our revenue picked up in 2021 as COVID-19 became more stable. We managed to have strong growth in sales of our scoring balloons due to our market expansion strategy in the PRC and the increase in sales of our peripheral balloons, in connection with the introduction of Jade OTW series in the U.S. market in the second half of 2020.

Our revenue increased from the first six months of 2021 to the same period of 2022, primarily due to the introduction of our several scoring balloons such as Scoreflex NC series, Scoreflex Trio series and Scoreflex series in several markets in 2022.

For more details, please refer to the paragraph headed "Financial Information – Revenue" in this document.

The following table sets forth our revenue by geographic area, in absolute amount and as a percentage of our total revenue, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
EMEA	27,421	28.5%	24,428	27.6%	34,122	29.3%	17,901	31.3%	16,567	24.0%
Japan	29,357	30.5%	28,164	31.8%	29,807	25.6%	14,748	25.7%	17,134	24.9%
APAC	26,969	27.9%	23,545	26.7%	27,988	24.0%	13,621	23.7%	14,819	21.6%
The PRC	8,269	8.6%	5,047	5.7%	17,077	14.7%	6,940	12.1%	13,319	19.3%
United States	4,326	4.5%	7,288	8.2%	7,468	6.4%	4,129	7.2%	7,012	10.2%
Total	96,342	100.0%	88,472	100.0%	116,462	100.0%	57,339	100.0%	68,851	100.0%

The decrease of revenue from 2019 to 2020 across all regions, except the United States, was mainly due to the COVID-19 pandemic, which reduced the number of PCI surgeries and thus demand for our products. We managed to increase our sales in the U.S. market with the introduction of our Jade OTW series in the second half of 2020.

Our revenue picked up in 2021 as COVID-19 become more stable. We managed to have strong growth in major markets like EMEA, APAC and in particular the PRC. Specifically, the significant increase in revenue in the PRC market was due to (i) the increase in average selling price due to the elimination of the intermediate layer of the previous exclusive distributor between us and the regional distributors/hospitals in the distribution process; (ii) the increase in the number of regional distributors to expand our hospital coverage; (iii) the success of the additional marketing efforts of our scoring coronary balloon which were not admitted under the centralized procurement policy and (iv) the wider market recognition of our products by physicians.

Our revenue increased from the first six months of 2021 to the same period of 2022, primarily due to the increase in revenue in the U.S., Japan and the PRC markets as a result of the introduction of our scoring balloons such as Scoreflex NC series, Scoreflex Trio series and Scoreflex series in these markets. Such increase was partially offset by the decrease in the EMEA market due to the recent Russo-Ukrainian conflict.

For more details, please refer to the paragraph "Financial Information – Revenue" in this document.

For an overview of the competitive landscape in the above geographic area, please refer to the paragraph headed "Our Industry" in this section.

The following table sets forth our revenue by sales channels, in absolute amount and as a percentage of our total revenue, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Direct Sales*	50,464	52.4%	49,079	55.5%	63,944	54.9%	30,998	54.1%	33,643	48.9%
Sales to Distributors	44,778	46.5%	38,312	43.3%	52,267	44.9%	26,282	45.8%	35,202	51.1%
Others	1,100	1.1%	1,081	1.2%	251	0.2%	59	0.1%	6	0.0%
Total	96,342	100.0%	88,472	100.0%	116,462	100.0%	57,339	100.0%	68,851	100.0%

* Include sales in Japan and Malaysia markets, where sales are through local procurement agents designated by hospitals under applicable local regulations and/or market practice. For 2021 and the six months ended June 30, 2021 and 2022, direct sales included sales in the PRC market made through qualified logistics services providers under the centralized procurement policy.

For sales to 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 and direct sales to hospitals (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. For direct sales to hospitals involving tender process, our sales team will handle the entire process and prepare bidding materials for tender submission. The prices we sell to hospitals are generally affected by local regulations and policies. For more details of our pricing strategy, please refer to section headed "Business – Sales, Marketing and Distribution – Pricing" in this document.

The COVID-19 pandemic which led to the temporary decrease in the number of PCI surgeries performed impacted both our direct sales and and sales to distributors in 2020. Our revenue recovered in both sales channels in 2021 as COVID-19 became more stable. In particular for sales to distributors, our expansion in the PRC market resulted in the significant increase in revenue from sales to distributors.

For the first six months of 2021 to the same period of 2022, our direct sales had grown stably and we managed to grow our sales to distributors further, which was a combined result of (i) the increase in sales volume of our Scoreflex NC series in the U.S. market, which was introduced to the U.S. market in 2022, and (ii) the increase in both sales volume and average selling price of our Scoreflex series in the PRC market.

For more details, please refer to the paragraph headed "Financial Information – Revenue" in this document.

The following table sets forth our gross profit and gross profit margin by business line and sales channels for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
By business line										
Coronary interventional medical devices										
Balloon	48,592	69.1%	39,869	65.5%	60,140	72.7%	28,955	74.0%	38,583	74.4%
Stent	6,885	58.1%	7,860	60.7%	7,951	58.3%	4,447	61.2%	2,462	39.3%
Subtotal	55,477	67.5%	47,729	64.6%	68,091	70.6%	33,402	72.0%	41,045	70.6%
Peripheral interventional medical devices										
Balloon	6,271	90.1%	6,494	86.9%	8,940	76.5%	5,136	76.6%	4,221	75.6%
Other medical accessories	3,055	60.3%	3,032	63.0%	2,442	66.2%	978	66.6%	1,739	70.0%
Third party products	644	30.7%	765	32.7%	1,699	36.2%	1,033	37.3%	709	26.7%
Total gross profit/ overall gross profit margin	65,447	67.9%	58,020	65.6%	81,172	69.7%	40,549	70.7%	47,714	69.3%
By sales channels										
Direct sales	41,845	82.9%	39,442	80.4%	50,250	78.6%	23,930	77.2%	26,312	78.2%
Sales to distributors	23,602	51.4%	18,578	47.2%	30,922	58.9%	16,619	63.1%	21,402	60.8%
Total gross profit/overall gross profit margin	65,447	67.9%	58,020	65.6%	81,172	69.7%	40,549	70.7%	47,714	69.3%

Our gross profit margin for coronary balloon products slightly decreased from 2019 to 2020, primarily due to a decrease in the average selling prices of our products in Japan. In 2021, our gross profit margin increased mainly due to our introduction of new generation of major products such as Sapphire 3 and Sapphire NC 24 balloons, which have higher average selling prices. Besides, increase in sales volume of scoring balloons, which have higher gross profit margin, in connection with the expansion of our sales network in the PRC also contributed to the increase in gross profit margin for coronary balloon products. Our gross profit margin for coronary balloon products was relatively stable for the first six months of 2021 and the same period of 2022.

Our gross profit margin for coronary stent products continued to increase from 2019 to 2020. The increase in 2020 was mainly due to our introduction of COMBO Plus dual therapy stent products in Japan, which had a higher average selling price. Our gross profit margin for coronary stent products remained stable in 2021. Our gross profit margin for coronary stent products decreased from the first six months of 2021 to the same period of 2022, primarily due to (i) the decrease in selling price in the Japan market as a result of the reduction in the government reimbursement price, (ii) the substantial depreciation of Japanese Yen against USD and (iii) provision for impairment increased as our stent products consigned in the hospitals increased as a result of our expanding hospital coverage in Japan since the launch of our COMBO Plus dual therapy stent products in 2020.

Our gross profit margin for peripheral balloon products remained stable in 2019 and 2020, and the decrease in 2021 was primarily due to the introduction of our new Jade OTW series in the U.S. market which led to lower average selling prices of our products after taking into the discount to local distributors. Gross profit margin for peripheral balloon products were higher than that of coronary balloon products, primarily because majority of our peripheral balloon products were sold in countries under the direct sales, such as Japan, where the average selling prices were higher. Our gross profit margin for peripheral balloon products remained relatively stable in the first six months of 2021 and the same period of 2022.

Our gross profit margin of medical device accessories increased during the Track Record Period, primarily due to the increase in the sales volume of our Teleport products and other accessories in direct sales countries or regions which had higher average selling price and thus higher gross profit margin.

Our gross profit margin for third party products remained relatively stable in 2019 and 2020. The increase from 2020 to 2021 was primarily due to the increase in sales volume of our coronary artery and peripheral orbital atherectomy products in certain countries under the direct sales model with higher average selling prices and thus gross margin. Our gross profit margin for third party products decreased from the first six months of 2021 to the same period of 2022, primarily because the gross profit margin for the distribution of drug eluting balloons launched in the Malaysia and Spain markets in 2022 was relatively low as a result of our commercial negotiations with a new supplier.

Our gross profit margin for direct sales channel decreased slightly from 82.9% in 2019 to 80.4% in 2020, which was primarily due to the decrease in average selling price of our balloon products in Spain and Germany markets and the decrease in average selling price of our stent products in Singapore market as a result of competition in the local markets. Such decrease was in line with the overall decreasing price trend of interventional medical devices.

Our gross profit margin for direct sales channel slightly decreased from 80.4% in 2020 to 78.6% in 2021, which was primarily due to certain of our products were sold under the centralized procurement policy in the PRC market which had a lower average selling price.

Our gross profit margin for direct sales channel remained stable in the first six months of 2021 and the same period of 2022.

Our gross profit margin for sales to distributors decreased from 51.4% in 2019 to 47.2% in 2020, which was primarily due to the decrease in average selling prices of our US and EMEA markets, which was in line with the decreasing price trend of interventional medical devices.

Our gross profit margin for sales to distributors increased from 47.2% in 2020 to 58.9% in 2021, which was primarily due to the expansion of sales network in the PRC by selling to the regional distributors directly. The average selling price of balloon products increased due to the elimination of the intermediate layer of the previous exclusive distributor and therefore increased the gross profit margin.

Our gross profit margin for sales to distributors decreased slightly from 63.1% in the first six months of 2021 to 60.8% in the same period in 2022, primarily due to the increase in sales volume of our balloon products in certain APAC countries with lower average selling price.

Selected Items of Consolidated Balance Sheets

	As of December 31,			As of June 30,
	2019	**2020**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*
Total non-current assets	21,515	29,179	33,172	50,412
Total current assets	74,177	74,467	235,355	228,368
Total non-current liabilities	103,302	13,284	68,965	4,865
Total current liabilities	144,681	55,466	16,450	21,189
Net current (liabilities)/assets	(70,504)	19,001	218,905	207,179
Total (deficit)/equity	(152,291)	34,896	183,112	252,726

We had accumulated losses of US$145.1 million, US$137.9 million, US$142.7 million and US$134.4 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. The significant amount of accumulated losses during the Track Record Period primarily contributed by our significant investment in R&D activities prior to the Track Record Period. Specifically, a substantial portion of such R&D expenses were used in the development of our COMBO and COMBO Plus dual therapy stents, which commenced in 2006. The relevant products obtained approval of CE Mark in 2016, approval by PMDA in Japan in 2019 and approval by NMPA in the PRC in 2020, respectively, and prior to these approvals we conducted a total of ten clinical trials as well as various studies in Europe, Japan, the PRC, the U.S. and certain Asia Pacific countries and regions with over 9,500 subjects enrolled under relevant trials and studies since 2006. A substantial majority of the related R&D and clinical trial expenses were paid and the total R&D and clinical trial expenses of COMBO and COMBO Plus and its older product versions accumulated to over US$100.0 million by the end of 2018. As a result, we recorded accumulated losses of US$152.2 million as of January 1, 2019 (being the beginning of the Track Record Period).

We turned around net current liabilities of US$70.5 million as of December 31, 2019 to net current assets of US$19.0 million as of December 31, 2020, primarily attributable to the waiver of an amount due to a related company as deemed contribution of US$88.2 million in the current liabilities and the recognition of such amount as other reserves in equity in 2020. Net current assets further increased to US$218.9 million as of December 31, 2021, which was primarily attributable to the receipt of US$202.5 million from our Series A and Series A-2 financing in 2021. Net current assets decreased by US$11.7 million from US$218.9 million as of December 31, 2021 to US$207.2 million as of June 30, 2022, primarily attributable to the purchase of the Commodity Linked Fixed Rate Note of US$20.0 million for the purpose of generating interest income with minimal credit and liquidity risk, which was classified as non-current asset, and resulted in a significant increase of our financial assets at fair value through profit or loss from December 31, 2021 to June 30, 2022, partially offset by the net cash generated from operations.

We turned around net liabilities of US$152.3 million as of December 31, 2019 to net assets of US$34.9 million as of December 31, 2020, primarily due to: (i) the waiver of an amount due to a related company as deemed contribution of US$187.8 million and the recognition of such amount as other reserves in the equity in 2020; and (ii) total comprehensive income of US$8.2 million in 2020, which were partly offset by the deemed distribution to shareholders of US$8.8 million. Net assets further increased to US$183.1 million as of December 31, 2021, which was primarily attributable to: (i) the reclassification of Series A-2 Preferred Shares of US$167.2 million to other reserves in the equity upon completion of the Reorganization; and (ii) the increase in other reserves of US$1.3 million in relation to employee share option scheme, which were partly offset by (iii) changes in value of Series A Preferred Shares upon completion of the Reorganization of US$12.1 million and (iv) total comprehensive loss of US$8.2 million in 2021. Net assets increased by US$69.6 million from US$183.1 million as of December 31, 2021 to US$252.7 million as of June 30, 2022, which was primarily attributable to the reclassification of Series A Preferred Shares of US$65.0 million to other reserves in the equity upon fulfillment of conditions attached in the relevant agreement in April 2022.

Summary of Consolidated Statements of Cash Flows

The following table sets forth a summary of our net cash flow for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net cash generated from operating activities	1,590	12,666	20,498	14,287	13,924
Net cash used in investing activities	(3,053)	(11,245)	(5,219)	(1,516)	(56,177)
Net cash generated from/(used in) financing activities	1,205	(473)	146,308	24,650	(852)

	For the year ended December 31,			For the six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net (decrease)/increase in cash and cash equivalents	(258)	948	161,587	37,421	(43,105)
Cash and cash equivalents at beginning of year	13,812	13,631	15,112	15,112	175,886
Effects of exchange rate changes on cash and cash equivalents	77	533	(813)	(873)	(1,162)
Cash and cash equivalents at end of year/period	13,631	15,112	175,886	51,660	131,619

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors:

- A major player in the fast-growing global PCI/PTA balloons markets, with well-established reputation and brand awareness;
- Diversified product portfolio indicating different endovascular interventional procedures;
- Robust and novel pipeline products backed by world leading technologies and strong R&D capabilities;
- Established global sales network and distinctive commercial competency;
- Advanced production facilities and strict quality control system which ensure stable supply for global markets; and
- Experienced management team supported by energetic and cohesive talent pool.

OUR STRATEGIES

We plan to execute the following key strategies:

- Leverage on our well-established brand recognition to further enhance our market penetration;
- Further enrich product offerings both vertically and horizontally;
- Work closely with physicians and KOLs in different therapeutic areas to further enhance our brand recognition and R&D capabilities;
- Pursue strategic acquisitions, partnerships and/or collaborations; and
- Expand production capacity and continuously improve operational efficiencies.

OUR DISTRIBUTION AND DIRECT SALES NETWORK

Our sales transactions are conducted through two main channels: direct sales and through 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, respectively. 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 controlling shareholder, all our distributors who purchase our products are Independent Third Parties, and our relationship with distributors is not that of a principal and an agent. 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 at a point in time when control has been transferred to the customer. Majority of such revenue are recognised when the products are dispatched from our warehouse.

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. By working closely with the physicians, we in turn gain valuable insights into the operations of each local market and the physicians' needs. In certain countries, such as Japan and Malaysia, local regulations and/or market practices require medical device products to be sold to the hospitals via local procurement agents with proper licenses or qualifications designated by hospitals. As a result, while we adopt a direct sales model in such countries, some of our products are sold to hospitals through designated procurement agents.

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, such as the TricValve Bicaval System and a sirolimus eluting coronary balloon catheter, in multiple countries/regions and create additional revenue stream.

OUR FACILITIES

Our Company is headquartered in the Hong Kong Science Park, and 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. 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.

For the six months ended June 30, 2022, 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 products per year. 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. We are constantly seeking to expand our production capacity, and expect it to increase in the future.

Leveraging our strict and 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. OrbusNeich maintains certification to QMS standards such as ISO 13485 certifications. In particular, our production facilities in the PRC have passed onsite inspections 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.

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.

During the Track Record Period, our Group has 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. For more details, please refer to the paragraphs headed "Business – Business Activities with Customers in Relation to Countries/Regions Subject to International Sanctions" and "Risk Factors – We could be adversely affected as a result of any sales we make to certain countries that are, or become subject to, sanctions administered by the United States, the European Union, the United Nations, Australia and other relevant sanctions authorities" in this document.

As advised by our International Sanctions Legal Advisors, our Group's transactions related to the Relevant Regions did not violate U.S. sanctions or sanctions laws imposed by other Relevant Jurisdictions. Nor did our Group engage in any Primary Sanctioned Activity during the Track Record Period and up to the Latest Practicable Date that violate applicable law or regulation. 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 "Business – Internal Control over Business Operations – Internal Control" in this document.

OUR RAW MATERIALS AND SUPPLIERS

Our cost of sales consists of raw material, manufacturing and direct labor costs, among which raw material costs constituted the largest component of our cost of sales during the Track Record Period. 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, and we have maintained stable relationships with many of our key suppliers.

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 for 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. During the Track Record Period and up to the Latest Practicable Date, we did not encounter any material dispute with our suppliers or any material breach of our supply contracts or agreements. To the best of our knowledge, as of the Latest Practicable Date, we were not aware of any information or arrangement that would lead to termination of our relationships with any of our major suppliers. During the Track Record Period, none of our Directors, their respective close associates or shareholders who own 5% or more of our issued share capital had any interest in any of our five largest suppliers in each year/period of the Track Record Period. During the Track Record Period, we had two suppliers who were also our customers (collectively referred to as "**Overlapping Customers-Suppliers**."). 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. For more details, pleaser refer to the section headed "Business – Our Suppliers – Overlapping Customers and Suppliers".

OUR INDUSTRY

According to the CIC Report, the market size of PCI procedural instruments is showing continuous growth globally. In the PRC, the market size by sales value was US$765.5 million in 2015 and US$1,270.4 million in 2021, and is expected to reach US$3,751.2 million in 2030. In APAC region, the market size by sales value was US$733.4 million in 2015 and US$1,266.1 million in 2021, and is expected to reach US$2,985.3 million in 2030. In Europe, the market size by sales value was US$582.7 million in 2015 and US$892.6 million in 2021, and is expected to reach US$2,010.9 million in 2030. In the U.S., the market size by sales value was US$400.4 million in 2015 and US$672.9 million in 2021, and is expected to reach US$1,907.4 million in 2030. In Japan, the market size by sales value was US$394.5 million in 2015 and US$484.6 million in 2021, and is expected to reach US$824.1 million in 2030.

According to the CIC Report, the market size of PTA procedural instruments is also showing continuous growth globally. In the PRC, the market size by sales value was US$166.0 million in 2015 and US$280.9 million in 2021, and is expected to reach US$976.6 million in 2030. In Japan, the market size by sales value was US$89.7 million in 2015 and US$161.1 million in 2021, and is expected to reach US$320.4 million in 2030. In the U.S., the market size by sales value was US$21.7 million in 2015 and US$36.3 million in 2021, and is expected to reach US$91.3 million in 2030. In Europe, the market size by sales value was US$61.0 million in 2015 and US$94.8 million in 2021, and is expected to reach US$194.7 million in 2030. In the APAC region, the market size by sales value was US$50.0 million in 2015 and US$93.2 million in 2021, and is expected to reach US$205.3 million in 2030.

For details of the prevalence of CAD/PAD and overview of the PCI/PTA instrument markets, please refer to the section headed "Industry Overview" in this document.

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.

KEY FINANCIAL RATIOS

The following table sets forth our key financial ratios for the periods and as of the dates indicated.

	For the year ended/as of December 31,			For the six months ended/as of June 30	
	2019	**2020**	**2021**	**2021**	**2022**
				(Unaudited)	
Gross profit margin[(1)]	67.9%	65.6%	69.7%	70.7%	69.3%
Net profit margin[(2)]	7.2%	8.0%	N/A[(7)]	5.8%	11.7%
Adjusted net profit margin (non-HKFRS measure)[(3)]	7.2%	8.0%	18.3%	19.2%	19.8%
Return on total assets[(4)]	7.3%	7.1%	N/A[(7)]	5.4%	5.9%
Current ratio[(5)]	0.5 times	1.3 times	14.3 times	2.1 times	10.8 times
Interest coverage ratio[(6)]	15.9 times	6.2 times	0.8 times	5.8 times	7.9 times

(1) Calculated by dividing gross profit for the year/period by total revenue.

(2) Calculated by dividing profit for the year/period by total revenue.

(3) Calculated by dividing the adjusted profit for the year/period (non-HKFRS measure) by total revenue.

(4) Calculated by dividing profit for the year by the average of total assets at the beginning and the end of each year/period. For return on total assets for the six months ended June 30, 2021 and 2022, the numbers are annualized by dividing the profit for these periods by 180 and multiplying it by 360, and then dividing it by the average of total assets at the beginning and end of the period.

(5) Calculated by dividing total current assets by total current liabilities.

(6) Calculated by dividing profit before income tax and interest expenses by interest expense.

(7) We recorded net loss during the year.

For the fluctuations of our gross profit margin and net profit margin, please refer to the sections headed "Financial Information – Description of Consolidated Statements of Profit or Loss" and "Financial Information – Results of Operations" in this document.

Our return on total assets in 2021 was nil, primarily attributable to the impact of fair value losses in connection with our convertible redeemable preferred shares. Our return on total assets was 7.3% in 2019, 7.1% in 2020, primarily reflecting the increases in our net profit in relevant periods.

Our return on total assets increased from nil in 2021 to 5.9% in the first six months of 2022, primarily reflecting the increases in our net profit in such period.

Our current ratio increased significantly from 1.3 times as of December 31, 2020 to 14.3 times as of December 31, 2021, primarily attributable to increased cash and cash equivalents in connection with our Series A and Series A-2 financing. Our current ratio increased from 0.5 times as of December 31, 2019 to 1.3 times as of December 31, 2020, primarily attributable to the capitalization of an amount due to a related company.

Our current ratio decreased from 14.3 times as of December 31, 2021 to 10.8 times as of June 30, 2022, primarily attributable to the purchase of the Commodity Linked Fixed Rate Note of US$20.0 million, which was classified as a non-current asset.

Our interest coverage ratio decreased from 6.2 times as of December 31, 2020 to 0.8 times as of December 31, 2021, primarily attributable to our decreased profit before income tax due to fair value loss of convertible redeemable preferred shares, as well as the higher interest expenses due to unwinding of interests on convertible redeemable preferred shares. Our interest coverage ratio decreased from 15.9 times as of December 31, 2019 to 6.2 times as of December 31, 2020, primarily attributable to the increased interest expenses due to an increase in the average bank loan balances.

Our interest coverage ratio increased from 0.8 times as of December 31, 2021 to 7.9 times as of June 30, 2022, primarily attributable to our increased profit before income tax, as well as the decreased interest expenses arising from the unwinding of interests on convertible redeemable preferred shares.

CONTROLLING SHAREHOLDERS

Immediately following the completion of the [**REDACTED**], HART will be interested in approximately [**REDACTED**]% of our issued share capital, without taking into account any Shares which may be allotted and issued under the Share Incentive Schemes. HART is owned as to 55% and 45% by Mr. David CHIEN and Ms. Kwai Ching Denise LAU, respectively. Accordingly, HART, Mr. David CHIEN and Ms. Kwai Ching Denise LAU are a group of Controlling Shareholders of our Company upon [**REDACTED**].

Please refer to the section headed "Relationship with Our Controlling Shareholders" for further details.

OUR PRE-[REDACTED] INVESTORS

In 2021, our Group opened to third party investments and completed two rounds of Pre-[**REDACTED**] Investments, raising US$202.5 million in aggregate from well-known institutional investors and family offices including entities controlled or owned by Shenzhen Capital Group Co., Ltd., China Construction Bank Corporation, CICC Capital Management Co., Ltd. and China Merchants Securities Investment Management (HK) Co., Ltd. For further details of the identity and background of the Pre-[**REDACTED**] Investors, and the principal terms of the Pre-[**REDACTED**] Investments, please refer to the paragraph headed "History, Development and Corporate Structure – Pre-[**REDACTED**] Investments."

IMPACT OF THE COVID-19 OUTBREAK

In order to prevent and control the outbreak of COVID-19, many countries and regions, including the PRC, Japan, Europe and the U.S. where we have operations, introduced various control measures such as restrictions on hospitals from conducting surgeries without immediate needs, traffic control, travel bans, thereby leading to a lower number of PCI/PTA procedures performed. The outbreak of COVID-19 has caused (i) temporary reduction of our sales for our PCI balloon products of approximately 66,000 units in 2020 as compared to the number of units sold in 2019, (ii) temporary suspension of our operations, and shortage of labor and raw materials leading to salary expenses of our production staff of US$1.4 million in connection with the temporary suspension of our production facilities in Shenzhen, the PRC in 2020; and (iii) increasing pressure on operational costs and expenses such as depreciation and utility expenses of US$0.2 million in 2020 due to idled facilities and equipment; (iv) delays in our shipment generally ranging from one to two weeks in 2020 to 2022; and (v) temporary suspension of production in our Shenzhen production facilities for about two weeks in March 2022. In the first half of 2022, the PRC government implemented pandemic control and management measures in certain cities or regions, including Shanghai, in response to the recurrences of COVID-19 during the period, including travel restrictions, mandatory cessations of business operations, etc. Subsequent to the Track Record Period and up to the Latest Practicable Date, there has not been any further suspension of production in our Shenzhen production facilities as a result of the recurrences of COVID-19. The recurrences of COVID-19 in the PRC and other countries and regions did not result in any material adverse impact on the Group's financial performance during the Track Record Period and up to the Latest Practicable Date. Our revenue increased by US$11.6 million from US$57.3 million in the first six months of 2021 to US$68.9 million in the first six months of 2022. Sales volume increased by 16.1% from approximately 678,000 units in the first eight months of 2021 to approximately 787,000 units in the first eight months of 2022.

COVID-19 has caused disruption and volatility in the global capital markets, and has led to an economic slowdown. Nonetheless, the pandemic has not materially affected our liquidity as we maintain sufficient cash reserves. We are constantly monitoring the situations of the COVID-19 outbreak as well as various regulatory and administrative measures adopted by the local governments to prevent and control the epidemics. If the situations deteriorate, we will continue to evaluate the impact from this outbreak on us and may enhance our measures such as to strategically stock up raw materials that are crucial to our production, adjust buffer stock level to manage any potential increase in lead time and dedicate resources to take actions to mitigate any adverse effect on our business operations, results of operations, financial positions and prospects.

[**REDACTED**]

The net [**REDACTED**] from the [**REDACTED**] which our Company will receive, after deducting the [**REDACTED**], the discretionary incentive fee (assuming the full payment of the discretionary incentive fee of [**REDACTED**]% of the aggregate [**REDACTED**] of all the [**REDACTED**] under the [**REDACTED**]) and the estimated expenses in relation to the [**REDACTED**] payable by us, will be approximately HK$[**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] (being the mid-point of the [**REDACTED**]).

Our Company intends to use the net [**REDACTED**], from the [**REDACTED**] for the following purposes:

Percentage and Amount of Net [REDACTED]	**Intended Application**
[**REDACTED**]%, or approximately HK$[**REDACTED**]	For the development and commercialization of our pipeline products
[**REDACTED**]%, or approximately HK$[**REDACTED**]	For expansion of our production capacities
[**REDACTED**]%, or approximately HK$[**REDACTED**]	For potential strategic acquisitions with an aim to expand our product portfolio and strengthen our R&D capabilities
[**REDACTED**]%, or approximately HK$[**REDACTED**]	For working capital and other general corporate purposes

For details, please refer to the section headed "Future Plans and [**REDACTED**]" in this document.

DIVIDENDS AND DIVIDEND POLICY

We retain distributable profits not distributed in a given year and make them available for distribution in subsequent years. We generally do not distribute dividends in a year in which we do not have any distributable profits. Shareholders must also approve the payment of any dividends at a shareholders' general meeting.

Our Board of Directors is responsible for submitting proposals for dividend payments to the shareholders' general meeting for approval. The determination of whether to pay a dividend and in which amount is based on our results of operations, cash flow, financial condition, future business prospects, statutory and regulatory restrictions and other factors that the Board of Directors deems relevant. We have not declared or paid any dividend during the Track Record Period. Any future declarations and payments of dividends will be at the absolute discretion of our Directors. There can be no assurance that we will be able to declare or distribute any dividend in the amount set out in any plan of the Board or at all. Currently, we do not have any dividend policy or intention to declare or pay any dividends in the near future.

[**REDACTED**]

SUMMARY OF MATERIAL RISK FACTORS

Our business faces risks including those set out in the section headed "Risk Factors" in this document. As different investors may have different interpretations and criteria when determining the significance of a risk, you should read the "Risk Factors" section in its entirety before you decide to invest in the [**REDACTED**]. Some of the major risks that we face include:

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

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

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

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

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

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

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

- If we become subject to litigations, legal or contract disputes, government investigations, administrative proceedings or international economic sanctions, it may divert the attention of the management, and incur substantial costs and liabilities.

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

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

[REDACTED] STATISTICS

	Based on an [REDACTED] of HK$[REDACTED] per [REDACTED]	Based on an [REDACTED] of HK$[REDACTED] per [REDACTED]
Market capitalization of our Shares upon completion of the [**REDACTED**][(1)(2)]	HK$[**REDACTED**]	HK$[**REDACTED**]
Unaudited pro forma adjusted consolidated net tangible assets per Share[(3)]	HK$[**REDACTED**] per Share	HK$[**REDACTED**] per Share

Notes:

(1) All statistics in this table are presented after taking into account the Share Consolidation but without taking into account any Shares which may be issued or allotted under the Share Incentive Schemes.

(2) The calculation of market capitalization is based on [**REDACTED**] Shares expected to be in issue and outstanding following the completion of the [**REDACTED**] and the market value of each Share being the [**REDACTED**].

(3) The unaudited pro forma adjusted consolidated net tangible asset per Share is arrived at after making the adjustments referred to in "Appendix II – Unaudited Pro Forma Financial Information" in this document.

IMPACT OF RECENT RUSSO-UKRAINIAN CONFLICT ON OUR BUSINESS ACTIVITIES

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 ("**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. Please refer to the section headed "Business – Our Customers" for further details. 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.

Subsequent to the Track Record Period and up to October 31, 2022, our aggregated sales to Russian Federation was approximately US$32,000, and we did not make any sales to Ukraine and Belarus. During the same period, we did not have any supplier in Russia, Ukraine or Belarus. As of October 31, 2022, we did not have any accounts receivable from the distributors in Russia Federation, Ukraine and Belarus and we believe that the recent Russo-Ukrainian conflict would not have a material adverse impact on the Group's financial performance in 2022.

RECENT DEVELOPMENT AND NO MATERIAL ADVERSE CHANGE

Our business continued to expand subsequent to the Track Record Period. Our revenue increased in the first nine months of 2022 as compared to the same period of 2021, primarily due to the increase of sales volume in the U.S., Japan and the PRC markets as a result of the introduction of our scoring balloons such as Scoreflex NC series, Scoreflex Trio series and Scoreflex series in these markets. Sales volume increased by 16.1% from approximately 756,000 units in the first nine months of 2021 to approximately 897,000 units in the first nine months of 2022.

Our Directors confirm that, there has been no material adverse change in our operational and financial position since June 30, 2022 (being the date of the latest audited consolidated balance sheets of our Group as set out in the Accountant's Report in Appendix I to this document) and up to the date of this document.

LEGAL COMPLIANCE AND PROCEEDINGS

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 adverse effect on our business, financial condition or results of operations, and we 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.

We consider the following incident immaterial or do not constitute material or systematic non-compliances. On June 3, 2021, OIBV, one of our Material Subsidiaries incorporated in the Netherlands, accepted an out-of-court settlement agreement offered by the Dutch Public Prosecution Service in relation to a criminal investigation conducted by the Fiscal Intelligence and Investigation Service of the Netherlands and the Dutch Public Prosecution Service, which relates to certain unusual transactions regarding a suspicion of OIBV having given gifts to certain Belgian cardiologists between 2011 and 2015, by which OIBV allegedly gained a more favorable position concerning the supply of medical products to six hospitals in Belgium where those cardiologists worked. Please refer to the section headed "Business – Legal Compliance and Proceedings" in the document for further details.

In this document, the following expressions shall have the meanings set out below unless the context otherwise requires.

"affiliate(s)"	means any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
"AFRC"	Accounting and Financial Reporting Council
"APAC"	means the 17 countries/regions out of the 21 members of the Asia-Pacific Economic Cooperation (APEC) excluding the PRC, Japan, Russia and the United States
"Articles" or "Articles of Association"	our amended and restated articles of association, as conditionally adopted on [●] and with effect from the [**REDACTED**] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix III to this document
"associate(s)"	has the meaning ascribed thereto under the Listing Rules
"Board" or "Board of Directors"	our board of Directors
"Business Day"	a day on which banks in Hong Kong are generally open for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong
"BVI"	the British Virgin Islands
"CAGR"	compound annual growth rate
	[**REDACTED**]
"Cayman Companies Act"	the *Companies Act, Cap. 22* (Act 3 of 1961, as consolidated and revised) of the Cayman Islands, as amended or supplemented or otherwise modified from time to time
"CCASS"	the Central Clearing and Settlement System established and operated by HKSCC
"CCASS Clearing Participant"	a person admitted to participate in CCASS as a direct clearing participant or general clearing participant
"CCASS Custodian Participant"	a person admitted to participate in CCASS as a custodian participant

[**REDACTED**]

"CCASS Investor Participant"	a person admitted to participate in CCASS as an investor participant, which may be an individual, joint individuals or a corporation
"CCASS Operational Procedures"	the Operational Procedures of HKSCC in relation to CCASS, containing the practices, procedures and administrative requirements relating to operations and functions of CCASS, as from time to time in force
"CCASS Participant"	a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant
"CE Mark"	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
"CIC" or "Industry Consultant"	China Insights Industry Consultancy Limited
"CIC Report"	an independent report prepared and issued by CIC with respect to this [**REDACTED**]
"close associate(s)"	has the meaning ascribed thereto under the Listing Rules
"Companies Ordinance"	the Companies Ordinance, Chapter 622 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)

"Companies (Winding Up and Miscellaneous Provisions) Ordinance"	the Companies (Winding Up and Miscellaneous Provisions) Ordinance, Chapter 32 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
"Company" or "our Company"	OrbusNeich Medical Group Holdings Limited (業聚醫療集團控股有限公司), an exempted company incorporated in the Cayman Islands on July 22, 2021
"connected person(s)"	has the meaning ascribed thereto under the Listing Rules
"Controlling Shareholders"	has the meaning ascribed thereto under the Listing Rules and in this context, refers to a group consisting of HART, Mr. David CHIEN and Ms. Kwai Ching Denise LAU
"core connected person(s)"	has the meaning ascribed thereto under the Listing Rules
"COSMIC"	Cosmic Ascent Limited, a company incorporated in the BVI on July 7, 2020, a directly wholly-owned subsidiary of our Company as of the date of this document
"Director(s)"	the director(s) of our Company or any one of them
"EAR"	Export Administration Regulations of the United States
"EMEA"	Europe, Middle East and Africa
"EUR"	Euros, the lawful currency of the member states of the Eurozone
"Extreme Conditions"	any extreme conditions or events, the occurrence of which will cause interruption to the ordinary course of business operations in Hong Kong and/or that may affect the [**REDACTED**]
"FDA"	the Food and Drug Administration of the United States
"First Share Swap"	the share swap between the Company and COSMIC, the details of which are set out in the paragraph headed "History, Development and Corporate Structure – Reorganization – Step 1: Share Swap between our Company and COSMIC" in this document
"General Rules of CCASS"	General Rules of CCASS published by the Stock Exchange and as amended from time to time

[**REDACTED**]

"Group", "our Group", "our", "we", or "us"	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
"HART"	Harmony Tree Limited, a company incorporated in the BVI on September 11, 2020 and one of our Controlling Shareholders
"HKFRS"	Hong Kong Financial Reporting Standards
"HKSCC"	the Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
"HKSCC Nominees"	HKSCC Nominees Limited, a wholly owned subsidiary of the HKSCC
"Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China
"Hong Kong dollars" or "HK dollars" or "HK$"	Hong Kong dollars, the lawful currency of Hong Kong

[**REDACTED**]

"Hong Kong Stock Exchange" or "Stock Exchange"	The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited
	[**REDACTED**]
"Independent Third Party" or "Independent Third Parties"	a person or entity who is not a connected person of the Company under the Listing Rules
"Initial COSMIC Shareholders"	a group of eight individuals (including Ching Chung John CHOW, our executive Director, Robert John COTTONE JR, our chief technical officer and Ms. Pik Lin Barbara WONG, a former employee of our Group) and their holding entity
	[**REDACTED**]
"International Sanctions"	all applicable laws and regulations relating to economic sanctions, export controls, trade embargoes and wider prohibitions and restrictions on international trade and investment related activities, including those adopted, administered and enforced by the U.S. government, the European Union and its member states, the United Kingdom, the United Nations or the government of Australia
"International Sanctions Legal Advisors"	Herbert Smith Freehills, our legal advisors as to International Sanctions laws in connection with the [**REDACTED**]

[**REDACTED**]

"Joint Sponsors"	the joint sponsors of the [**REDACTED**], being China International Capital Corporation Hong Kong Securities Limited and CCB International Capital Limited
"JPY"	Japanese Yen, the lawful currency of Japan
"Latest Practicable Date"	November 16, 2022, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

[**REDACTED**]

"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)
"Macau"	the Macau Special Administrative Region of the People's Republic of China

"Main Board"	the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange
"Mainland China" or "PRC"	the People's Republic of China excluding, for the purposes of this document and geographical reference only and except where the context requires otherwise, Hong Kong, Macau and Taiwan
"Memorandum" or "Memorandum of Association"	the amended and restated memorandum of association of our Company as conditionally adopted on [●] 2022 with effect from the [**REDACTED**] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix III to this document
"NB"	a third-party auditing organization recognized in the EU that assesses quality and conformity of medical devices
"NLG"	Dutch Guilder
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局) (formerly known as the China National Drug Administration and the China Food and Drug Administration)
"OFAC"	The U.S. Department of Treasury's Office of Foreign Assets Control

[**REDACTED**]

"OIBV"	Orbus International B.V., a company incorporated with limited liability in the Netherlands on March 10, 1999, an indirect wholly-owned subsidiary of our Company

"ON GmBH"	OrbusNeich Medical GmbH, a company incorporated with limited liability in Germany on December 7, 2007, an indirect wholly-owned subsidiary of our Company
"ON P&F"	OrbusNeich P+F Company Limited, a company incorporated in the BVI on May 15, 2017, a subsidiary indirectly owned as to 50% by the Company
"ON P&F (HK)"	OrbusNeich P&F (Hong Kong) Company Limited (業聚培福(香港)有限公司), a company incorporated in Hong Kong on June 9, 2017, a subsidiary indirectly owned as to 50% by the Company
"ONM BV"	OrbusNeich Medical B.V., a company incorporated with limited liability in the Netherlands on July 13, 2006, an indirect wholly-owned subsidiary of our Company
"ONM BVI"	OrbusNeich Medical Company Limited, a company incorporated in the BVI on January 5, 2000, formerly known as Multi-Well Development Limited and Neich Medical Company Limited
"ONM Group Ltd."	OrbusNeich Medical Group Limited (業聚醫療集團有限公司), an exempted company incorporated in the Cayman Islands on June 8, 2017, formerly known as Top Charter Investments Limited and OrbusNeich Medical Group Limited (祥豐醫療集團有限公司), an indirect wholly-owned subsidiary of our Company
"ONM HK"	OrbusNeich Medical Company Limited (業聚醫療有限公司), a limited liability company incorporated in Hong Kong on February 23, 1998, an indirect wholly-owned subsidiary of our Company
"ONM Investment Holdings"	OrbusNeich Medical Investment Holdings Limited, a company incorporated in BVI on May 15, 2017, an indirect wholly-owned subsidiary of our Company
"ONM Japan"	OrbusNeich Medical K.K., a limited liability company incorporated in Japan on September 13, 2001, an indirect wholly-owned subsidiary of our Company
"ONM Manu Hold's (APAC)"	OrbusNeich Medical Manufacturing Holdings (APAC) Company Limited, a company incorporated in the BVI on May 15, 2017, an indirect wholly-owned subsidiary of our Company

"ONM Shenzhen"	OrbusNeich Medical (Shenzhen) Company Limited* (業聚醫療器械(深圳)有限公司), a limited liability company incorporated in the PRC on May 29, 2000, an indirect wholly-owned subsidiary of our Company
"ONM Singapore"	OrbusNeich Medical Pte. Ltd., a company incorporated in Singapore on August 15, 1995 under its former name Neich Medical (Singapore) Pte Ltd., an indirect wholly-owned subsidiary of our Company
"Ordinary Shares"	the ordinary shares of our Company, with par value of US$0.0001 each prior to the Share Consolidation and par value of US$0.0005 subsequent to the Share Consolidation
	[**REDACTED**]
"PMDA"	the Pharmaceuticals and Medical Devices Agency under Japan Ministry of Health, Labor and Welfare
"Post-[**REDACTED**] Share Option Scheme"	the share option scheme [conditionally adopted] by our Company on [●] for the benefit of any director, employee, advisor and consultant, of our Company or any of our subsidiaries, a summary of the principal terms is set forth in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 2. Post-[**REDACTED**] Share Option Scheme" in Appendix IV to this document
"Pre-[**REDACTED**] Investment(s)"	the pre-[**REDACTED**] investment(s) in our Company, details of which are set out in the section headed "History, Development and Corporate Structure – Pre-[**REDACTED**] Investments"
"Pre-[**REDACTED**] Investor(s)"	the investor(s) of Pre-[**REDACTED**] Investments

"Pre-[**REDACTED**] Share Option Scheme"	the share option scheme approved and adopted by ONM Group Ltd. on December 18, 2020 and assigned to our Company on September 21, 2021 for the benefit of any director, employee, advisor and consultant, of our Company or any of our subsidiaries, a summary of the principal terms is set forth in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document
"Preferred Share(s)"	the Series A Preferred Shares and Series A-2 Preferred Shares

[**REDACTED**]

"Primary Sanctioned Activity"	any activities in a Sanctioned Country or (1) with; or (2) directly or indirectly benefiting or involving the property or interests in property of, a Sanctioned Party by the Company incorporated or located in a Relevant Jurisdiction or which otherwise has a nexus with such jurisdiction with respect to the relevant activity, such that it is subject to the relevant sanctions law and regulation
"Regulation S"	Regulation S under the U.S. Securities Act
"Relevant Jurisdiction"	any jurisdiction that is relevant to the Company and has sanctions related law or regulation restricting, among other things, its nationals and/or entities which are incorporated or located in that jurisdiction from directly or indirectly making assets or services available to or otherwise dealing in assets of certain countries, governments, persons or entities targeted by such law or regulation
"Relevant Regions"	Iran, Syria, Russian Federation, Ukraine, Egypt, Lebanon, Myanmar, Belarus, Serbia and Tunisia

"Reorganization"	the reorganization of corporate structure of our Group in preparation for the [**REDACTED**], details of which are set out in the paragraph headed "History, Development and Corporate Structure – Reorganization" in this document
"RMB" or "Renminbi"	Renminbi, the lawful currency of the PRC
"Sanctioned Country"	the following countries subject to a general and comprehensive export, import, financial or investment embargo under sanctions related law or regulation of the U.S, EU, UK or Australia: Cuba, Iran, North Korea, Sudan, and Syria, the Crimea region of Ukraine and the Donetsk and Luhansk People's Republics
"Sanctioned Party"	(i) any individual or entity domiciled in, organized under the laws of or which has its headquarters or principal place of business in a Sanctioned Country, (ii) any official or entity of the government of a Sanctioned Country, or otherwise owned or controlled by the government of a Sanctioned Country, (iii) any individual or entity designated on the OFAC SDN List or SSI List, (iv) any individual or entity designated or targeted under any economic or financial sanctions administered by Australia, the European Union, the United Kingdom, or the United Nations, and (v) any entity that is, directly or indirectly, owned 50% or more or is otherwise controlled by one or more persons or entities described in (iii) or (iv) above
"Second Share Swap"	the share swap between the Company and ONM Group Ltd., the details of which are set out in the paragraph headed "History, Development and Corporate Structure – Reorganization – Step 2: Share Swap between our Company and ONM Group Ltd." in this document
"Secondary Sanctionable Activity"	activity by the Company that may result in the imposition of sanctions against the Relevant Person(s) by a Relevant Jurisdiction (including designation as a Sanctioned Party or the imposition of penalties), even though the Company is not incorporated or located in that Relevant Jurisdiction and does not otherwise have any nexus with that Relevant Jurisdiction

"Sectoral Sanctions Identifications List" or "SSI List"	the list of Sectoral Sanctions Identifications maintained by OFAC, which sets forth entities designated by OFAC in Russia's energy, financial and/or defence sectors that are subject to more limited, sectoral, sanctions imposed under one or more OFAC Directives that prohibit certain (but not all) dealing with U.S. persons or within the United States
"Series A Preferred Shares"	the series A preferred shares of our Company, with par value of US$0.0005 each subsequent to the Share Consolidation
"Series A-2 Preferred Shares"	the series A-2 preferred shares of our Company, with par value of US$0.0005 each subsequent to the Share Consolidation
"SFC"	the Securities and Futures Commission of Hong Kong
"SFO"	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
"Share(s)"	ordinary share(s) in the capital of our Company with a nominal value of US$0.0001 each
"Share Consolidation"	the consolidation of every five shares with par value of US$0.0001 each in the Company's issued and unissued share capital into one share of the corresponding class with par value of US$0.0005 each, the details of which are set out in the paragraph headed "Statutory and General Information – A. Further Information about Our Group – 4. Resolutions of the Shareholders of the Company Passed on [●]"
"Share Incentive Schemes"	the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme
"Shareholder(s)"	holder(s) of the Share(s)
"Specially Designated Nationals and Blocked Persons List" or "SDN List"	the list of Specially Designated Nationals, and Blocked Persons maintained by OFAC, which sets forth individuals and entities that are subject to its sanctions and restricted from dealings with U.S. persons
"subsidiary" or "subsidiaries"	has the meaning ascribed thereto under the Listing Rules

"substantial shareholder(s)"	has the meaning ascribed thereto under the Listing Rules
"Takeovers Code"	the Code on Takeovers and Mergers and Share Buy-backs, as published by the SFC (as amended, supplemented or otherwise modified from time to time)
"Track Record Period"	[the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022]

[**REDACTED**]

"United States" or "U.S."	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"U.S. dollars", "US$" or "USD"	United States dollars, the lawful currency of the United States
"U.S. Persons"	any of the following individual, group or entity (company, partnership, limited liability company or any other organisation): (a) a U.S. citizen or a permanent resident alien (so called "Green Card" holder) wherever located or employed in the world, (b) an entity established under U.S. law, including its foreign branches, and (c) any person physically in the United States
"U.S. Securities Act"	the United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder

[**REDACTED**]

"%"	percent

In this document, the terms "associate", "close associate", "connected person", "core connected person", "connected transaction", "subsidiaries" and "substantial shareholder" shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

Certain amounts and percentage figures included in this document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

For ease of reference, the names of the PRC established companies or entities, laws or regulations have been included in this document in both the Chinese and English languages; in the event of any inconsistency, the Chinese versions shall prevail.

* *For identification purpose only*

GLOSSARY

"active pharmaceutical ingredient" or "API"	active pharmaceutical ingredient, the substance in a pharmaceutical drug that is biologically active
"aneurysm embolization"	aneurysm is the enlargement of an artery caused by weakness in the arterial wall, and at risk of rupture. In aneurysm embolization procedure, physicians use image guidance to place small, soft metal coils within the aneurysm, where it helps block the flow of blood and prevent rupture of the aneurysm
"anti-restenotic"	prevention of the re-narrowing (restenotic) of blood vessels
"anti-thrombotic"	prevention of blood clot formation (thrombus)
"anticoagulants"	a medicine that helps prevent blood clots and to reduce risk of strokes and heart attacks due to formation of clots
"aortic regurgitation"	a condition where the heart aortic valve is not able to close completely, causing a backflow of blood from the aorta into the left ventricle
"aortic stenosis"	the narrowing of aortic valve opening, restricting blood flow from left ventricle to the aorta
"aorto-(bi)femoral bypass"	a surgery to redirect blood around narrowed or blocked vessels in the belly or groin, to increase blood flow to the legs
"arteriovenous fistula"	an irregular connection between an artery and a vein
"aspiration thrombectomy"	a catheter that is used for removal of thrombus/blood clots from blood vessel via suction
"atherosclerosis"	the buildup of fatty material/plaque inside the blood vessel, causing it to be narrowed and hence limiting the blood flow
"ATM"	the standard atmosphere, a unit of pressure
"balloon angioplasty/stent"	a catheter procedure to restore blood flow of a blocked arteries by using a balloon or a stent
"balloon rewrap"	to wrap again the balloon that has been inflated so that profile of the balloon is good for re-crossing

GLOSSARY

"bare metal stent"	a stent with delivery system but without any drug, polymer, or antibody coating on it
"beta-blocker"	a class of medications that are predominantly used to manage abnormal heart rhythms, treat chest pain and reduce high blood pressure
"carotid artery stents"	a procedure to implant a stent in the narrowed carotid artery to open it up to improve blood flow and prevent risk of stroke
"chronic total occlusion" or "CTO"	100% occlusion of a coronary artery for a duration of at least three months based on angiographic evidence
"compliant balloon"	balloon of which diameter increases as the inflation pressure increases, which usually have lower nominal and rated burst pressure compared to non-compliant balloon
"coronary artery atherosclerosis"	a disease in which the plaque/fatty material builds up inside the coronary arteries
"coronary artery bypass grafting", or "CABG"	a surgical procedure that diverts/bypass blood around the narrowed/blockage of blood vessels to improve blood flow and oxygen supply to the heart by grafting a blood vessel between the aorta and a point along the coronary artery, past the narrowed area
"coronary artery dissection"	a tear in the blood vessel of the heart
"coronary artery patency"	heart vessel being open or unobstructed
"coronary artery spasm"	a temporary tightening (constriction) of the muscles in the wall of one of the arteries that send blood to the heart. A spasm can decrease or completely block blood flow to part of the heart
"critical limb ischaemia" or "CLI"	severe blockage in the arteries of the lower extremities, which markedly reduces blood flow. It is a serious form of peripheral arterial disease
"crossability"	the ability of a catheter to cross a lesion in a vessel that has been narrowed or occluded

GLOSSARY

"CTO balloon"	balloon catheter specifically designed for crossing a totally blocked vessel (CTO-chronic total occlusion)
"DAPT"	dual antiplatelet therapy, usually combination of aspirin with one of the following ADP/PZY inhibitors, clopidogrel or prasugrel or ticagrelor, which is typically prescribed after percutaneous coronary intervention
"diuretics"	also known as water pills, which help rid the body of salt and water
"drug-coated balloon"	balloon catheter coated with anti-proliferative medicine to reduce re-narrowing of the blood vessel and hence reduce repeat procedure for the patient
"drug eluting balloon"	conventional semi-compliant angioplasty balloons covered with drug which is released into the vessel wall during inflation of the balloon, usually at nominal pressures with a specific minimal inflation time
"drug-eluting stents"	a stent with delivery system and usually with polymer or well to hold anti proliferative drug
"ECMO"	extracorporeal membrane oxygenation, is a machine to provide prolonged cardiac and respiratory support to a person whose heart and lungs are unable to provide an adequate amount of gas exchange or perfusion to sustain life
"endothelial progenitor cells" or "EPC"	EPCs are thought to originate from bone marrow, mobilize in response to ischemia, and home to sites of vascular injury. EPCs are believed to promote vascular regeneration
"EU Emissions Allowances"	allowances or credits in the EU Emissions Trading System which allow the holders of such allowances or credits to emit greenhouse gas emissions
"extra-anatomical bypass"	an arterial bypass that does not follow the normal anatomic pathway
"general anesthetic (GA)"	a state of controlled unconsciousness. During GA, medicine is used to put patient to sleep, so, patient do not move or feel pain during the procedure

"hydrophilic coating"	a coating that is being used to reduce surface friction and enhance lubricity. Hydrophilic means that it has an affinity for water (water loving)
"hypotube shaft"	a long metal tube with micro-engineered features along its length
"intracranial stenosis"	a narrowing of an artery in the brain
"intravenous thrombolysis", or "IVT"	an injection of clot-busting drugs through an intravenous line to dissolve blood clots that have blocked blood vessels and pose serious life or life threatening implications
"ischemia"	an inadequate supply of blood to an organ or part of the body that is due to narrowing of a blood vessel
"ischemic heart diseases", or "IHDs"	a condition of recurring chest pain or discomfort that occurs due to narrowed heart arteries
"ischemic stroke"	a condition occurs when a blood clot blocks or narrows an artery leading to the brain
"ISO 13485:2016"	a quality standard established by the International Organization for Standardization which specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements
"LDL cholesterol"	low density lipoprotein cholesterol. When LDL is high, it caused deposition in the walls of blood vessels caused it to be narrowed and reducing blood flow
"lesion"	a term used for plaque buildup in the wall of the arteries
"lumen"	an opening -can refer to the central space in an artery, vein or capillary. It can also refer to the channel within a catheter or tubing
"mitral regurgitation"	a condition where the heart mitral valve is leaky. The mitral valve does not close completely, causing a backflow of blood from the left ventricle into the left atrium

GLOSSARY

"mitral stenosis"	the narrowing of the heart's mitral valve. The valve doesn't open properly, obstructing the blood flow into the left ventricle.
"myocardial infarction"	MI or heart attack. MI happens when one or more areas of the heart muscle don't get enough oxygen due to narrowed coronary arteries
"NAI"	no action indicator, which means no observations are found during the onsite inspection of factories by the FDA
"non-compliant balloon"	balloon with very little growth in diameter versus the pressure increase, and a higher nominal and rated burst pressure as compared to a compliant balloon
"over-the-wire"	a type of catheter design where the entire length of the catheter traverses over a guidewire to access the desired anatomy
"paclitaxel particle abscission"	a process of removal/separation of paclitaxel particle
"paclitaxel-carrying balloons"	a balloon that is coated with paclitaxel drug
"Paris Course for Revascularization" or "PCR"	a renowned medical device conference with the objectives of sharing knowledge, experience and practice in cardiovascular interventional medicine
"percutaneous coronary intervention" or "PCI"	a minimally invasive procedure to open narrowed coronary arteries to restore blood to the heart
"percutaneous pulmonary valve implantation" or "PPVI"	a minimally invasive procedure to replace a pulmonary valve via catheterization through a vein
"percutaneous transluminal angioplasty" or "PTA"	a minimally invasive procedure to open a blocked blood vessel using a balloon catheter to restore the blood flow
"peripheral vascular intervention"	a minimally invasive procedure used to treat peripheral (outside of heart) artery disease
"PMA"	premarket approval, issued to Class III medical devices which have a large impact on human health and as such, their evaluation undergo more thorough scientific and regulatory processes to determine their safety and effectiveness

"post stent dilatation"	a balloon is dilated inside the stent to further open the stent area post stent deployment
"pre-dilatation balloon catheter"	balloons that are used to open the narrowed blood vessel to allow stent to cross and be deployed
"pro-healing"	the promotion of the restoration of a complete and functional endothelial cellular layer which lines inside the heart and blood vessels
"rated burst pressure"	the operating pressure where a balloon catheter has been shown to operate repeatably and reliably
"resistant lesion"	a lesion that requires high pressure balloon dilatation and sometimes cannot be opened up using a normal balloon catheter but require other device like scoring balloon or atherectomy
"restenosis"	a renarrowing of the blood vessel
"sirolimus"	a macrolide compound used to coat coronary stents to prevent renarrowing of the stented vessel
"smooth muscle cells (SMC) proliferation"	rapid increase of SMC
"scoring balloon"	a balloon catheter with scoring wire to help to crack the plaque via controlled manner
"standard balloon"	a balloon catheter that is used for dilating a narrowed blood vessel
"stenosis"	a term used when the plaque buildup caused narrowing or blockage of the arteries
"thrombectomy"	a procedure of removing a blood clot from arteries or veins. It can be surgical or minimally invasive procedure
"thrombus"	a blood clot
"trackability"	the ability of a catheter to track along the vessel that not always straight but has some tortuosity
"transcatheter aortic valve replacement", or "TAVR"	a minimally invasive procedure using a catheter-based technique to replace the diseased aortic valve with a new aortic valve

GLOSSARY

"transcatheter cardiovascular therapeutics", or "TCT"	TCT is organized by Cardiovascular Research Foundation (CRF) and one of the world largest cardiovascular educational conference for physicians and industry held in USA
"transcatheter edge-to-edge mitral valve repair", or "TEER"	TEER is a minimally invasive procedure that treats severe leakage of the mitral valve in patients deemed to be at prohibitive risk by a heart team
"transcatheter intervention"	a minimally invasive procedure that is catheter-based
"transcatheter mitral valve implantation", or "TMVI"	a minimally invasive procedure using a catheter-based technique to replace the diseased mitral valve with a new mitral valve
"tricuspid regurgitation"	a condition where the tricuspid valve is not able to close completely, causing a backflow of blood from the right ventricle to the right atrium
"tricuspid stenosis"	a narrowing of the tricuspid valve opening that slows blood flow from the right atrium to the right ventricle
"TricValve" or "TricValve Bicaval System"	TricValve is a bicaval transcatheter tricuspid valve implantation system, which includes the transcatheter bicaval valve for superior vena cava and the transcatheter bicaval valve for inferior vena cava. The TricValve transcatheter bicaval valves are already pre-mounted into the delivery system
"valvular heart disease"	a category of diseases where any valve in the heart is narrowed or does not close properly
"vasodilators"	medications that promotes the dilatation of blood vessels, so blood flows easily through the blood vessels
"ventricular abnormalities"	ventricular abnormalities or ventricular arrhythmias are abnormal heartbeats that originates in the lower heart chambers (the ventricles), cause the heart to beat too fast, which prevent oxygen rich blood from circulating to the brain and body and may result in cardiac arrest
"Zero Observation" or "No Action Indicated"	meaning no objectionable conditions or practices were found during an inspection by the U.S. FDA (or the significance of the documented objectionable conditions found does not justify further action)

FORWARD-LOOKING STATEMENTS CONTAINED IN THIS DOCUMENT ARE SUBJECT TO RISKS AND UNCERTAINTIES

This document contains forward-looking statements relating to our plans, objectives, expectations and intentions, which may not represent our overall performance for the periods of time to which such statements relate. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing the Company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our operations and business prospects;
- our ability to maintain relationship with, and the actions and developments affecting, our major customers and suppliers;
- future developments, trends and conditions in the industries and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- changes to the regulatory environment in the industries and markets in which we operate;
- our ability to maintain the market positions;
- our pipeline products under development or planning;
- the actions and developments of our competitors;
- our ability to effectively contain costs and offer competitive prices;
- the ability of third parties to perform in accordance with contractual terms and specifications;
- our ability to retain senior management and key personnel, and recruit qualified staff;
- our business strategies and plans to achieve these strategies, including our expansion plans;

- our ability to defend our intellectual rights and protect confidentiality;
- change or volatility in interest rates, foreign exchange rates, equity prices, trading volumes, commodity prices and overall market trends;
- capital market developments; and
- our dividend policy.

In some cases, we use the words "aim," "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "going forward," "intend," "ought to," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and similar expressions to identify forward-looking statements. In particular, we use these forward-looking statements in the "Business" and "Financial Information" sections of this document in relation to future events, our future financial, business or other performance and development, the future development of our industry and the future development of the general economy of our key markets.

These forward-looking statements are based on current plans and estimates, and speak only as of the date they were made. We undertake no obligation to update or revise any forward-looking statements in light of new information, future events or otherwise. Forward-looking statements involve inherent risks and uncertainties and are subject to assumptions, some of which are beyond our control. We caution you that a number of important factors could cause actual outcomes to differ, or to differ materially, from those expressed in any forward-looking statements.

Our Directors confirm that the forward-looking statements are made after reasonable care and due consideration. Nonetheless, due to the risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect, or at all.

Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

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

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

RISKS RELATING TO OUR EXISTING AND PIPELINE PRODUCTS

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

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

Continued market acceptance and demand for our endovascular interventional medical device products will be critical to our success. If we are unable to manufacture or sell these products due to commercial, regulatory, intellectual property or any other reasons, or if demand for these products is reduced, our revenue would significantly decline, and our business, financial condition and results of operations would be materially and adversely affected.

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

Our current and future products may cause undesirable or unintended severe adverse events as a result of a number of factors, many of which are outside of our control. These factors include potential complications not revealed in clinical trials, unusual but severe complications and adverse events in isolated cases, defective products not detected by our quality control policies and system or misuse of our products. Our products may also be perceived to cause adverse events when a conclusive determination as to the cause of the adverse events is not obtained or is unobtainable.

In addition, our products may be perceived to cause severe adverse events if one or more regulators, such as the NMPA, FDA, PMDA or NB, determine that other companies' products containing the same or similar key parts or using the same delivery technologies as our products' cause or are perceived to have caused severe adverse events. If our products cause, or are perceived to cause, severe adverse events, we may face a number of consequences, including:

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

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

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

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

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

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

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

We intend to spend approximately HK$[**REDACTED**] of the [**REDACTED**] from this [**REDACTED**] to continue to enhance our technical capabilities in research, development and manufacturing of our pipeline products, which require substantial technical, financial and human resources. We may not have the financial resources necessary to fund all of these projects. In addition, we cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so could harm our business prospects.

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

Medical devices are classified according to a catalogue into different categories by NMPA, FDA, PMDA and NB, depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. As of the June 30, 2022, we had a robust product pipeline consisting around 40 products in various development stages, some of which are Class III medical devices. To obtain product registrations for medical devices of Class III, we may need to conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate the safety and efficacy of our products.

Clinical trials may involve lengthy and expensive process with uncertain outcomes. A failure of one or more of our clinical trials can occur at any stage of testing and clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. In addition, there can be significant variability in safety and/or efficacy results between different trials of the same pipeline products due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations and the rate of dropout among clinical trial participants.

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

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

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

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

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

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

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

- we might have to suspend, delay or terminate clinical trials of our pipeline products for various reasons, including a finding of lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks or reasons outside of our control, such as occurrences of epidemics like the outbreak of COVID-19;

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

- the cost of clinical trials of our pipeline products may be greater than anticipated; and

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

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

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

- the size and nature of the patient population;

- the patient eligibility criteria defined in the protocol;

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

- the proximity of patients to trial sites;

- the design of the trial;

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

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

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

Our clinical trials will likely compete with other clinical trials for pipeline products that are in the same therapeutic areas as our pipeline products. This competition will reduce the number and types of patients available to us as some patients who might have opted to enroll in a trial being conducted by one of our competitors instead of ours. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development and timely commercialization of our pipeline products.

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

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

We cannot assure you that we will be able to maintain or strengthen our relationships with these industry participants, or that our efforts to maintain or strengthen such relationships will yield the successful development of new products or increased sales. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our research and development process, may be inaccurate and lead us to develop products that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Moreover, we cannot assure you that our marketing strategies will continue to be effective. Industry participants, particularly in the specialties of endovascular intervention area, may no longer want to collaborate with us, and our marketing strategy may no longer be able to yield larger hospital coverage or increased sales commensurate to our efforts spent. In addition, the key opinion leaders, physicians and hospitals that we focus on may not continue to have a significant demand for our products. If we are unable to develop new products or generate returns from our relationships with industry participants as anticipated, or at all, our business prospects, financial condition and results of operations may be materially and adversely affected.

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

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

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

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

RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATIONS

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

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

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

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

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

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

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

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

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

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

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

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

For example, in the PRC, some provinces have implemented the "Two-Invoice System" in the field of medical consumables in order to reduce the circulation of high-value medical consumables and promote the transparency of purchase and sales. For further details, please refer to the paragraph headed "Regulatory Overview – PRC Regulatory Overview – Laws and Regulations Relating to Medical Devices Administration – Two-Invoice System" in this document. As the interpretation and enforcement of the "Two-Invoice System" in the medical device industry are evolving and subject to uncertainty, we cannot predict how the implementation and enforcement will evolve in different provinces in the PRC, or whether and how that will affect our business prospects and results of operations in the future.

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

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

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

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to institutional review boards or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

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

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

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

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

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

- regulatory authorities may withdraw approvals of the product;

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

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

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

Even after our products are approved, they will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities. For example, manufacturers and manufacturers' facilities are required to comply with extensive regulatory requirements from the NMPA and/or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA, FDA, PMDA, NB or other authorities.

The NMPA, FDA, PMDA, NB or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if problems occur after the product reaches the market. Later discovery of previously unknown problems with our existing and pipeline products or with our manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

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

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

The policies of the NMPA, FDA, PMDA, NB and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our pipeline products. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in the markets in which our products are sold, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

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

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

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

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

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

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

In addition, the regulatory frameworks for the medical device industry in countries where we have operations are constantly evolving, and we expect they will continue to evolve. For example, the healthcare regulatory framework in the PRC has undergone significant changes in recent years, in particular with respect to quality control, supply, pricing and tender process for medical devices. We cannot predict the likelihood, nature or extent of regulatory changes that may arise from existing or future legislation in the PRC, the United States, the European Union, Japan and other countries or regions. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional permits, licenses or certificates. There is no assurance that we will respond successfully and timely to such changes. Such changes may also result in increased compliance costs or prevent our successful development, manufacture or commercialization of products in the PRC and other countries or regions in the abovesaid jurisdictions, which would adversely affect our business prospects, financial condition and results of operations.

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

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

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

RISKS RELATING TO OUR BUSINESS AND OPERATIONS

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

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

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

- greater financial and other resources;

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

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

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

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

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

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

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

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

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

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

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

- the assumption of additional indebtedness or contingents;

- the issuance of our equity securities;

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

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

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

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

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

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

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

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

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

might relinquish some or all of the control over the future success of that pipeline product to the third party. For any pipeline products that we may seek to in-license from third parties, we may face significant competition from other medical device companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

Further, collaborations involving our existing and pipeline products are subject to numerous risks, which may include the following:

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

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

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

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

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

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

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

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

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

As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships or the license of our third-party products if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a pipeline product, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our pipeline products or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

stainless steel, polyester, nylon or other raw materials may be affected by a number of factors, including market supply and demand, the international environmental and regulatory requirements, natural disasters such as fires, outbreak of epidemics or diseases and the global economic conditions. A significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins and, more generally, our business prospects, financial condition and results of operations.

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

If we become subject to litigations, legal or contract disputes, government investigations, administrative proceedings or international economic sanctions, it may divert the attention of the management, and incur substantial costs and liabilities.

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. On June 3, 2021, OIBV, one of our Material Subsidiaries incorporated in the Netherlands, accepted an out-of-court settlement agreement offered by the Dutch Public Prosecution Service in relation to a criminal investigation conducted by the Fiscal Intelligence and Investigation Service of the Netherlands and the Dutch Public Prosecution Service, which relates to certain unusual transactions regarding a suspicion of OIBV having given gifts to certain Belgian cardiologists between 2011 and 2015, by which OIBV allegedly gained a more favorable position concerning the supply of medical products to six hospitals in Belgium where those cardiologists worked. Please refer to section headed "Business — Legal Compliance and Proceedings" in the document for further details. As of the Latest Practicable Date, we were not involved in any litigations and legal proceedings that may materially affect our research and development of our pipeline products, business prospects and results of operations. On-going or threatened litigation, legal or contractual disputes, government investigations, administrative proceedings or international economic sanctions may divert our management's attention and consume their time and our other resources. In addition, any similar claims, disputes or legal proceedings involving us or our employees may result in damages or liabilities, as well as legal and other costs and may cause a distraction to our management. Furthermore, any litigation, legal or contractual disputes, government investigations, administrative proceedings or international economic sanctions which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss,

the monetary amount at stake and the parties involved. If any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. Consequently, our business prospects, financial condition and results of operations may be materially and adversely affected.

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

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

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

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

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

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

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

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

Furthermore, external parties may attempt to penetrate our systems or those of our vendors or deceptively induce our personnel or personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. The number and complexity of these threats will continue to increase over time. If there is a serious intrusion into our or our vendors' information technology systems, the market's perception of the effectiveness of our security measures could be damaged, and our reputation and credibility could be damaged. We may need to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation due to privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data and unfair or deceptive practices.

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

Our operations are subject to hazards and risks associated with our research and manufacturing operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies, such as personal accident insurance. For details, please refer to the paragraph headed "Business – Insurance" in this document. We maintain insurance policies that are required under laws and regulations where we have operations, as well as based on our assessment of our operational needs and industry

practice. In line with industry practice in the countries where we have operations, we have elected not to maintain certain types of insurances, such as property damage insurance, keyman insurance and inland transit/marine cargo insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Losses incurred and associated liabilities may have a material adverse effect on our results of operations if such losses or liabilities are not covered by our insurance policies.

RISKS RELATING TO MANUFACTURING AND SUPPLY OF OUR PRODUCTS

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

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

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

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

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

The manufacture of our products is highly complex and subject to strict quality controls. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Despite our quality control and assurance system and procedures, we cannot eliminate the risk of product defects or failure. Problems can arise during the manufacturing process for a number of reasons, including facilities and equipment malfunction, failure to follow protocols and procedures, defects or other issues in raw material, or human error. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Furthermore, if contaminants are discovered in our raw materials, products or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Stability failures and other issues relating to the manufacture of our products or pipeline products could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions.

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

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

We may need to increase or scale up the production capacity and utilization rate to supply our products in sufficient volumes to meet market demand. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete, and therefore we may also need to develop advanced manufacturing techniques and process controls in order to fully utilize our facilities Also, we may need to employ more task personnel to enhance our production capacity. If we are unable to do so, or if the process to do so is delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to supply our products in a sufficient quantity to meet future demand, which would limit our development and commercialization activities and our opportunities for growth.

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

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

RISKS RELATING TO COMMERCIALIZATION AND DISTRIBUTION OF OUR PRODUCTS

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

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

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

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

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

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

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

- failing to adequately promote our products;

- failing to meet certain target sales amounts;

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

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

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

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

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

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

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

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

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

Our future growth and success significantly depend on our ability to successfully market our products to hospitals and other medical institutions through our in-house sales and marketing team and our distributors. Hospitals and medical institutions may organize public tenders either by themselves or through local governments. The procedures of such public tenders vary from hospital to hospital and from region to region, and there could be uncertainties with respect to the timing of such procedures. Other than our in-house sales and marketing team, we are also dependent on experienced local distributors to assist us during such procedures. However, we may not always be able to locate a sufficient number of experienced local distributors to sell our products to hospitals and other medical institutions.

Furthermore, even if we could locate a sufficient number of experienced distributors, our bids during the public tender process may not be successful and our products may not be chosen for a number of reasons, including where: (i) our prices are not competitive; (ii) our products fail to meet the technical or quality requirements imposed by the hospitals or are less clinically effective than competing products;(iii) our reputation is adversely affected by unforeseeable events; or (iv) any other aspect of our operation fails to meet the relevant requirements. If we fail in the tender process, we may face difficulties in maintaining the existing level of sales of our products, and we may find it difficult to sell our pipeline products (upon commercialization) and our revenue may decline, materially adversely affecting our results of operations and financial condition.

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATING TO DOING BUSINESS IN COUNTRIES WHERE WE HAVE OPERATIONS

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

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

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

International expansion may be costly, time consuming and difficult.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of the Latest Practicable Date, our Directors confirmed that we had not been notified that any International Sanctions penalties would be imposed on us for our historical sales to the Relevant Regions. We have no intention to undertake and will not conduct any future business with persons on the SDN Lists, although we will continue to have the dealings that present low sanctions risks as described and explained above, including sales to Iran and Syria through distributors located in those countries. In addition, we have implemented and will implement enhanced internal control and risk management measures which we believe enable us to monitor and evaluate our business to address economic sanctions risks. Please refer to the paragraph headed "Business – Internal Control over Business Operations – Internal Control." in this document. Given the scope of the [**REDACTED**] and the expected [**REDACTED**] as set out in this document, our International Sanctions Legal Advisors are of the view that the involvement by parties in the [**REDACTED**] will not implicate any applicable International Sanctions on such parties, including our Company and our subsidiaries, the respective Directors and employees of our Company and our subsidiaries, our Company's or our subsidiaries' investors, shareholders as well as the Stock Exchange and its [**REDACTED**] and group companies, or any person involved in the [**REDACTED**] and accordingly, the sanction risk exposure to our Company, its investors and shareholders, and persons who might, directly or indirectly, be involved in permitting the [**REDACTED**], trading and clearing of our Shares (including the Stock Exchange, its [**REDACTED**] and related group companies) is low.

We cannot predict the interpretation or implementation of the International Sanctions with respect to any past activities by us. If any government agencies or organizations were to determine that we were deemed to be engaged in prohibited or sanctionable activities targeted by the International Sanctions, we could be subject to certain sanctions or penalties and our reputation and future business prospects could be adversely affected. In addition, sanctions laws and regulations are constantly evolving and new requirements or restrictions could come into effect which might increase the scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions or being sanctionable. We cannot entirely exclude the risk of any changes in sanctions laws and regulations resulting in our Group having greater exposure to International Sanctions penalties in connection with future sales to the Relevant Regions. Our internal control and risk management measures may not be able to react timely or comprehensively to such changes. There is no assurance that our activities in any particular country or region will be in compliance with evolving applicable rules and regulations or that they will not result in negative media attention or reputational damage.

RISKS RELATING TO OUR FINANCIAL POSITION

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

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

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

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

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

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

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

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

We have historically received government grants in the form of subsidies received from local government intended to support our research and development activities and business operations. For the years ended December 31, 2019, 2020 and 2021 and for the six months ended June 30, 2022, we recognized government grants under other net income of US$1.1 million, US$2.3 million, US$1.2 million and US$0.3 million, respectively. For details, please refer to the paragraph headed "Financial Information – Description of Consolidated Statements of Profit or Loss – Other Income" in this document. Our eligibility for government grants is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the research and development progress made by other peer companies. In addition, the policies according to which we historically received government grants may be halted by the relevant government entities at their sole discretion. There is no assurance that we will continue to receive such government grants or receive similar level of government grants, or at all, in the future.

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

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

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

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

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

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

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

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

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, the United States and other jurisdictions such as the European Union and Japan. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA, the United States Patent and Trademark Office (USPTO) or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or pipeline products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize existing and pipeline products without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the CNIPA, the USPTO or other related intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and pipeline products. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or pipeline products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. We may face competition for any existing products and approved pipeline products even if we successfully obtain patent protection once the patent life has expired for the product. The issued patents and pending patent applications, if issued, for our existing and pipeline products are expected to expire on various dates. Please refer to the paragraph headed "Business – Intellectual Property Rights" in this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business prospects and results of operations may be adversely affected.

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

able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects, financial condition and results of operations.

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

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

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

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

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

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

Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

Furthermore, some of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation in the PRC, the United States, the European Union, Japan and other jurisdictions may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance.

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

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

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

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

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

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

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

Our success depends, in part, on our ability to protect our proprietary technologies. We have built a comprehensive intellectual property portfolio in the countries where we have operations to protect our technologies, inventions and know-how and ensure our future success with commercializing our products. Please refer to the paragraph headed "Business – Intellectual Property Rights" in this document. Due to the different regulatory bodies and varying requirements in these jurisdictions, we cannot assure you that we will be able to obtain patent protection for all or any aspects of our products in all or any of these jurisdictions. The process of seeking patent protection can be lengthy and expensive, and we cannot assure you that our patent applications will result in patents being issued, or that our existing or future issued patents will be sufficient to provide us with meaningful protection or commercial advantage. We cannot assure you that our current or potential competitors, many of which have substantial resources and have made substantial investments in competing technologies, do not have, and will not obtain, patents that will prevent, limit or interfere with our ability to make, use or sell our products in jurisdictions such as the PRC, the United States, the European Union and Japan. In addition, if we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

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

RISKS RELATING TO THE [REDACTED]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WAIVER FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In preparation for the [**REDACTED**], our Company has sought and has been [granted] the following waiver from strict compliance with the relevant provisions of the Listing Rules and exemption from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

WAIVER AND EXEMPTION IN RELATION TO THE PRE-[REDACTED] SHARE OPTION SCHEME

Under the Third Schedule to the Companies (Winding up and Miscellaneous Provisions) Ordinance, the prospectus of the Company is required to include details of the number, description and amount of any shares which any person has, or is entitled to be given, an option to subscribe for, together with certain particulars of each option, namely the period during which it is exercisable, the price to be paid for the Shares or debentures subscribed for under it, the consideration (if any) given or to be given for it and the names and addresses of the persons to whom it was given.

Under Rule 17.02(1)(b) of the Listing Rules, a new listing applicant must disclose in the prospectus full details of all outstanding options. Paragraph 27 of Part A of Appendix 1 to the Listing Rules also requires the disclosure of particulars of any capital of any member of the Group which is under option, or agreed conditionally or unconditionally to be put under option, including the consideration for which the option was or will be granted and the price and duration of the option, and the name and address of the grantees.

According to the Guidance Letter HKEX-GL11-09 (July 2009) (Updated in March 2014), the Stock Exchange would normally grant waivers from disclosing the names and addresses of certain grantees if the issuer could demonstrate that such disclosures would be irrelevant and unduly burdensome, subject to certain conditions specified therein.

As of the Latest Practicable Date, our Company had outstanding options granted under the Pre-[**REDACTED**] Share Option Scheme to 102 grantees, including a total of four Directors and senior management of our Company and 98 other current employees or consultants of our Group, to subscribe for an aggregate of 46,374,500 Shares (equivalent to [9,274,900] Shares as adjusted by Share Consolidation), representing approximately [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming no Shares are allotted and issued under the Share Incentive Schemes), on the terms set out in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document.

In addition, as of the Latest Practicable Date, awards for an aggregate of 7,000,000 Shares (which will be 1,400,000 Shares after the Share Consolidation) representing approximately [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming no Shares are allotted and issued under the Share Incentive Schemes) have been granted to four eligible participants (being a Director or member of senior management) by our Company under the Pre-[**REDACTED**] Share Option Scheme. For details, please refer to the section headed "Statutory and General information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to the document.

WAIVER FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Our Company has applied to the Stock Exchange and the SFC, respectively, for (i) a waiver from strict compliance with the disclosure requirements under Rule 17.02(1)(b) of, and paragraph 27 of Appendix 1A to, the Listing Rules; and (ii) a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with the disclosure requirements under paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the ground that strict compliance with the above requirements would be unduly burdensome for our Company for the following reasons:

(a) given that 102 grantees are involved, strict compliance with such disclosure requirements in setting out full details of all the grantees under the Pre-[**REDACTED**] Share Option Scheme in the document would be costly and unduly burdensome for our Company in light of a significant increase in cost and timing for information compilation, document preparation and printing;

(b) as of the Latest Practicable Date, among all the grantees, four grantees were Directors and senior management of our Company and the remaining 98 grantees were current employees or consultants of our Group, strict compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance and Listing Rules to disclose names, addresses, and entitlements on an individual basis in this document will therefore require about 15 pages of additional disclosure that does not provide any material information to the investing public;

(c) the grant and exercise in full of the options under the Pre-[**REDACTED**] Share Option Scheme will not cause any material adverse impact to the financial position of our Company;

(d) non-compliance with the above disclosure requirements would not prevent our Company from providing its potential investors with an informed assessment of the activities, assets, liabilities, financial position, management and prospects of our Company; and

(e) material information relating to the options under the Pre-[**REDACTED**] Share Option Scheme will be disclosed in this document, including the aggregate number of grantees, the total number of Shares subject to the Pre-[**REDACTED**] Share Option Scheme, the consideration paid for the grant of the options under the Pre-[**REDACTED**] Share Option Scheme (if any), the exercise period and the exercise price per Share (if applicable) and the potential dilution effect on the shareholding upon full allotment and issuance under the Pre-[**REDACTED**] Share Option Scheme. Our Directors consider that the information that is reasonably necessary for potential investors to make an informed assessment of our Company in their investment decision making process has been included in this document.

In light of the above, our Directors are of the view that the grant of the waiver and exemption sought under this application will not prejudice the interests of the investing public.

The Stock Exchange has [granted] to us the requested waiver, subject to the conditions that:

(a) full details of the options granted by the Company under the Pre-[**REDACTED**] Share Option Scheme to each of our Directors and senior management of our Company will be disclosed in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document, as required under Rule 17.02(1)(b) of, and paragraph 27 of Appendix 1A to, the Listing Rules, and paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;

(b) in respect of the options granted by the Company under the Pre-[**REDACTED**] Share Option Scheme to current employees or consultants (grantees other than those referred to in point (a) above), disclosure will be made, on an aggregate basis, of (1) aggregate number of grantees and number of Shares underlying the options under the Pre-[**REDACTED**] Share Option Scheme, (2) the consideration paid for the grant of the options granted under the Pre-[**REDACTED**] Share Option Scheme (if any), and (3) the exercise period and the exercise price of the options granted under the Pre-[**REDACTED**] Share Option Scheme;

(c) the aggregate number of Shares underlying the options granted under the Pre-[**REDACTED**] Share Option Scheme and the percentage of our Company's total issued share capital represented by such number of Shares are disclosed in this document;

(d) the dilutive effect upon the full exercise of the options granted under the Pre-[**REDACTED**] Share Option Scheme are disclosed in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document;

(e) a summary of the major terms of the Pre-[**REDACTED**] Share Option Scheme are disclosed in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document;

(f) the particulars of the waiver are disclosed in this document;

(g) a full list of all the grantees (including the persons referred to in point (a) above) who have been granted options under the Pre-[**REDACTED**] Share Option Scheme, containing all the particulars as required under the above requirements, will be made available on display in accordance with the section headed "Documents Delivered to the Registrar of Companies and Available on Display" in Appendix V to this document; and

(h) the grant of certificate of exemption under the Companies (Winding Up and Miscellaneous Provisions) Ordinance from the SFC exempting our Company from the disclosure requirements provided in paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

The SFC has [granted] to our Company the certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with paragraph 10(d) subject to the conditions that:

(a) full details of the options granted by our Company under the Pre-[**REDACTED**] Share Option Scheme to each of our Directors and senior management of our Company, and other grantees who have been granted options to subscribe for [9,274,900] Shares (as adjusted after Share Consolidation) or more, are disclosed in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document, such details to include all the particulars required under paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;

(b) in respect of the options granted by our Company under the Pre-[**REDACTED**] Share Option Scheme to current employees or consultants other than those referred to in point (a) above, the following details are disclosed in this document: (1) aggregate number of grantees and number of Shares underlying the options granted under the Pre-[**REDACTED**] Share Option Scheme, (2) the consideration paid for the grant of the options under the Pre-[**REDACTED**] Share Option Scheme (if any), and (3) the exercise period and the exercise price for the options granted under the Pre-[**REDACTED**] Share Option Scheme;

(c) a full list of all the grantees (including the persons referred to in point (a) above) who have been granted options to subscribe for Shares under the Pre-[**REDACTED**] Share Option Scheme, containing all the particulars as required in paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, be made available on display in accordance with the section headed "Documents Delivered to the Registrar of Companies and Available on Display" in Appendix V to this document; and

(d) the particulars of the exemption are disclosed in this document and this document will be issued on or before [**REDACTED**].

Further details of the Pre-[**REDACTED**] Share Option Scheme are set forth in the section headed "Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[**REDACTED**] Share Option Scheme" in Appendix IV to this document.

[**REDACTED**]

[REDACTED]

[REDACTED]

[REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
David CHIEN (錢永勛)	7/F, Opus Hong Kong 53 Stubbs Road The Peak Hong Kong	Chinese
Kwai Ching Denise LAU (劉桂禎)	7/F, Opus Hong Kong 53 Stubbs Road The Peak Hong Kong	Chinese
Wing Shing CHEN (陳泳成)	Flat A, 6/F, Tower 16 Mayfair by the Sea I No. 23 Fo Chun Road Tai Po, N.T. Hong Kong	Chinese
Ching Chung John CHOW (周靜忠)	Flat 6 2/F, Block B Villa Lotto 18 Broadwood Road Hong Kong	Chinese
Non-executive Director		
Yi ZHOU (周伊)	5A 1901 3038 Qiaoxiang Road Futian District Shenzhen PRC	Chinese

Name	Address	Nationality
Independent non-executive Directors		
Yip Keung CHAN (陳業強)	Flat C, Floor 36, Block 4 Royal Peninsula 8 Hung Lai Road Hung Hom, Kowloon Hong Kong	Chinese
Lai Fan Gloria TAM (譚麗芬)	Flat 1A, Block 1 Clovelly Court 12 May Road Mid-Levels Hong Kong	Chinese
Ka Keung LAU (樓家強)	House 37 Tycoon Place 38 Lo Fai Road Tai Po, New Territories Hong Kong	Chinese

For further information regarding our Directors, please refer to the section headed "Directors and Senior Management".

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

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29th Floor, One International Finance Centre
1 Harbour View Street
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Hong Kong

CCB International Capital Limited
12/F, CCB Tower
3 Connaught Road Central
Central
Hong Kong

[**REDACTED**]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

[**REDACTED**]

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The information and statistics set out in this section and other sections of this document were extracted from the report prepared by CIC, which was commissioned by us, and from various official governmental publications and other publicly available publications. We engaged CIC to prepare the CIC Report, an independent industry report, in connection with the [**REDACTED**]. *The information from official government sources has not been independently verified by us, the Joint Sponsors, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**] *or any of our or their respective directors, senior management, representatives, advisers or any other person involved in the* [**REDACTED**] *and no representation is given as to its accuracy.*

ABOUT CHINA INSIGHTS INDUSTRY CONSULTANCY LIMITED

We commissioned China Insights Industry Consultancy Limited, an independent third party, to prepare a report on the global endovascular interventional instrument market in April 2022, which is cited in this document. The total fee we paid for the report prepared by China Insights Industry Consultancy Limited was RMB650,000. China Insights Industry Consultancy Limited, founded in Hong Kong, provides professional services including, among others, industry consulting, commercial due diligence and strategic consulting.

During the preparation of the CIC Report, China Insights Industry Consultancy Limited performed both primary and secondary researches, and obtained knowledge, statistics, information on and industry insights into the global endovascular interventional instrument market. Primary research involved interviewing key industry experts and leading industry participants. Secondary research involved analyzing data from various publicly available data sources, such as the government derived information, annual reports and industry association statistics. The CIC Report was compiled based on the following assumptions: (1) the overall social, economic, and political environment in the global economy is expected to remain stable during the forecast period; (2) relevant key drivers are likely to drive the continued growth of the global endovascular interventional instrument market throughout the forecast period; and (3) there is no extreme force majeure or unforeseen industry regulations in which the industry may be affected in either a dramatic or fundamental way. All forecasts in relation to market size are based on the general economic conditions as of the Latest Practicable Date, which would be adjusted if the COVID-19 outbreak persists or escalates and has an unpredicted negative impact on the general economy. The assumptions adopted in the CIC Report in relation to the COVID-19 pandemic include (i) surgeries in different regions experienced an obvious but short-term drop in 2020 compared to in 2019 due to the quarantine and temporarily shut down of hospitals pursuant to which all surgeries were suspended, (ii) the volume of surgery recovered and increased in 2021 and thereafter, as there was no material change in prevalence and prices of surgeries charged by the hospitals, which was based on the samples collected from hospitals and expert interview by China Insights Industry Consultancy Limited.

China Insights Industry Consultancy Limited has exercised due care in collecting and reviewing the information so collected and believes that the basic assumptions are factual and correct and the interpretations are reasonable. China Insights Industry Consultancy Limited has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected.

OVERVIEW OF CARDIOVASCULAR DISEASES

According to the World Health Organization, cardiovascular diseases (CVDs) are a group of disorders of the heart and blood vessels, which primarily include, among others:

- coronary artery disease – a disease of the blood vessels supplying the heart muscle;
- peripheral arterial disease – a disease of blood vessels supplying the arms and legs; and
- cerebrovascular disease – a disease of the blood vessels supplying the brain

In addition, CVDs are one of the leading causes of death worldwide. According to the CIC Report, peripheral arterial diseases are the most common types of CVDs. In 2021, coronary artery disease, peripheral artery disease and cerebrovascular disease, accounted for approximately 29.9%, 51.1% and 18.3% of CVDs globally, respectively.

OVERVIEW OF PERCUTANEOUS CORONARY INTERVENTION PROCEDURAL INSTRUMENT MARKET

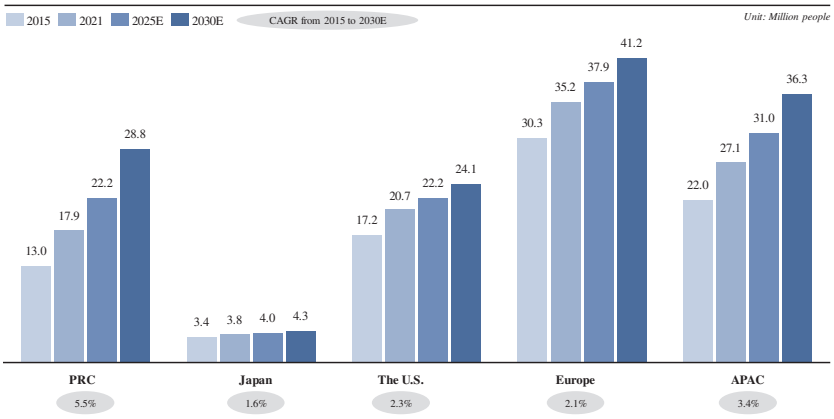
Overview of coronary artery disease

Coronary artery disease (CAD), as the most common type of heart disease, is primarily caused by a buildup of plaque in the walls of coronary arteries, namely the arteries that supply blood to the heart. Atherosclerosis serves as the most usual cause of CAD, in which the buildup of plaque inside the arterial wall gradually reduces the interior lumen of the artery, blocking the blood flow partially or completely. Other less usual causes include coronary artery spasm and coronary artery dissection.

According to the CIC Report, the prevalence of CAD has grown steadily on a global scale. In the PRC, the CAD prevalence has grown from 13.0 million in 2015 to 17.9 million in 2021, and is expected to continue growing to 28.8 million in 2030. In Japan, the CAD prevalence has grown from 3.4 million in 2015 to 3.8 million in 2021, and is expected to continue growing to 4.3 million in 2030. In the U.S., the CAD prevalence has grown from 17.2 million in 2015 to 20.7 million in 2021, and is expected to continue growing to 24.1 million in 2030. In Europe, the CAD prevalence has grown from 30.3 million in 2015 to 35.2 million in 2021, and is expected to continue growing to 41.2 million in 2030. In APAC region, the CAD prevalence has grown from 22.0 million in 2015 to 27.2 million in 2021, and is expected to continue growing to 36.3 million in 2030.

The following chart shows the global prevalence data of CAD by region:

Global prevalence of CAD, by region, 2015 vs. 2021 vs. 2025E vs. 2030E



Source: China Insights Industry Consultancy Limited, American Heart Association, Journal of American College of Cardiology, Centers for Disease Control and Prevention, Census Bureau, European Society of Cardiology, Europe Association of PCI, Chinese Circulation Journal, National Healthcare Security Administration, World Heart Federation, Ministry of Health, Labour and Welfare (Japan) and other literature review and expert interviews

Medical treatment for CADs

Medical treatment for CAD depends on their symptoms, cardiac function, and presence of other disorders. There are three primary methods of treating CAD, namely:

1. ***Medical therapy***: medical therapy is the most basic form of treating CAD out of the three methods of treatment. It involves the administration of medication aimed at managing CAD patients' symptoms. All CAD patients in stable condition require medical therapy to prevent disease progression and recurrent cardiovascular events. Recommended therapy includes antiplatelet drugs to prevent blood clot formation, and statins to lower LDL cholesterol. Where medical therapy is ineffective, PCI or CABG may be adopted instead.

2. ***Percutaneous coronary intervention (PCI)***: PCI is a minimally invasive procedure which involves the use of interventional instruments (e.g. catheters) to insert small structures such as balloons and stents into blood vessels to facilitate their dilation. This procedure does not require open-heart surgery, and is short in duration (around one hour, after which the patient may be discharged). PCI therefore has advantages of small trauma, quick recovery after operation, few complications, low risk, and low cost.

3. ***Coronary artery bypass grafting (CABG)***: CABG is an invasive surgical procedure which involves taking a blood vessel from another part of the body (i.e. the graft), and attaching it to the coronary artery above and below the narrowed or blocked area. This procedure diverts blood around the narrowed or blocked parts of the coronary arteries. This procedure is carried out under a general anesthetic, and usually takes around three to six hours. Patients who have undergone CABG will

usually be required to stay in hospital for at least seven days after the bypass surgery. The risks of CABG include stroke and myocardial infarction. However, CABG would be the preferred treatment for patients with diabetes, or with multivessel diseases.

Since PCI carries lower risk and costs, but still enjoys a similar treatment success rate compared to CABG, it is often the preferred form of treating CAD. In a PCI procedure, a semi-compliant balloon is used to pre-expand the blood vessel, following which either a stent or drug-coated balloon will be inserted into the blood vessel for clearing the blockage.

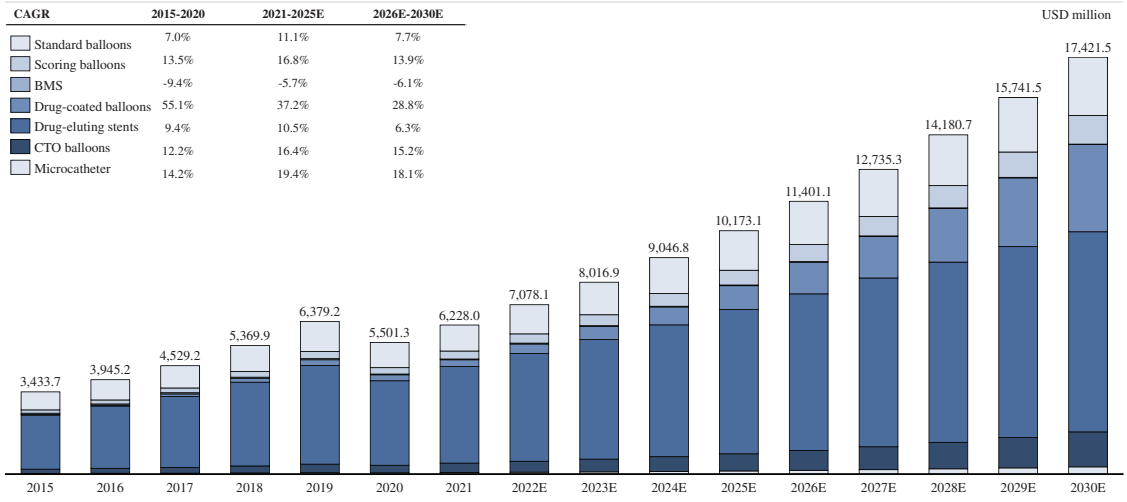
PCI market overview

According to the CIC Report, the volume of PCI differs between countries due to different penetration rate of PCI procedure or local treatment guideline. "Volume" of PCI refers to the number of PCI surgeries performed in a specific region in a given year, while "Penetration Rate" of PCI refers to the percentage of patients that can be treated with PCI surgeries actually proceeded with PCI surgeries in a specific region at a specific time. The calculation of PCI volume is based on prevalence multiplied by PCI penetration. The historical data of prevalence and PCI surgery volume are mainly from American Heart Association, European Society of Cardiology, Chinese Circulation Journal and sample hospital physicians interviews. The future penetration rate growth is in line with the historical trends. In the PRC, PCI volume had grown from 567,600 in 2015 to 1.2 million in 2021, and is expected to continue growing to 3.1 million in 2030; PCI penetration rate had grown from 4.4% in 2015 to 6.7% in 2021, and is expected to continue growing to 10.8% in 2030. In Japan, PCI volume had grown from 212,000 in 2015 to 272,800 in 2021, and is expected to continue growing to 572,300 in 2030; PCI penetration rate had grown from 6.2% in 2015 to 7.2% in 2021, and is expected to continue growing to 13.3% in 2030. In the U.S., PCI volume had grown from 592,700 in 2015 to 1.0 million in 2021, and is expected to continue growing to 3.5 million in 2030; PCI penetration rate had grown from 3.5% in 2015 to 5.0% in 2021, and is expected to continue growing to 14.6% in 2030. In Europe, PCI volume had grown from 890,000 in 2015 to 1.4 million in 2021, and is expected to continue growing to 3.8 million in 2030; PCI penetration rate had grown from 2.9% in 2015 to 4.1% in 2021, and is expected to continue growing to 9.1% in 2030. In APAC region, PCI volume had grown from 1.1 million in 2015 to 2.0 million in 2021, and is expected to continue growing to 6.0 million in 2030; PCI penetration rate had grown from 5.0% in 2015 to 7.4% in 2021, and is expected to continue growing to 16.6% in 2030.

According to the CIC Report, the market size of PCI procedural instruments is also showing continuous growth globally. In the PRC, the market size by sales value was US$765.5 million in 2015 and US$1,270.4 million in 2021, and is expected to reach US$3,751.2 million in 2030. In APAC region, the market size by sales value was US$733.4 million in 2015 and US$1,266.1 million in 2021, and is expected to reach US$2,985.3 million in 2030. In Europe, the market size by sales value was US$582.7 million in 2015 and US$892.6 million in 2021, and is expected to reach US$2,010.9 million in 2030. In the U.S., the market size by sales value was US$400.4 million in 2015 and US$672.9 million in 2021, and is expected to reach US$1,907.4 million in 2030. In Japan, the market size by sales value was US$394.5 million in 2015 and US$484.6 million in 2021, and is expected to reach US$824.1 million in 2030.

PCI procedural instruments primarily include standard balloons, scoring balloons, CTO balloons, drug-coated balloons, bare metal stents, drug-eluting stents, and microcatheters. The following chart shows the global market size of PCI interventional procedural instrument:

Global market size of PCI procedural instrument market, in terms of sales value*, 2015-2030E



Source: China Insights Industry Consultancy Limited, expert interviews and public information

Being the key instrument used for PCI procedures, balloon showed steady growth and is expected to take up the majority of the PCI procedural instrument market by 2030, according to CIC Report. In the PRC, balloon volume had grown from 874,100 in 2015 to 2.1 million in 2021, and is expected to continue growing to 6.4 million in 2030. In Japan, balloon volume had grown from 338,100 in 2015 to 450,400 in 2021, and is expected to continue growing to 1.1 million in 2030. In the U.S., balloon volume had grown from 918,600 in 2015 to 1.6 million in 2021, and is expected to continue growing to 6.2 million in 2030. In Europe, balloon volume had grown from 1.4 million in 2015 to 2.2 million in 2021, and is expected to continue growing to 6.3 million in 2030. In APAC region, balloon volume had grown from 1.7 million in 2015 to 3.2 million in 2021, and is expected to continue growing to 11.3 million in 2030.

Competitive landscape

We are a major PCI balloon developer and manufacturer selling our PCI balloons in over 70 countries and regions around the world. In terms of sales volume of PCI balloons in 2021, we ranked No. 2 in Japan market, No. 4 in the Europe market and No. 6 in both the PRC and U.S. markets. We achieved market share in PCI balloon market in terms of sales volume in 2021 in the Japan, Europe, the PRC and the U.S. of 20%, 11%, 8% and 3%, respectively. Our ability to lead the market is primarily due to the following reasons: (i) our track record of high product quality has been well-recognized by hospitals and physicians and are widely adopted in PCI procedures; (ii) we constantly improve and modify our products to accommodate the evolving needs of physicians and patients, and provide physicians with more customized options and convenience; and (iii) we have benefited from favorable PRC policies that

encourage the development and purchase of domestically-produced medical devices and price control of pharmaceutical products. For instance, there are local policies in Shanghai, Jiangsu, Zhejiang and Anhui with respect to a favorable reimbursement percentage by medical insurance for domestically-produced high-value medical consumables such as coronary interventional medical devices. The key PCI market players in the PRC include Medtronic, Abbott, Terumo, Boston Scientific and Lepu. The key PCI market players in Japan include Terumo, Nipro, Japan Lifeline and Abbott. The key PCI market players in the U.S. include Abbott, Boston Scientific, Medtronic, Cordis and B.Braun. The key PCI market players in Europe include Medtronic, Abbott, Boston Scientific and B.Braun. The following tables set forth the competitive landscape of PCI balloons in the PRC, Japan, the U.S. and Europe markets in terms of sales volume in 2021.

Market share of PCI balloon in terms of sales volume in 2021 by different countries/regions

PRC		Japan		U.S.		Europe	
Company A (the U.S.)	~20%	Company C (Japan)	30%-35%	Company B (the U.S.)	~30%	Company A (the U.S.)	~30%
Company B (the U.S.)	15%~18%	**OrbusNeich (Hong Kong, China)**	**20%**	Company D (the U.S.)	~28%	Company B (the U.S.)	~25%
Company C (Japan)	15%~18%	Company F (Japan)	~15%	Company A (the U.S.)	~22%	Company D (the U.S.)	~23%
Company D (the U.S.)	10%-15%	Company G (Japan)	~10%	Company J (the U.S.)	~10%	**OrbusNeich (Hong Kong, China)**	**11%**
Company E (PRC)	~8%	Company B (the U.S.)	<5%	Company H (Europe)	<5%	Company H (Europe)	~10%
OrbusNeich (Hong Kong, China)	**8%**			**OrbusNeich (Hong Kong, China)**	**3%**		

Note: countries/regions in bracket denote the places of headquarter of respective market players. For the background, principal business and principal places of operations/network coverage of the above top market players, please refer to "– Overview of Percutaneous Transluminal Angioplasty Procedural Instrument Market – Competitive Landscape" in this section for details.

Significant market share of OrbusNeich of PCI balloon in terms of sale volume in 2021 in other countries/regions					
Hongkong	~52%	Pakistan	~59%	Russia	~26%
Singapore	~57%	Indonesia	~38%	Switzerland	~26%
Malaysia	~41%	Italy	~20%	Czech Republic	~33%
Taiwan	~40%	Slovakia	~40%	The Netherlands	~25%

Source: China Insights Industry Consultancy Limited, expert interviews and public information

In terms of sales volume of PCI stents in 2021, the top five market players in each of Japan and Europe accounted for collectively approximately 91% and 94% of the market share, respectively, and our market share was approximately 2% and 0.3% in Japan and Europe, the major regions where we sell PCI stents, respectively.

Growth drivers and future trends

There are four primary growth drivers and future trends that can be seen of the global coronary artery interventional instrument market:

1. ***Increasing CAD prevalence***: CAD prevalence increases with an aging population, and also amongst the younger population that engage in unhealthy consumption habits such as smoking and alcohol consumption, and increased stress levels.

2. ***Favorable government policies***: given the importance of the coronary artery interventional instrument market for CAD treatment, governments are paying more attention to this market, and are introducing favorable policies to develop this area, which in turn encourages further investments to leverage on such policies. Manufacturers are expected to continuously invest in research and development in constant improvement of their products. For instance, the Reform Plan for the Control of High-value Medical Consumables (治理高值醫用耗材改革方案) encourages the research, development and manufacturing of medical consumables. In addition, policies in Shenzhen such as the Shenzhen Dedicated Funds Support Policy on the Development of Strategic Emerging Industries (深圳市戰略性新興產業發展專項資金扶持政策) and the Shenzhen Technology Research and Development Funds Administration Measures (深圳市科技研發資金管理辦法) provide the basis for the government grant to support of R&D investment.

3. ***Rising demand for PCI operations***: CAD patients are more willing to choose PCI operations due to its low trauma and reliability compared to traditional methods of treatment. Doctors also prefer PCI due to its lower risk compared to other methods of surgical treatment.

4. ***Continuous product development***: as development and innovation of medical devices accelerates, medical devices treating CAD are expected to increase in quality and prominence, and achieve better penetration in the global market. As such, the continuous development and innovation of medical devices also enhances room for market expansion.

Threats and Challenges

The major threats and challenges of the global coronary/peripheral artery interventional instrument market primarily include:

Product upgrade and substitution: The coronary/peripheral artery interventional instrument products continue to go through upgrades and substitutions. Companies would continuously research, innovate and develop new generations of products with better surgical results, and as a result, older generation products would gradually become obsolete. For example, after the development of drug eluting stents, the market share of bare metal stents shrunk drastically. The drug eluting stents also compete with dual therapy stents or absorbable

stents. Therefore, the nature of the importance of continuous product upgrade and substitution poses can pose significant threat challenge on PCI/PTA instrument companies, and it is important for them to continuously upgrade their products.

Government regulatory risk: The medical device industry is heavily influenced by the regulations or policies promulgated by the government, which primarily include:

Strict approval regulations: Medical devices are required to go through stringent approval processes. Companies must obtain relative licenses and certificates to produce and sell medical devices and register again if they become invalid after expiry. Strict access systems and complex regulations are major challenges for medical device companies.

Government pricing-related policies: In many countries, government would control prices of medical devices through regulatory means in order to maintain costs of government medical insurances. The centralized procurement policies promulgated by the PRC government under which the purchases of the medical devices included in the centralized procurement scope by the public hospitals should be made through the public bidding or tender processes on the centralized procurement platform established by the respective local governments, often lead to a substantial decrease in the profitability of medical device products manufacturers. Other countries, such as Japan and the U.S., also have policies which would influence the profit margin of medical device products.

COVID-19 pandemic: The COVID-19 pandemic imposes negative effect on the whole medical health industry. Due to the pandemic, many hospitals enforce strict policies on hospital visits and limit the number of patients going to hospitals so that the resources being reallocated to treat COVID patients. Furthermore, the pandemic hit the global economy heavily, and the public's affordability of advanced medical services are impaired. Therefore, the pandemic heavily influences the global health expenditure, which as a result becomes a challenge for medical device companies to make a profit.

Low public awareness: The public awareness of peripheral artery diseases is generally lower than that of cerebral artery diseases or coronary artery diseases. The low public awareness results in low surgical penetration rate. For example, in 2021, the surgical penetration rate of PTA intervention is 0.6% in the PRC, far lower than that of PCI intervention, which is 6.7%, although it is expected to grow to 1.4% in 2030 as a result of various factors including patients awareness of peripheral artery disease, the education from physician conferences or companies and government reimbursement policies. Increased awareness and education of the public about the seriousness of PAD diseases can overcome this challenge.

Major Entry Barriers

The major entry barriers for new participants of the global coronary/peripheral artery interventional instrument market primarily include:

Intensive technology and continuous product innovation: Multi-disciplinary expertise in material and mechanical engineering, product design and manufacturing are necessary in the development of coronary/peripheral artery interventional instruments. In addition, coronary/peripheral artery is very important and complex, which implies a higher level of sophistication of means related to the surgical instruments. New entrants may generally find it difficult to recruit the necessary professionals and acquire the technologies in a short term. On the other hand, continuous product innovation is also important for medical device companies to maintain profitability. The key to success in the medical technology industry has been continuous innovation and a dedication to research and development. A key driver for this continuous innovation is the short lifecycles within the sector. Once a breakthrough technology has been established, improvements are made continuously. The value-based innovations of the medical device industry have proven to not only improve the lives of millions of patients, but also play an important role in making healthcare systems more efficient, which has become a priority for all governments.

Also, the global PCI/PTA market players often challenge the intellectual property of their competitors. Therefore, robust intellectual property protection is important to survive, the building up of which may be costly and time consuming.

Commercialization capability: It is important for medical device manufacturers to develop its global commercialization capabilities and utilize the distributorship sales model to access the global coronary/peripheral artery interventional instrument market. It requires market players to have the ability of mass production at a high quality standard that meets various regulatory bodies' requirements across the globe. In addition, establishing local sales offices with the relevant industry and cultural knowledge to manage direct sales and distributors can be difficult. Identifying suitable distributors in the development of a strong distribution network can also be time consuming. Moreover, gaining brand reputation and awareness plays an important part in product commercialization, which partly means to acquire recognition from target stakeholders such as hospitals and physicians. However, it typically takes years of efforts for a brand to establish solid relationships with physicians and hospitals, especially with KOLs and top-tier hospitals.

Heavy capital investment: Participation in the global PCI/PTA intervention instrument market requires heavy capital investment. Costs of research and development of coronary/peripheral artery interventional instrument products, enhancement of product quality and performance, brand promotion and marketing channel construction, establishing factories which enable mass production at a strict quality standard all require significant capital expenditure and investments. Particularly, a large amount of capital is necessary if the players hope to survive and continuously expand in this industry. Financial pressure is an inevitable challenge for most of the medical device startups in their initial years before they can break

even, and it can take substantial time to achieve profitability. Attracting sufficient investments and utilizing the funds effectively and efficiently are practically hard to fulfill, presenting a huge barrier especially for new entrants in the market.

OVERVIEW OF PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY PROCEDURAL INSTRUMENT MARKET

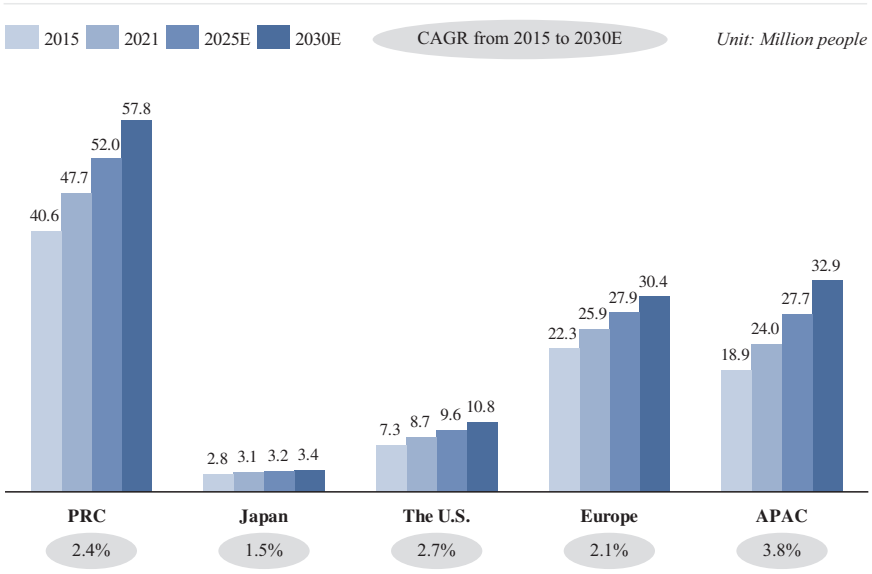
Overview of peripheral artery disease

Peripheral artery disease (PAD) is a common type of vascular diseases, primarily caused by atherosclerosis in the arteries in the limbs. In turn, this causes restricted blood flow to the arms, legs, kidneys, and stomach. Severe cases of PAD can lead to critical limb ischaemia, ulceration, gangrene and may result in amputation of the limbs. PAD is age-related, with its prevalence increasing significantly with age. While PAD can impact various parts of a human body, the PTA procedural instruments developed and manufactured by us primarily focus on treating the lower limb PAD as the main division and accounted for more than 60% of PAD according to epidemiology.

According to the CIC Report, the lower limb PAD prevalence has grown steadily on a global scale. In the PRC, the lower limb PAD prevalence had grown from 40.6 million in 2015 to 47.7 million in 2021, and is expected to continue growing to 57.8 million in 2030. In Japan, the lower limb PAD prevalence had grown from 2.8 million in 2015 to 3.1 million in 2021, and is expected to continue growing to 3.4 million in 2030. In the U.S., the lower limb PAD prevalence had grown from 7.3 million in 2015 to 8.7 million in 2021, and is expected to continue growing to 10.8 million in 2030. In Europe, the lower limb PAD prevalence had grown from 22.3 million in 2015 to 25.9 million in 2021, and is expected to continue growing to 30.4 million in 2030. In APAC region, the lower limb PAD prevalence had grown from 18.9 million in 2015 to 24.0 million in 2021, and is expected to continue growing to 32.9 million in 2030.

Peripheral artery disease is age-related, with its prevalence increasing significantly with advancing age. Currently, the prevalence in high-income countries is higher than that in low-to-middle-income countries. The following chart shows the global prevalence data of the lower limb PAD prevalence by region:

Global prevalence of PAD (lower limb), by region, 2015 vs. 2021 vs. 2025E vs. 2030E



Source: The Lancent; ESC guidelines on the diagnosis and treatment of PAD; China Insights Industry Consultancy Limited

Medical treatment for peripheral arterial disease

Similar with CADs, the three primary methods of treating PADs are medical treatment, surgical treatment and interventional treatment. Surgical treatment methods include aorto-(bi)femoral bypass, open surgery, and extra-anatomical bypass. Interventional treatment methods include endovascular therapy, primary stent implantation, drug-eluting balloons and drug-eluting stents. Percutaneous transluminal angioplasty (PTA) is a medical treatment procedure that can open up a blocked blood vessel using a catheter and a balloon, which inflates to open the blood vessel in order to restore normal blood flow. Sometimes, interventional and surgical methods may be adopted together to treat PAD. The treatment type and method depends on the type and extent of lesion being suffered by the PAD patient.

Market overview

According to the CIC Report, while the volume and penetration rate of peripheral PTA differs between countries, it is showing continuous growth globally. "Volume" of PTA refers to the number of PTA surgeries performed in a specific region in a given year, while "Penetration rate" of PTA refers to the percentage of patients that can be treated with PTA surgeries actually proceeded with PTA surgeries in a specific region at a specific time. The calculation of PTA volume is based on prevalence multiplied by PTA penetration. The historical data of prevalence and PTA surgery volume are mainly from American Heart Association, European Society of Cardiology, Chinese Circulation Journal and sample hospital physicians interviews. The future penetration rate growth is in line with the historical trends. In the PRC, peripheral PTA volume had grown from 162,400 in 2015 to 273,100 in 2021, and is expected to continue growing to 823,200 in 2030; peripheral PTA penetration rate had grown

from 0.4% in 2015 to 0.6% in 2021, and is expected to continue growing to 1.4% in 2030. In Japan, peripheral PTA volume had grown from 52,200 in 2015 to 95,100 in 2021, and is expected to continue growing to 217,000 in 2030; peripheral PTA penetration rate had grown from 1.9% in 2015 to 3.1% in 2021, and is expected to continue growing to 6.3% in 2030. In the U.S., peripheral PTA volume had grown from 34,500 in 2015 to 60,800 in 2021, and is expected to continue growing to 198,100 in 2030; peripheral PTA penetration rate had grown from 0.5% in 2015 to 0.7% in 2021, and is expected to continue growing to 1.8% in 2030. In Europe, peripheral PTA volume had grown from 96,900 in 2015 to 160,700 in 2021, and is expected to continue growing to 415,400 in 2030; peripheral PTA penetration rate had grown from 0.4% in 2015 to 0.6% in 2021, and is expected to continue growing to 1.4% in 2030. In APAC region, peripheral PTA volume had grown from 79,200 in 2015 to 160,000 in 2021, and is expected to continue growing to 437,200 in 2030; peripheral PTA penetration rate had grown from 0.4% in 2015 to 0.7% in 2021, and is expected to continue growing to 1.3% in 2030.

Further, according to the CIC Report, the market size of PTA procedural instruments is also showing continuous growth globally. In the PRC, the market size by sales value was US$166.0 million in 2015 and US$280.9 million in 2021, and is expected to reach US$976.6 million in 2030. In Japan, the market size by sales value was US$89.7 million in 2015 and US$161.1 million in 2021, and is expected to reach US$320.4 million in 2030. In the U.S., the market size by sales value was US$21.7 million in 2015 and US$36.3 million in 2021, and is expected to reach US$91.3 million in 2030. In Europe, the market size by sales value was US$61.0 million in 2015 and US$94.8 million in 2021, and is expected to reach US$194.7 million in 2030. In APAC region, the market size by sales value was US$50.0 million in 2015 and US$93.2 million in 2021, and is expected to reach US$205.3 million in 2030.

Competitive landscape

We are a major PTA balloon developer and manufacturer in the Japan and U.S. markets. In terms of sales volume of PTA balloons in 2021, we ranked No. 3 in the Japan market and No. 4 in the U.S. market. We achieved market share in PTA balloon market in terms of sales volume in 2021 in Japan and the U.S. of 13% and 12%, respectively. Our ability to lead the market is primarily due to the following reasons: (i) our track record of high product quality has been well-recognized by hospitals and physicians and widely adopted in PTA procedures and (ii) we constantly improve and modify our products to accommodate the evolving needs to the physicians and patients, and provide physicians with more customized options and convenience. In addition, we had a 1% market share in terms of sales volume in 2021 in the Europe PTA balloon market. We also actively seek opportunities in the PRC PTA balloon market. The key PTA market players in the PRC include Medtronic, Boston Scientific, Merit, Cordis and Acotec. The key PTA market players in Japan include Terumo, Asahi, Boston Scientific and Medtronic. The key PTA market players in the U.S. include Medtronic, Cordis, Boston Scientific and Biosensors. The key PTA market players in Europe include Medtronic, Boston Scientific, Abbott, BD and B.Braun. The following table sets forth the top five players of peripheral balloons in the PRC, Japan, the U.S. and Europe markets in terms of sales volume in 2021.

Market share of PTA balloon in terms of sales volume in 2021 by different countries/regions

PRC*		Japan		U.S.		Europe	
Company A (the U.S.)	~30%	Company C (Japan)	~30%	Company A (the U.S.)	~30%	Company A (the U.S.)	~30%
Company D (the U.S.)	~20%	Company K (Japan)	~20%	Company J (the U.S.)	~15%	Company D (the U.S.)	~25%
Company I (the U.S.)	~16%	**OrbusNeich (Hong Kong, China)**	**13%**	Company D (the U.S.)	~15%	Company B (the U.S.)	~20%
Company J (the U.S.)	~15%	Company D (the U.S.)	~10%	**OrbusNeich (Hong Kong, China)**	**12%**	Company M (the U.S.)	~12%
Company N (PRC)	~13%	Company A (the U.S.)	~10%	Company L (Europe)	~8%	Company H (the U.S.)	<10%
						OrbusNeich (Hong Kong, China)	**1% ranked 6-10**

Note: countries/regions in bracket denote the places of headquarter of respective market players

Source: China Insights Industry Consultancy Limited, expert interviews and public information

* We did not commence sales of PTA balloons in the PRC in 2021.

The table below sets forth the background, principal business and principal places of operations/network coverage of the top market players in the PCI/PTA instrument markets:

Competitor	Background and principal business	Principal place of operations/network coverage	Business scale(number of employees)
Company A	Company A is a New York Stock Exchange listed medical device company that generates revenues from four business segments: cardiac and vascular, minimally invasive therapies, restorative therapies, and diabetes.	Global	Over 100,000
Company B	Company B is a New York Stock Exchange listed company primarily focuses on product lines including rhythm management, electrophysiology, heart failure, vascular and structural heart devices for the treatment of cardiovascular diseases, and diabetes care products for diabetes patients, as well as neuromodulation devices for the management of chronic pain and movement disorders.	Global	Over 100,000
Company C	Company C is a Tokyo Stock Exchange listed manufacturer of medical supplies which focuses on the cardiac and vascular segment and is engaged in the manufacture of catheter system and cardiopulmonary system products, the import of the cardiopulmonary systems and artificial blood vessels, as well as the sale of products mainly to hospitals and clinics nationwide through agents.	Global	Over 25,000
Company D	Company D is a New York Stock Exchange listed company offers medical device products covering interventional cardiology, peripheral interventions, cardiac rhythm management, electrophysiology, endoscopy, urology and pelvic health, neuromodulation, and specialty pharmaceuticals.	Global	Over 40,000

Competitor	Background and principal business	Principal place of operations/network coverage	Business scale(number of employees)
Company E	Company E is a PRC-based Shenzhen Stock Exchange listed company principally engaged in the research, development, production and sale of cardiovascular related medical equipment, medicines and health products, as well as in the provision of related medical services.	The PRC	Over 10,000
Company F	Company F is a Tokyo Stock Exchange listed company has three segments: the medical-related segment involves in the sale of injections and infusions, artificial organs, high function and dialysis related medical equipment, and diabetes, generics and kits related medicine products.	Mainly Japan and Asian countries	Over 35,000
Company G	Company G is a Tokyo Stock Exchange lised company mainly engaged in the production of rhythm devices, electrophysiological (EP) and ablations, surgical products and intervention products.	Japan	501-1,000
Company H	Company H is a private medical device manufacturer which supplies products ranging from catheters to surgical instruments.	Mainly Europe, North America and Asia-Pacific	Over 60,000
Company I	Company I is a NASDAQ Stock Exchange listed company designs, develops, manufactures and markets medical products for interventional and diagnostic procedures in the cardiovascular and endoscopy segments.	Mainly the U.S.	5,001-10,000
Company J	Company J is a private U.S. based medical device manufacturer focusing on interventional vascular medicine and neuroscience.	Global	Over 3,500
Company K	Company K is a Tokyo Stock Exchange listed company engaged in the development, manufacturing and sale of medical devices of ultra-fine stainless steel wire ropes, terminal processed products, etc.	Mainly Japan and the PRC	5,001-10,000
Company L	Company L is a private company operates globally, offering interventional devices and solutions for patients living with coronary artery diseases.	Mainly Europe, the PRC and Japan	0-500
Company M	Company M is a New York Stock Exchange listed company focuses on developing innovative surgical, endovascular interventions that not only meet clinical needs but also deliver value to health systems and improve patients' lives.	Global	Over 60,000
Company N	Company N is a PRC-based Hongkong Stock Exchange listed interventional medical device company and its products are mainly used for vascular interventional treatment.	The PRC	0-500

Growth drivers and future trends

There are four primary growth drivers and future trends that can be seen of the global peripheral artery interventional instrument market:

1. ***Increasing PAD prevalence***: PAD prevalence is directly related to increasing age, particularly among those aged over 40 years old in the population. PAD prevalence is expected to increase in line with the global trend of aging population.

2. ***Growing popularity of early diagnosis***: with technological and medical advancements, the ability of early diagnosis for peripheral vascular diseases will continue to improve. Rising concern for healthcare especially in developing countries, coupled with the growing popularity of early diagnosis and GDP growth, is expected to have a positive impact on the growth of the peripheral arterial disease treatment market.

3. ***Continuous product upgrades and innovation***: constant improvement and innovation of PAD treatment medical devices is expected to drive the development of this industry in the global market.

4. ***Rising demand for PTA operations***: PAD patients are expected to prefer minimally invasive surgery owing to shorter recovery time, lesser scaring and lower risk of post-surgery complications. This is expected to drive the demand for the PTA market.

Threats and Challenges

For the major threats and challenges of the global peripheral artery interventional instrument market, please refer to "– Overview of Percutaneous Coronary Intervention Procedural Instrument Market – Threats and Challenges".

Major Entry Barriers

For the major entry barriers of the global peripheral artery interventional instrument market, please refer to "– Overview of Percutaneous Coronary Intervention Procedural Instrument Market – Major Entry Barriers".

OVERVIEW OF NEURO INTERVENTIONAL INSTRUMENT MARKET

Overview of intracranial vascular disease

Intracranial vascular disease is the most common life-threatening neurological event, including all disorders in which an area of the brain is temporarily or permanently affected by ischemia or bleeding and one or more of the cerebral blood vessels are involved in the pathological process. Restrictions in blood flow may occur from vessel narrowing (stenosis), clot formation (thrombosis), blockage (embolism) or blood vessel rupture (hemorrhage).

Treatment for Intracranial Vascular Diseases

There are three primary methods of treating intracranial vascular diseases, namely:

1. ***Intravenous thrombolysis (IVT)***: intravenous thrombolysis is a method using thrombolytic drugs to treat thrombosis. In the situation of ischemic stroke, this term specifically refers to degradation of fibrin, dissolving blood clots by activating plasminogen.

2. ***Neuro-interventional procedures***: minimally invasive procedures, including thrombectomy, aneurysm embolization and balloon/stent angioplasty, that are used to treat problems affecting the blood vessels with the help of radiology and advanced image-guidance technology. It is a cutting-edge method as a catheter-based approach is applied on intracranial vascular diseases. A neuro-interventional procedure allows a longer time window for treatment and comparable drug effect when compared to IVT, while it allows minimal damage, recovery cycle and side effects when compared to open surgery.

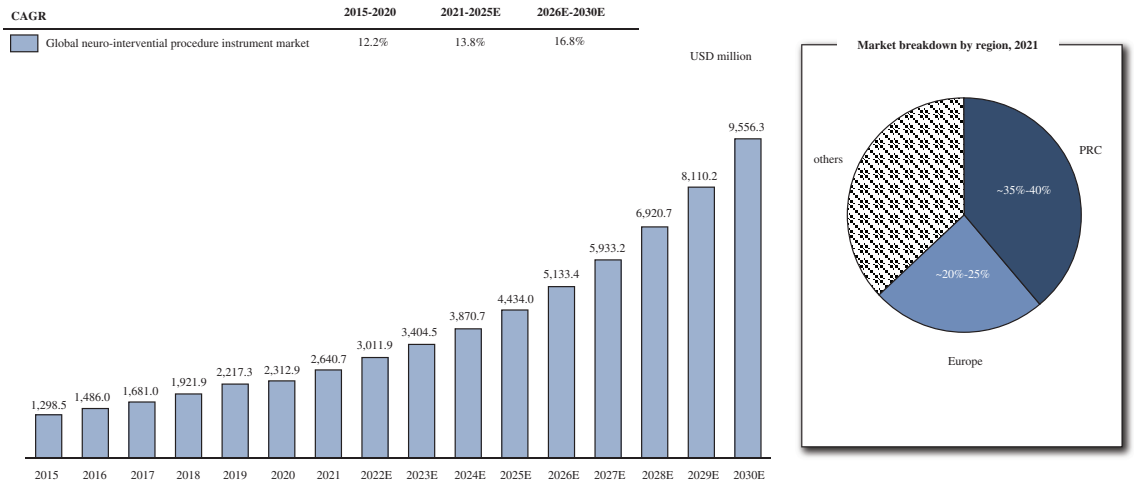
3. ***Open surgery***: the traditional type of surgery in which an incision is made using a scalpel. By opening the skull, surgeons can find the diseased vessels visually and do operations on them directly.

Stent retrieving thrombectomy serves as the first-line neuro-interventional treatment for acute ischemic stroke, while aspiration thrombectomy is experiencing fast development in recent years with great efficacy, according to the CIC Report. Neuro artery stenting serves as an important treatment for intracranial stenosis, and drug-eluting balloon as well as drug-eluting stenting are anticipated to experience fast development in the future.

Market overview

According to the CIC Report, the global neuro-interventional instrument market in terms of sale value has grown from US$1,298.5 million in 2015 to US$2,640.7 million in 2021, and is expected to continue growing to US$4,434.0 million in 2025, representing a CAGR of 13.8% from 2021 to 2025, and further grow to US$9,556.3 million in 2030, representing a CAGR of 16.8% from 2026 to 2030. In 2021, each of the PRC and Europe represented approximately 35%-40% and 20%-25% of the global neuro-interventional instrument market, respectively.

Global market size of Neuro interventional instrument market, in terms of sales value*, 2015-2030E



Source: China Insights Industry Consultancy Limited, expert interviews and public information

Growth drivers and future trends

In view of the above, there are four primary growth drivers and future trends that can be seen of the global neuro-interventional instrument market:

1. ***Increasing prevalence of stroke***: stroke is an age-related disease with an increasing prevalence for the elderly group. Considering the trend of aging population globally, it is expected that an increasing number of patients will suffer from stroke in the future.

2. ***Increasing number and penetration of neuro-interventional procedures***: with more innovative neuro-interventional procedures developed for various indications, doctors and patients will have a wider range of choices, resulting in an increasing number of neuro-interventional procedures. Despite the currently limited number of physicians capable of performing the procedures, more physicians will be trained to meet the large patient demand, allowing the neuro-interventional procedures to become a common clinical practice.

3. ***Continuous product improvement and innovation***: neuro-interventional procedure devices are typically high-end medical instruments, representing technological advances, transforming the way of clinical care with innovation. For example, smaller incisions could reduce surgical trauma and shorten recovery time for patients. The emergence and iteration of neuro-interventional medical devices will promote the development of global neuro-interventional medical device market.

4. ***Advances in imaging techniques may improve access to vascular interventional therapy***: in recent years, with the development of imaging technology and its increasing application in clinical practice, the intravascular environment can be better seen and the detection rate of vascular diseases (such as unruptured intracranial aneurysms, intermittent claudication, and threatening limb ischemia) can be improved. In addition, technological innovations such as ischemic penumbra have provided the basis for early stroke screening and prevention, resulting in the discovery of more eligible patients at high risk of stroke and the expansion of the patient population. As the use of AI algorithms increases, back-end automation of imaging systems and analytics software will accelerate in the coming years and help doctors achieve more efficient diagnoses.

Threats and Challenges

The major threats and challenges of the global neuro-interventional instrument market primarily include:

Uncertainties in macro-control: In certain countries, such as the PRC, the government regards precision medical products as a key development area and considers it to be a national development strategy. For example, the Chinese government's policies in the medical field related to people's livelihood and health are very strong, which may have a great impact on the income and profit of the investors. It is not ruled out that the government will introduce restrictive policies for the industry due to economic factors, political factors, macro-control and other factors. If the government's policies and regulations on the management of medical institutions are strict and not biased, it will cause policy risks.

Lack of core competitiveness: Although the R&D investment of enterprises in neuro intervention industry is increasing year by year, the R&D investment of new enterprises is far less than that of large multinational corporations due to the limited operating income of the new enterprises. The low R&D investment may have negative impact on the quality of products and the core competitiveness of the new enterprise.

Major Entry barriers

The major entry barriers for new participants of the global neuro-interventional instrument market primarily include:

Product portfolio and solutions: Different procedures require various types and specifications of neuro-interventional medical devices. New entrants may not be able to compete with other market players in terms of synergies for R&D, manufacturing and commercialization capabilities and economies of scale, and therefore cannot offer a comprehensive product portfolio to meet the various needs.

Registration and regulatory requirements: In certain countries, such as the PRC, Class III neuro-interventional medical devices generally require product registration testing and clinical trials if they are not exempted from clinical trials under the catalog published by the NMPA. Rigorous registration standards on safety and efficacy are implemented to regulate the development and commercialization of these medical devices. Furthermore, the product development and registration process may take up to five years and neuro-interventional medical device manufacturers need to obtain manufacturing licenses and to maintain strict compliance with GMP requirements and other various regulations in the PRC. As a result, registration and regulatory requirements in relevant jurisdictions would become entry barriers for new entrants in the market.

Heavy capital investment: Participation in the global neuro-intervention instrument market requires heavy capital investment. Costs of research and development of neuro-interventional instrument products, enhancement of product quality and performance, brand promotion and marketing channel construction, establishing factories which enable mass production at a strict quality standard all require significant capital expenditure and investments. Particularly, a large amount of capital is necessary if the players hope to survive and continuously expand in this industry. Financial pressure is an inevitable challenge for most of the medical device startups in their initial years before they can break even, and it can take substantial time to achieve profitability. Attracting sufficient investments and utilizing the funds effectively and efficiently are practically hard to fulfill, presenting a huge barrier especially for new entrants in the market.

OVERVIEW OF STRUCTURAL HEART DISEASE INTERVENTIONAL PROCEDURAL INSTRUMENT MARKET

Overview of structural heart disease

Structural heart disease refers to physical and physiological changes to the heart caused by anatomical abnormalities of the heat tissues or valves. Many structural heart diseases are present at birth (i.e. congenital), whilst others develop later in life. Types of structural heart disease include valvular heart disease (stenosis or regurgitation of the heart valves), congenital heart disease, heart failure, cardiomyopathy and ventricular abnormalities. Regional variation in the prevalence of valvular heart disease is apparent. For example, screening studies in populations of older individuals have demonstrated a prevalence of moderate or severe tricuspid regurgitation of 2.7% in the UK and 1.1% in the PRC.

1. Tricuspid valve disease

Prevalence of tricuspid regurgitation and tricuspid stenosis in the PRC, Japan and the APAC region has been steadily increasing, and is expected to continue to increase. Tricuspid regurgitation prevalence in the PRC was 9.5 million in 2015, rising to 11.7 million in 2021, and is expected to increase to 15.2 million in 2030; tricuspid stenosis prevalence in the PRC was 0.2 million in 2015, rising to 0.3 million in 2021, and is expected to maintain at 0.3 million in 2030. Tricuspid regurgitation prevalence in Japan was 0.6 million in 2015, rising to 0.7

million in 2021, and is expected to increase to 0.8 million in 2030; tricuspid stenosis prevalence in Japan was 0.4 million in 2015, rising to 0.5 million in 2021, and is expected to maintain at 0.5 million in 2030. Tricuspid regurgitation prevalence in APAC region was 4.4 million in 2015, rising to 5.2 million in 2021, and is expected to increase to 6.6 million in 2030; tricuspid stenosis prevalence in APAC region was 3.1 million in 2015, rising to 3.7 million in 2021, and is expected to increase to 4.6 million in 2030.

2. Mitral valve disease

Prevalence of mitral regurgitation and mitral stenosis in the PRC, Japan and the APAC region has been steadily increasing, and is expected to continue to increase. Mitral regurgitation prevalence in the PRC was 8.6 million in 2015, rising to 10.5 million in 2021, and is expected to increase to 13.5 million in 2030; mitral stenosis prevalence in the PRC was 0.6 million in 2015, rising to 0.8 million in 2021, and is expected to increase to 1.0 million in 2030. Mitral regurgitation prevalence in Japan was 2.2 million in 2015, rising to 2.4 million in 2021, and is expected to increase to 2.6 million in 2030; mitral stenosis prevalence in Japan was 0.1 million in 2015, maintained at 0.1 million in 2021, and is expected to increase to 0.2 million in 2030. Mitral regurgitation prevalence in APAC region was 14.9 million in 2015, rising to 17.8 million in 2021, and is expected to increase to 22.5 million in 2030; mitral stenosis prevalence in APAC region was 0.9 million in 2015, rising to 1.1 million in 2021, and is expected to increase to 1.3 million in 2030.

3. Aortic valve disease

Prevalence of aortic regurgitation and aortic stenosis in the PRC, Japan and the APAC region has been steadily increasing, and is expected to continue to increase. Aortic regurgitation prevalence in the PRC was 11.4 million in 2015, rising to 14.0 million in 2021, and is expected to increase to 18.0 million in 2030; aortic stenosis prevalence in the PRC was 0.5 million in 2015, rising to 0.6 million in 2021, and is expected to increase to 0.8 million in 2030. Aortic regurgitation prevalence in Japan was 0.6 million in 2015, rising to 0.7 million in 2021, and is expected to increase to 0.8 million in 2030; aortic stenosis prevalence in Japan was 0.5 million in 2015, rising to 0.6 million in 2021, and is expected to maintain at 0.6 million in 2030. Aortic regurgitation prevalence in APAC region was 4.4 million in 2015, rising to 5.2 million in 2021, and is expected to increase to 6.6 million in 2030; aortic stenosis prevalence in APAC region was 3.5 million in 2015, rising to 4.2 million in 2021, and is expected to increase to 5.3 million in 2030.

Treatment for Structural Heart Disease

There are three primary methods of treating structural heart diseases, namely:

1. ***Medication therapy***: drugs such as inhibitors, antibiotics, anticoagulants, beta-blockers, diuretics and vasodilators are administered to increase the heart's pumping ability, control irregular heartbeats, relieve cardiovascular discomfort and prevent blood clots. It is suitable for patients with very mild heart disease, or where surgery is unsuitable.

2. ***Transcatheter intervention***: minimally invasive procedures that involve the implantation of medical devices in the patient's blood vessels, such as transcatheter tricuspid valve replacement (TTVR), transcatheter mitral valve replacement (TMVR), transcatheter aortic valve replacement (TAVR), transcatheter mitral valve implantation (TMVI), percutaneous pulmonary valve implantation (PPVI), and transcatheter edge-to-edge mitral valve repair (TEER). It is suitable for high-risk patients with valvular or congenital heart diseases.

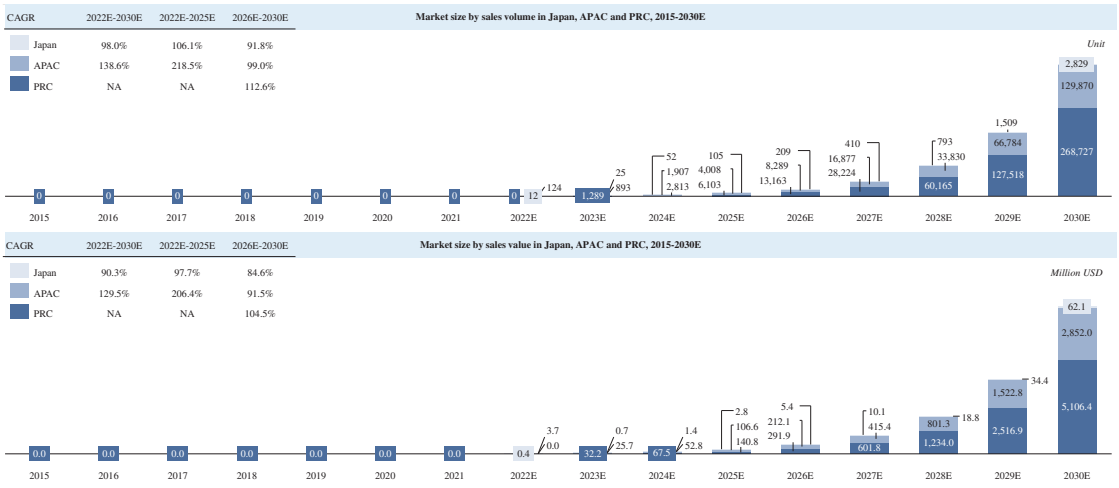
3. ***Open-heart surgery***: an invasive procedure where surgery will be conducted under general anesthetic, and patients will be placed on a cardiopulmonary bypass machine, which will temporarily act as the patient's heart and lungs whilst surgery is being performed. This method is suitable for patients with more advanced stage of heart disease with severe symptoms.

Valve Replacement Market overview

1. Transcatheter Tricuspid Valve Replacement (TTVR)

According to the CIC Report, it is expected that the first tricuspid replacement interventional surgical device in the PRC will be launched in 2023, reaching an expected sales volume of 1,289 units that year, growing exponentially to 6,103 by 2025 and 268,727 by 2030, representing a CAGR of 112.6% from 2026 to 2030, translating to US$32.2 million in terms of market size by sales value in the PRC in 2023, and rising to US$140.8 million by 2025 and US$5,106.4 million by 2030. According to the CIC Report, it is expected that the first tricuspid replacement interventional surgical device in Japan will be launched in 2022, reaching an expected sales volume of 12 units that year, growing exponentially to 105 units by 2025 and 2,829 units by 2030, representing a CAGR of 106.1% from 2022 to 2025 and 91.8% from 2026 to 2030, translating to US$0.4 million in terms of market size by sales value in Japan in 2022, and rising to US$2.8 million by 2025 and US$62.1 million by 2030. According to the CIC Report, it is expected that the first tricuspid replacement interventional surgical device in APAC region will be launched in 2022, reaching an expected sales volume of 124 units that year, growing exponentially to 4,008 by 2025 and 129,870 by 2030, representing a CAGR of 218.5% from 2022 to 2025 and 99.0% from 2026 to 2030, translating to US$3.7 million in terms of market size by sales value in APAC region in 2022, and rising to US$106.6 million by 2025 and US$2,852.0 million by 2030.

Japan, APAC and PRC market size of transcatheter tricuspid valve replacement surgical device



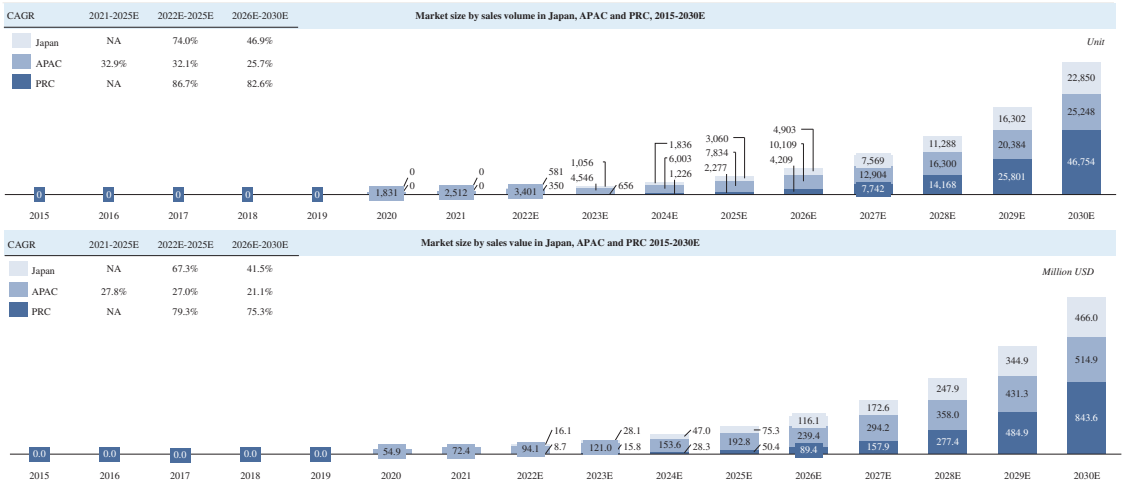
Source: China Insights Industry Consultancy Limited, expert interviews and public information

TricValve® Transcatheter Bicaval Valves is a system of two self-expanding biological valves for the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux. The prostheses are implanted percutaneously into the inferior and superior vena cava without disturbing the native tricuspid valve. It is especially intended for use for patients at extreme risk or who are inoperable for open surgical therapy. TricValve® Transcatheter Bicaval Valves System is a method to address tricuspid regurgitation and caval reflux without disturbing the natural tricuspid valve. TricValve® Transcatheter Bicaval Valves System is the only CAVAL valve implantation available and has received CE Mark. As of the Latest Practicable Date, there is no other TTVR product approved for commercialization globally.

2. Transcatheter Mitral Valve Replacement (TMVR)

According to the CIC Report, the first mitral valve replacement interventional surgical device in the PRC is expected to be launched in 2022, reaching a sales volume of 350 units that year, and is expected to grow exponentially to 2,277 units by 2025 and 46,754 units by 2030, representing a CAGR of 86.7% from 2022 to 2025 and 82.6% from 2026 to 2030, translating to US$8.7 million in terms of market size by sales value in the PRC in 2022, rising to US$50.4 million by 2025 and US$843.6 million by 2030. According to the CIC Report, the first mitral valve replacement interventional surgical device in Japan is expected to be launched in 2022, reaching a sales volume of 581 units that year, and is expected to grow exponentially to 3,060 units by 2025 and 22,850 units by 2030, representing a CAGR of 74.0% from 2022 to 2025 and 46.9% from 2026 to 2030, translating to US$16.1 million in terms of market size by sales value in Japan in 2022, rising to US$75.3 million by 2025 and US$466.0 million by 2030. According to the CIC Report, the first mitral valve replacement interventional surgical device in APAC region was launched in 2020, reaching a sales volume of 1,831 units that year, and is expected to grow exponentially to 7,834 units by 2025 and 25,248 units by 2030, representing a CAGR of 32.9% from 2021 to 2025 and 25.7% from 2026 to 2030, translating to US$54.9 million in terms of market size by sales value in APAC region in 2020, rising to US$192.8 million by 2025 and US$514.9 million by 2030.

Japan, APAC and PRC market size of transcatheter mitral valve replacement surgical device

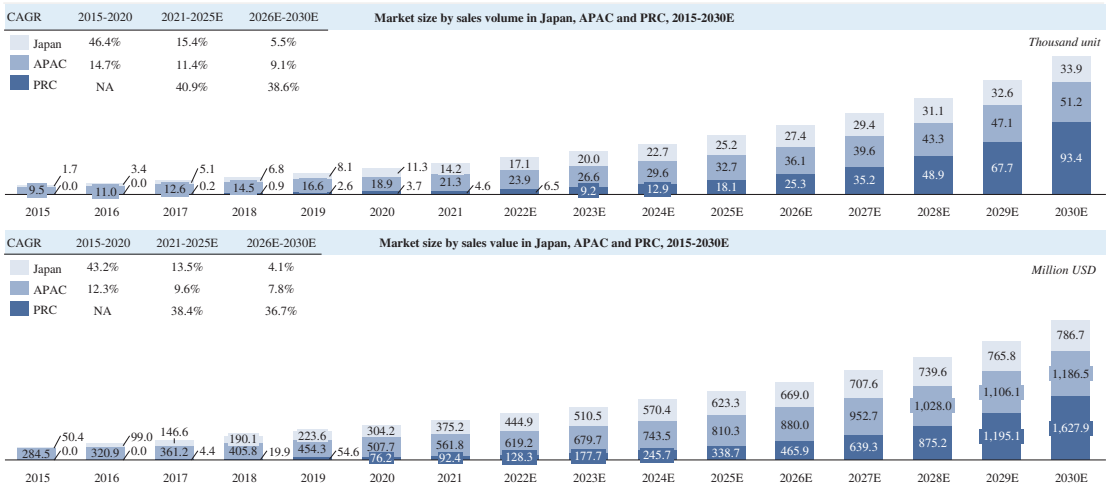


Source: China Insights Industry Consultancy Limited, expert interviews and public information

3. Transcatheter Aortic Valve Replacement (TAVR)

According to the CIC Report, the aortic replacement interventional surgical device market in the PRC has grown steadily from 200 units in 2017 to 4,600 in 2021, and is expected to reach 93,400 by 2030, translating to US$4.4 million in terms of market size by sales value in the PRC in 2017, rising to US$92.4 million in 2021 and further to US$1,627.9 million by 2030. The aortic replacement interventional surgical device market in Japan has grown steadily from 1,700 units in 2015 to 14,200 in 2021, and is expected to reach 33,900 by 2030, translating to US$50.4 million in terms of market size by sales value in Japan in 2015, rising to US$375.2 million in 2021 and further to US$786.7 million by 2030. According to the CIC Report, the aortic replacement interventional surgical device market in APAC region has grown steadily from 9,484 units in 2015 to 21,300 in 2021, and is expected to reach 51,200 by 2030, translating to US$284.5 million in terms of market size by sales value in APAC region in 2015, rising to US$561.8 million in 2021 and further to US$1,186.5 million by 2030.

Japan, APAC and PRC market size of transcatheter aortic valve replacement surgical device



Source: China Insights Industry Consultancy Limited, expert interviews and public information

Growth drivers and future trends

In view of the above, there are three primary growth drivers and future trends that can be seen of the structural heart interventional surgery market:

1. ***Aging population with high prevalence of cardiac disease***: structural heart disease prevalence is directly related with increasing age, and in particular, valvular diseases have high mortality rate. The aging population is expected to drive demand for interventional surgery.

2. ***Improvement of bio-valve technology***: with technological and medical advancements in bio-valve technology and more market education, the market share of bio-valve devices in the PRC is expected to increase gradually.

3. ***Emerging interventional procedure*** : constant improvement and innovation of structural heart interventional treatment medical devices is expected to drive the development of this industry in the global market.

Threats and Challenges

The major threats and challenges of the global structural heart disease interventional instrument market primarily include:

Patient acceptance and pricing: The risk awareness of structural heart disease is still in an early stages to the public, and it may be difficult for patients to accept even the world's leading technology products immediately. The pricing of the commercialized heart valve products is considered expensive to most of the patients, and therefore how to adjust the price to a widely accepted range becomes a challenge to the industry.

Lifetime rejection reaction: Patients who went through transcathter valve replacement surgeries usually would experience rejection reactions, and are required to take anti-rejection medications throughout lifetime. The improvement of valve designs and materials can reduce the rejection reactions. Thus, it is a challenge for companies to design and produce artificial valve products with reduced rejection reactions.

Major Entry barriers

The major entry barriers for new participants of the global structural heart disease interventional instrument market primarily include:

Intensive technology and continuous product innovation: Multi-disciplinary expertise in material and mechanical engineering, product design and manufacturing are highly demanded in structure heart interventional instrument industry. The complexity of heart and heart valve required highly sophisticated and precision interventional instruments. Difficulty to New entrants may generally find it difficult to hire professionals and acquire the technologies in a short term.

Heavy capital investment: Costs of R&D on structural heart interventional instrument are heavy, which are mainly for the enhancement of product quality and performance, payment to the professional developers and laboratory in the long term, brand promotion and marketing channel construction all need fund to a significant extent. If a manufacturer hopes to survive and subsequently expand in this industry, financial pressure is an inevitable challenge for most of them especially in the initial years before finally breaking even. Attracting sufficient investments and arranging the funds effectively and efficiently are practically hard to fulfill for new entrants.

PRICE TRENDS OF MAJOR RAW MATERIALS AND PRICE TREND

Major Raw Materials

The key raw materials used in producing our balloon and stent products are medical grade stainless steel, polyester and nylon. Fluctuations in prices of these raw materials may be affected by the cost structure, product pricing and profitability of balloon and stent market players.

The average price of medical grade stainless steel in the PRC was approximately RMB15.2 per kilogram, RMB15.6 per kilogram, RMB15.1 per kilogram, RMB14.3 per kilogram and RMB14.9 per kilogram in 2017, 2018, 2019, 2020 and 2021, respectively. Over the past five years, the average price of medical grade stainless steel in the PRC has been fluctuating, yet the price is demonstrating a growing trend overall. The average price of medical grade stainless steel is expected to increase to RMB16.6 per kilogram in 2025.

The average price of polyester in the PRC was approximately RMB7.9 per kilogram, RMB9.2 per kilogram, RMB7.6 per kilogram, RMB5.4 per kilogram and RMB5.6 per kilogram in 2017, 2018, 2019, 2020 and 2021, respectively. Over the past five years, the average price of polyester in the PRC has been fluctuating, yet it demonstrates a gradual downward trend overall. The average price of polyester is expected to decrease to RMB4.2 per kilogram in 2025.

The average price of nylon in the PRC was approximately RMB17.8 per kilogram, RMB18.1 per kilogram, RMB14.1 per kilogram, RMB11.6 per kilogram and RMB13.1 per kilogram in 2017, 2018, 2019, 2020 and 2021, respectively. Over the past five years, the average price of nylon in the PRC has been fluctuating, but exhibits a gradual downward trend. The average price of nylon is expected to decrease to RMB10.2 per kilogram in 2025.

PRICE TREND OF BALLOONS AND STENTS

According to CIC Report, the average price of same model of standard PCI balloons is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch. In light of advances in technology and more medical device manufacturers entering into this market, the price of same model balloon will demonstrate a gradual downward trend in the future and new or more advanced generation of products will enjoy a higher average selling price.

According to CIC Report, the average price of same model of standard PTA balloons is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch.

The average price of same model of drug eluting stent is generally expected to decrease over time at approximately 2% per annum after its commercialization and product launch. In light of advances in technology and more medical device manufacturers entering into this market, the price of same model stent will demonstrate a gradual downward trend in the future and new or more advanced generation of products will enjoy a higher average selling price.

Our products are medical devices subject to extensive regulation in the markets in which we operate, and such regulations vary from jurisdiction to jurisdiction. The following section sets out summaries of certain relevant laws, regulations and requirements that we are subject to in the key jurisdictions in which we operate.

EU REGULATORY OVERVIEW

Medical devices can be commercialized in the member states of the European Economic Area ("**EEA**") only if they meet the following requirements and obtain CE (Conformité Européenne) Mark (including countries which have signed Mutual Recognition Agreement with EU):

(1) Regulation (EU) 2017/745 on medical devices ("**MDR**").

(2) Medical Device Directive ("**MDD**") 93/42/EEC.

On May 26, 2021, MDD was repealed and replaced by the MDR which has become a regulation versus a former directive, for the manufacturers who plan to commercialize medical devices in this region. The MDR is subject to a transition period during which manufacturers of medical devices must update their technical information and processes in line with the new MDR. During the transition period, manufacturers may elect whether to put any new medical devices under the MDD's regime or under the new MDR. Under European law, a Regulation differs from a Directive since it, as a Regulation, is directly effective in each Member State, without the need for implementing legislation (which is required for a Directive). The new Medical Devices Regulation has the same basic requirements as the EU Medical Devices Directive, but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies. There is also more emphasis on vigilance and post-market surveillance.

Device Classifications under MDD and MDR

In the EEA, based on MDD and MDR, devices are classified into Class I, Class IIa, Class IIb, and Class III. The classification is a risk-based mechanism according to the nature of human body contact and the contact duration of the medical devices. There are specific classification rules in both MDD and MDR.

Documents required for CE conformity under MDD and MDR

Generally the medical device manufacturer shall prepare the documents for device CE conformity assessment per MDD and MDR.

Under the regulatory frame of MDD, Class IIa and Class IIb devices shall have a technical file ("**TF**"). Class III device will need a design dossier ("**DD**") for the purpose of conformity assessment.

Under MDR, manufacturers of all classes will need to prepare a technical documentation ("**TD**") for the device conformity assessment.

MDD TF/DD requirements

The TF/DD shall be prepared according to the outlines in MDD with supporting documents, including a general description of the product, its intended use(s), the design specifications, the applicable standards, the pre-clinical evaluation, the clinical evaluation, the draft label and, where appropriate, instructions for use. Normally the notified body ("**NB**"), which is a third-party auditing organization that assesses quality and conformity of medical devices, will provide a format for the TF/DD. Certain part of the TF/DD shall follow the guidance issued by European Commission, e.g. MEDDEV 2.7/1 for clinical evaluation.

MDR TD Requirements

TD under MDR shall be prepared in accordance with MDR since Date of Application on May 26, 2021. Technical Documentation includes both pre-market and post market sections, the detail content requirements are listed in the Annex II and Annex III of MDR regulation (Regulation (EU) no. 2017/745).

Assessment of Conformity

Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet regulatory requirements to ensure they are safe and perform as intended. EU Member States can designate accredited notified bodies to conduct conformity assessments. For example, British Standards Institute, and TÜV SUD are accredited notified bodies. The conformity assessment procedures are outlined in both MDD and MDR. After May 26, 2021, the medical device conformity assessment shall follow the procedures per Section 2 of Chapter V in MDR according to the classification and device specialties. The manufacturer of Class IIa, IIb, III medical devices and certain Class I medical devices (device with measuring function, sterile device, and reusable surgical instrument) will need to lodge with a NB to assess the conformity to MDR and other applicable regulations (e.g. Directive 2001/83/EC for medicinal products for human use) by submitting the compiled TD per the MDR. The conformity assessment procedures also call out the requirements for the manufacturer's quality system. The assessment to quality system applies to all the aforementioned devices, but varies in system functional scope for the named Class I medical devices. Class I devices other than the specified three categories do not need NB for the conformity assessment.

Administrative requirements under MDD/MDR

Many medical devices require a CE Mark before they can be sole in the EU. The CE Mark may generally only be affixed to a medical device if the product has passed the conformity assessment per the procedures outlined in MDD/MDR, and obtained the respective CE certificates (e.g. EU quality management system certificate, and EU technical documentation assessment certificate per MDR Annex IX).

The CE certificates will have a maximum validity period of 5 years. The NB will perform surveillance audit annually and unannounced audit to the manufacturer, and the suppliers and/or subcontractors, if appropriate.

If the requirements for application of the CE Mark are not (or no longer) fulfilled, or in other cases of non-compliance with applicable medical devices law:

- the Notified Body has the power to withdraw, suspend or limit the scope of the applicable certificate of conformity, in accordance with the principle of proportionality;

- the competent supervisory authority of the EU member state or contracting state of the EEA may enforce the provisions of the MDR, e.g. by preventing the product from being put on the market, ordering a recall or shutting down a manufacturing site; and

- criminal or administrative sanctions (e.g. fines) may apply.

In principle, the manufacturer is responsible to ensure compliance with applicable provisions including affixing the CE Mark to his products. If a manufacturer does not have a physical location in the EU, he is required to appoint a so called "Authorized Representative" who ensures compliance with the regulatory requirements for medical devices set out in the MDR.

Medical Device Operation and Product Quality

Among EU laws applicable to product safety, the MDR mandates a substantial increase in safety obligations of manufacturers (e.g. Article 10 and Annex I of the MDR). For instance, medical device manufacturers are generally required to have systems for risk management, quality management and post-market surveillance. Specifically, implementing and maintaining a risk management system requires identifying and analyzing any known risks and implementing solutions to eliminate or control these risks. Medical device manufacturers generally have to conduct clinical evaluations, compile technical documentation, and undertake a conformity assessment procedure. In addition, medical device manufacturers must ensure that their authorized representatives have the necessary documentation permanently available, and that the devices are accompanied by the required information. Medical device manufacturers must also have a system for recording and reporting of incidents. If there were to be a serious incident involving the products, the reporting timeline to a health authority would typically be no later than 15 days after medical device manufacturers became aware of the incident, and two days in case of serious public health threat.

The EU rules on product safety also require that the products sold in the European Economic Area (EEA) hold certifications of conformity with the relevant harmonized standards (Article 56 of the MDR). Once medical device manufacturers completed all applicable obligations, they must draw up a declaration of conformity (Articles 10 §6 and 19 of the MDR)

and apply CE marking of conformity to our devices (Articles 10 §6 and 20 of the MDR, and Article 30 of Regulation (EC) No 765/2008). The products we sell in the EU have EC certificates and CE marking. These EC certificates cover products categorized as devices in Class IIa and Class III. Any other products we would sell in the EEA and that would not be covered by these EC certificates and/or would not have CE marking would require additional EC certification and/or CE marking. Once devices are compliant with the MDR requirements, member states cannot refuse, prohibit or restrict the making available on the market or putting into service within their territory of these devices on the basis of the MDR (Article 24 of the MDR).

Advertising and Sales Activities

Legislation on advertising and promotion of medical devices is not harmonized under European law. As a result, the legal landscape differs from one EU member or contracting state to the other. However, at the EU level, medical device manufacturers are represented by MedTech Europe, who has established a code of business practice which ensures that promotional materials are fair, balanced, objective and unambiguous. In addition, all information related to a medical device including labeling, instructions for use, presentations, brochures and advertising, must be in line with the language requirements as regulated individually by each member state.

Despite not being specific to the advertising of medical devices, further European directives such as Directive 2006/114/EC concerning misleading and comparative advertising or Directive 2005/29/EC concerning unfair business-to-consumer commercial practices can also be applicable to the medical device industry. Advertising towards doctors or other healthcare professionals may be subject to an even stricter national regulatory framework, particularly including sophisticated anti-bribery and anti-corruption laws as well as criminal laws.

Product Liability

The set of product liability rules applicable to medical devices in the EEA is contained among others in the MDR, and in general product liability laws based on national laws implementing the Directive 85/374/EEC on Product Liability ("PLD") and on national laws of torts of practically all EU member states. These product liability regimes apply in parallel.

Under the MDR, medical device manufacturers must assume responsibility for compliance with all EU legal texts applicable to these devices. The MDR adds that manufacturers are responsible for their devices once they are on the market. Natural or legal persons may claim compensation for damage caused by defective devices in accordance with the applicable EU and national laws. In addition, the MDR requires medical device manufacturers to have systems in place to cover our financial responsibility in relation to our potential liability under the PLD (the PLD requirements will be presented below), without prejudice to more protective measures under national law.

The national laws implementing the PLD create a strict liability regime (i.e. without fault). Under the PLD, liability principally rests upon the "producer" of the defective product, component part or raw material. The notion of "producer" covers (i) any person who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as the producer; (ii) any importer which has imported the defective product, component or raw material into the EU market; and (iii) any supplier (e.g. the retailer, distributor or a wholesaler) if the producer cannot be identified. For the products we sell in the EU and the ones sold by our distributors in the EU, we qualify as a producer.

Liability under the PLD could be limited if medical device manufacturers can prove that the consumer's negligence caused or contributed to the damage. Liability under the PLD will expire after three years starting from the date on which the claimant became aware or reasonably could have become aware of the damage and its cause, the defect and the identity of the producer. Irrespective of knowledge, a producer's liability expires ten years from the date on which the producer put the product into circulation. National laws of torts of EU member states also provide other liability regimes which are for example fault-based (negligence). A claimant may seek to recover damages beyond the limitations mentioned above under these other regimes.

Post Market Surveillance and Vigilance

Starting from May 26, 2021, as regulated by MDR per Chapter VII, the post market surveillance (PMS) and vigilance of a medical device shall have a PMS system to actively gather and analysis the PMS data throughout the device's lifetime. Proactive PMS plan and report shall be performed at an appropriate frequency based on the device's risk-based class. For Class IIa, IIb and III medical devices, as the result of the PMS plan, a Periodic Safety Update Report ("**PSUR**") will be generated either biennially (for IIa) or annually (for IIb and III) and made available to the NB and competent authorities. The medical device manufacturers are also requested by the regulation to report serious incidents and field safety corrective actions, additionally the trend report for any statistical significant increase in the frequency or severity of the non-serious incidents. The aforementioned reporting and PSUR submission shall follow the electronic system established by European Commission.

Import Requirements

We sell our products in the EU to distributors. Under the MDR, strict requirements on manufacturers, importers and distributors of medical devices in the European Economic Area (EEA) are imposed. Failure to comply with the regulatory requirements may render medical device manufacturers to lose their marketing approvals or be subject to fines or other sanctions. Also, as a condition to granting marketing approval of a product, the applicable regulatory agencies may require a company to conduct additional clinical trials or remediate Current Good Manufacturing Practice ("cGMP") issues, the results of which could result in the subsequent loss of marketing approval, changes in product labeling or new or increased concerns about side effects or efficacy of a product. Medical device manufacturers must also have a named

person responsible for regulatory compliance, who possesses the requisite expertise in the field of medical devices. Medical device manufacturers must assign a Basic UDI-DI code to the device and provide the code to the UDI database.

It should be noted that under the MDR, an importer, distributor or any natural or legal person is the one who must assume the obligations incumbent on manufacturers if it does any of the following: (a) it makes available on the EEA market a device under its own name, registered trade name or registered trademark, except if the manufacturer agreed to be identified as such on the label and to be responsible for the MDR manufacturers obligations;(b) it changes the intended purpose of a device already placed on the market or put into service; and (c) it modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected (Article 16 of the MDR).

Our EU distributors sell our products under our company name, they do not change the intended purpose of our devices and they do not modify them in a way that affects their compliance with applicable requirements. In addition, to the best of our knowledge the activities of our customers who are end-users (e.g. hospitals) do not fall within any of the three above-mentioned categories. Therefore, our specific obligations as manufacturers under the MDR are not transferred to our distributors or end-users customers.

Intellectual Property

Each of the 27 member states of the EU has its own intellectual property law which covers the acquisition, maintenance and enforcement of intellectual property rights. Aspects of the national intellectual property laws are controlled by EU regulations, directives and treaties for harmonization purposes and to set a minimum standard. The national intellectual property laws provide for monopolies limited in time and scope with respect to, inter alia, inventions, trademarks, and works of copyright, including computer software, films and recorded music. Upon expiration of all applicable intellectual property rights, the underlying invention or work of copyright automatically becomes part of the public domain and may be freely used by the public and further developed or improved to make new inventions and new developments or works of copyright.

International treaties in the field of intellectual property set forth minimum monopoly standard levels that contracting states agree to maintain in their territory. The EU member states are members of most international intellectual property treaties and maintain standards that in some cases exceed the minimal standards set in those treaties.

It is the national intellectual property offices that have the authority to facilitate formal protection for intellectual property through the registration of patents, designs, trademarks and appellations of origin.

In parallel, some rights may also be registered with and/or managed by central offices such as the European Union Intellectual Property Office ("**EUIPO**") or the European Patent Office ("**EPO**"). In addition, certain regulations provide for the protection designations of origin, protected geographical indications and traditional specialties. Most granted rights are subject to the examination of an application. The EU does not maintain a formal copyright registry, but, to our best of knowledge, some of the member states offer a discretionary option to register copyrights.

Patents

Each of the 27 member states of the EU has its own national patent law, but there are regulations, directives and treaties to try to harmonize certain aspects of the national laws. All member states of the EU are members of the Paris Convention for the Protection of Industrial Property, members of the PCT, and members of the European Patent Convention ("**EPC**"). In general, in the EU, the owner of a patentable invention may apply to a national patent office or to the EPO for a patent.

Most Member States define a patentable invention on the basis of the EPC, which states that a patentable invention must be new, industrially applicable and based on an inventive step.

Each of these has detailed criteria under either the EPC or the national law of the member states. The EPC and the national law of the member states have adopted the "first to file" standard; if more than one applicant applied for a patent for the same invention, the patent will be granted to the applicant who first validly applied for it. The term of a patent is 20 years from the date of filing.

However, in the EU member states, Regulation (EC) No 469/2009 permits the granting of Supplementary Protection Certificates, which in practical effect extend the term of patents for specific pharmaceutical products by up to 5 years. A further six months' extension can be obtained under Regulation (EC) No 1901/2006 for certain pharmaceutical products for children.

The EU "Enforcement Directive" (2004/48/EG) provides that all EU member states must have in place injunction procedures for stopping infringements of intellectual property rights.

Environmental Protection

In the Netherlands, waste prevention and handling is regulated in the Dutch Environmental Management Act, which implements the European Union Waste Framework Directive and sector-specific EU waste legislation. Waste generated at a production site in the Netherlands has to be separated and records of waste disposal have to be kept. Non-hazardous industrial waste, such as the packaging waste from goods delivered to the site or household like waste, is generally collected by municipal authorities or can be disposed of at the drop-off point of the municipal waste disposal site. Collection or waste disposal charges are generally due. Hazardous waste has to be kept separated at all times and may only be disposed of by

surrendering it to a certified waste collector/transporter that transports the waste to an authorized processor. In addition, cross-border transport of waste is regulated by the European Union Regulation on the Transboundary Shipment of Waste. Notifications or approvals and financial security may be required for the shipment of waste, depending on the type of waste. Shipment of hazardous waste requires both prior approval of both the sending and the receiving member states and provision of financial security.

JAPAN REGULATORY OVERVIEW

Competent Authorities and Regulation

Pharmaceuticals and Medical Devices Agency ("**PMDA**") under Japan Ministry of Health, Labor and Welfare ("**MHLW**") is the regulatory agency for medical device control and approve. Placing medical device onto Japan market shall follow the Pharmaceutical and Medical Device Act. MHLW also issued series of regulations covering product classification, registration, quality system, PMS and guidances on specific product or topic, e.g. MHLW Ministerial Ordinance No. 169, 2004 for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents, Japanese Medical Device Nomenclature, and Notice No. 0401038 the standard for approval for PTCA catheter.

Medical Device classification

Medical devices are categorized as four classes, namely Class I, II, III and IV, respectively for General medical devices (Class I), controlled medical devices (Class II) and special controlled medical devices (Class III and IV).

Pharmaceutical and Medical Device Act

Manufacturers and sellers of medical devices in Japan are primarily subject to the supervision of the Minister of Health, Labor and Welfare of Japan (the "Minister") under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices of Japan (the "Pharmaceutical and Medical Device Act"). A part of the work performed under the authority of the Minister is delegated to prefectural governors.

Under the Pharmaceutical and Medical Device Act, a person who intends to conduct the business of selling, leasing or providing medical devices that are manufactured (including outsourcing the manufacturing process to a third party) or imported is required to obtain from the Minister a manufacturing and sales license that has to be renewed every five years. The Minister has the power not to grant the license if (i) the quality control methods for the Designated Products are not in conformity with the Quality Management System ("QMS") standards as stipulated by the ministerial ordinance of the Ministry of Health, Labor and Welfare of Japan (the "MHLW"); (ii) the post-sales safety control (i.e., the collection and analysis of information and data necessary for proper use, including those related to quality, effectiveness and safety, and necessary measures to be taken based on the results thereof) methods of the medical device are not in conformity with the Good Vigilance Practice

standards as stipulated by the ministerial ordinance of the MHLW; or (iii) an applicant falls under certain disqualifying provisions of the Pharmaceutical and Medical Device Act. Manufacturers and sellers that have obtained the manufacturing and sales license must appoint a qualified general manufacturing and sales supervisor to supervise product quality control and post-sales safety control. Such manufacturer and seller must also comply with various other items stipulated by the ministerial ordinances of the MHLW in the process of conducting the licensed business.

In order to conduct the business of manufacturing medical devices, the manufacturer is also required to make a renewable, five-year manufacturing registration with the Minister for each manufacturing site, which is classified in accordance with the ministerial ordinance of the MHLW. The Minister has the power not to register the manufacturing site if an applicant falls under certain disqualifying provisions of the Pharmaceutical and Medical Device Act.

In addition, the manufacture or sale of medical devices requires (i) product approval from the Minister, (ii) third party certification or (iii) registration for each kind of product, depending on the type of the medical device.

If any manufacturing and sales license holder becomes aware of matters concerning the effectiveness and safety prescribed by the ministerial ordinance of the MHLW, such as an alleged harm due to a defect in the medical device or an infection occurring from use of the medical device, the manufacturing and sales license holder must notify the Minister in accordance with the ministerial ordinance of the MHLW. Subject to the severity of the incident, the notification must generally be made within 15 or 30 days of the license holder becoming aware of the incident.

Furthermore, under the Pharmaceutical and Medical Device Act, the Minister or a prefectural governor may take various measures to monitor the activities of licensed manufacturers and sellers. For example, if deemed necessary to monitor their compliance with the laws and regulations, the Minister or a prefectural governor may require licensed manufacturers and sellers of medical devices to submit reports or carry out inspections at their factories or offices. The Minister has the power to order licensed manufacturers and sellers to temporarily suspend the selling, leasing or providing the medical devices in order to prevent or mitigate any risks to public health. Further, the Minister may revoke a license granted to or registration made by a manufacturing and sales license holder, or order a temporary business suspension under certain limited circumstances such as the violation of laws relating to medical devices.

Registration and Marketing of Medical Device

In relation to medical devices to be placed on Japan market, there are two types of licenses: (i) a business license and (ii) a license for a product, in Japanese regulation on medical devices.

With respect to the business license, a company who intends to engage in the business of manufacturing medical devices must obtain registration for each manufacturing facility (a company who intends to manufacture medical devices in a foreign country and export such medical devices to Japan must obtain registration as a Foreign Manufacturer of Medical Devices for each manufacturing facility). Our Group has obtained a Registration Certificate for Manufacturing Medical Devices for the manufacturing of medical devices in Japan.

In addition, a company who intends to engage in the business of marketing medical devices must obtain a marketing license in accordance with the criteria for medical devices set forth in the following table:

Criteria for medical devices	**Criteria for license**
Specially-controlled medical devices	First-class marketing license for medical devices
Controlled medical devices	Second-class marketing license for medical devices
General medical devices	Third-class marketing license for medical devices

With respect to the license for a product, a company who intends to market medical devices must make a notification (todokede), or obtain certification (ninsho) or marketing approval (shonin) for each product, depending on the class of the product (with respect to medical devices to be manufactured in foreign countries and exported to Japan, a Foreign Manufacturer of Medical Devices (which is referred to as a "person with special approval for foreign-manufactured medical devices"), instead of the marketer, can (and is not obliged to) apply for the marketing authorization of such product, but the marketing authorization will belong to the marketer (which is referred to as a "designated holder of marketing authorization for foreign-manufactured medical devices") appointed by such applicant even in such case). Our Group has obtained a First-Class Marketing License for Medical Devices (第一種醫療機器製造販売業許可證), a Sales License for Specially Controlled Medical Devices, etc. (高度管理醫療機器等販売業許可證) issued by Ohta-ku and a Sales License for Specially Controlled Medical Devices, etc. (高度管理醫療機器等販売業許可證) issued by Shibuya-ku for its sales and marketing activities of medical devices in Japan.

U.S. REGULATORY OVERVIEW

The U.S. Food and Drug Administration's Regulation of Medical Devices

In the United States, the Food and Drug Administration (FDA) regulates medical devices under the Federal Food, Drug, and Cosmetic Act ("**FDCA**") and its implementing regulations.

I. Classification of Medical Device in the U.S.

Medical devices are classified as Class I, Class II and Class III in the U.S. based on elevated risks from general control and special control to premarket approval. The regulatory requirements varies per the product class. In U.S. Code of Federal Regulation, Part 21 (Title 21 CFR) sets the classification regulations and the corresponding controls by product group from Part 862 (clinical chemistry and clinical toxicology devices) through Part 892 (radiology devices).

Class I devices possess minimal potential risk for patients and are comparatively simpler in design than Class II and Class II devices. Due to the lowest risk Class I devices pose to patients, they are typically subject only to FDA's general control provisions such as device registration and listing; prohibition against adulteration and misbranding; notification and repair, replacement and refund; record keeping; unique device identifiers and device tracking, as applicable; adverse event and other reporting; Good Manufacturing Practice requirements embodied in FDA's Quality System Regulation ("QSR"); and in limited instances, premarket notification.

Class II devices possess risk level between Class I and Class III; most medical devices are Class II devices. Class II devices are devices which the abovesaid general controls are not sufficient to ensure their safety and effectiveness. The FDCA imposes special controls on top of general controls. Special controls are usually device-specific, and include performance standards, post market surveillance, patient registries, special labelling requirements, and pre market data requirements. Class II devices are usually subject to premarket notification requirements (i.e. 510(k) clearance). Our JADE NC Balloon Catheter and Scoreflex PTA BTK scoring balloon, for example, are Class II devices.

Class III devices possess the highest risk level to patients, they are usually devices used to sustain or support life, implants and can present potential unreasonable risks of illness and injury. General controls in the abovesaid cannot ensure the saety and effectiveness of Class III devices. Class III devices are subject to premarket approval requirements. For example, our TricValve and Sapphire 3 Semi compliant balloon are Class III devices.

FDA also provide an online classification database to allow the users to identify the product classification by product general name. The database will return the classification, the corresponding regulation number and submission type.

II. FDA Regulatory Regime

The FDA has three levels of clearance for medical devices; 510(k), premarket approval and the De Novo Pathway, each of which needs specific criteria to be fulfilled in order to be granted. Such three levels of clearance and their respective criteria are summarized as below:

Level of FDA Clearance	**Description**
510(k) Clearance	A 510(k) clearance is granted when it has been shown to be at least as safe and effective as another similar, legally marketed medical device. The submitter seeking this clearance must provide substantial proof of equivalence in their application. Without an approval of being substantially equivalent to the other medical device, the one pending approval cannot be legally marketed.
Premarket Approval "**PMA**"	Premarket approval is issued to Class III medical devices which have a large impact on human health and as such, their evaluation undergo more thorough scientific and regulatory processes to determine their safety and effectiveness. In order to approve an application, the FDA determines that the device's safety and effectiveness is supported by satisfactory scientific evidence. Upon approval, the applicant can proceed with commercialization of the product.
De Novo Pathway	Regarding the de novo classification, it is used to classify those novel medical devices for which there are no legally commercialized counterparts, but which offer adequate safety and effectiveness with general controls. The FDA performs a risk based assessment of the device in question before approval and allowing the device to be commercialized.

Investigational Device Exemption

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempted, must have approved IDEs before any study can be initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by the FDA;

- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study; and
- required records and reports.

Breakthrough Device Program

The Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for 510(k) clearance, premarket approval, and De Novo marketing authorization, in order to protect and promote public health.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Our TricValve was designated as a "breakthrough device" by the FDA in December 2020 as it provides for more effective treatment in irreversibly debilitating human conditions and offers significant advantages over existing approved or cleared alternative medical devices. The designation also indicates that the product represents breakthrough technology and its availability is in the best interest of patients. After the designation, the product was entitled to an expedited process of the development, assessment, and review by the FDA.

III. Regulatory pathway for Medical Device in the U.S.

Generally speaking most of Class I medical devices are subject to general control, and can be put into market after establishment registration and device listing. Most of Class II medical devices will need a 510(k) notification to FDA, and after the receipt of the 510(k) clearance, the product can be put into market on the basis of fulfilling the other special control requirements outlined in Title 21 CFR. Normally Class III device will need Premarket Approval from FDA.

General controls usually include device registration and listing, Good Manufacturing Practice requirements embodied in Part 820 Quality System Regulation ("**QSR**") of Title 21 CFR. Special controls, per Title 21 CFR, include device specific performance standards, postmarket surveillance, patient registries, special labeling requirements, and premarket data requirements.

For instance, per regulation 870.5100 of Title 21 CFR, a standard Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter is classified as Class II. The special control for this device is "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty ("**PTCA**") Catheters." While per the same regulation, a Cutting/scoring PTCA Catheter is classified as Class III, and will need approval before commercial distribution.

IV. Pre-Clinical and/or Clinical Evaluations

The marketing authorization for medical devices requires a developer of the medical device in development to prepare information and data demonstrating the device's safety and effectiveness. Certain devices, such as implantable devices, their safety and effectiveness may need to be demonstrated through clinical evaluations. When conducting clinical evaluations, the manufactuerers, sponsors, clinical investigators and institutional review boards are subject to the FDA regulation known as the Good Clinical Practices, and various regulations regarding gnformed consent (21.C.F.R.50) responsibilities of Institutional Review Boards ("IRBs") (21 C.F.R. 56), certain disclosure requirements for clinical investigators (21 C.F.R. 54), and regulatory requirements for Investigational Devices (21 C.F.R. 812) need to be complied with.

Investigational Device Exemptions

Before starting clinical evaluations, the FDA may request the sponsors to submit IDE applications, usually when there is a significant risk device that will be used in the clinical studies, or when the clinical study is exempt from the informed consent requirement or if the FDA deemed necessary otherwise. A significant risk device is a device that is intended to be used as an implant, or a device to be used in supporting or sustaining human life, or a device intended to be used with substantial importance in diagnosing, curing, mitigating, or treating disease; or otherwise a device which can prevent impairment of human health; and therefore possesses the potentially serious risks to the health, safety and welfare of the test subject. If the FDA requires the sponsors to submit an IDE application, then the clinical study cannot proceed until the FDA has approved the IDE application. Vice versa, if a device to be studies is not a significant risk device, then an FDA's review of the IDE application will not be necessary. If the sponsors or investigators want to make changes to the investigation plan that may affect its scientific soundness; study indication; or the rights, safety, or welfare of human subjects, IDE supplements must be submitted to and approved by the FDA.

The FDA may disapprove and deny an IDE application upon review if the FDA has reasons to believe that the risks to the test subjects outweigh the anticipated benefits to the test subjects or the data and information to be collected or gained. The FDA can disapprove and deny an IDE application if it believes there isn't adequate informed consent, the clinical studies are scientifically unsound, or it questions the safety and the effectiveness of the devices. The FDA can also disapprove and deny an IDE application if the sponsors fail to respond to the FDA's requests for additional information, if there is/are untrue statement(s) of material facts or omission of material facts in the application, or the FDA has other concerns in general.

Clinical Studies for Medical Devices

There are several types of clinical studies that may be needed to demonstrate the safety and effectiveness of a medical device in development; they are early feasibility studies, traditional feasibility studies and pivotal studies.

An early feasibility study is a limited clinical investigation of a medical device before non-clinical testing can be used, or information is lacking for advancing the development process. Early feasibility studies are designed to test specific indications, for example, to test an innovative device for a new or existing intended use, or a commercialized device for a new clinical application, and usually involve limited number of test subjects, typically less than ten. A traditional feasibility study aims to provide preliminary safety and effectiveness information or data on a final or near-final product design, for the purpose of preparing for a pivotal study. A traditional feasibility study does not necessarily need to be preceded by an early feasibility study. A pivotal study is a clinical study that is design to provide definitive evidence of a device's safety and effectiveness for its specific indication. Pivotal studies are usually conducted on a statistically justified testing group size. A pivotal study may or may not be preceded by a traditional feasibility test.

The sponsors may start the clinical studies 30 days after the FDA receives the IDE application, but sponsors cannot proceed with the clinical studies if the FDA notifies the sponsor of any delay.

Informed Consent Requirement

Given the fact that many devices used in the abovementioned clinical studies have not previously been approved by the FDA for its safety and effectiveness, most FDA regulations require informed consent from test subjects so to ensure that the subjects are fully aware of the potential risks involved with participating in the clinical study along with other necessary information. FDA regulations require the investigator of a clinical investigations to obtain legally effective informed consent from the test subjects before the investigation can begin. Although there are exemptions from the informed consent requirement, it is still required for most clinical investigations.

Institutional Review Boards (IRBs)

IRBs are designated to ensure, in advance and periodically, that appropriate measures are taken to protect the rights, safety and welfare of humans subjects in a research. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. IRBs use a group process to review research protocols and related materials (e.g., the informed consent documents referenced above) and they must monitor and review an investigation throughout the clinical study. If an IRB decides that a clinical investigation involves a significant risk device, then it must inform the investigator and the sponsor if necessary. The sponsor may not proceed with the investigation until the FDA has approved it.

FDA regulations govern that IRBs are group of professionals that has been engage to review and monitor biomedical research on human subjects. IRBs have to be registered. IRBs must fully comply with all applicable IRB regulation requirements. The FDA does periodic inspections of the IRB's records and procedures to determine compliance with the regulations.

V. U.S. Pricing and Reimbursement

Sales of medical devices in the U.S. market, will depend, in part, on their coverage by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Therefore, pricing of our products are predominately subject to market forces.

The Patient Protection and Affordable Care Act (ACA) came into effect in 2010. The ACA intends to widen the coverage of health insurance, including for at least a portion of drug costs, through the combination of insurance market reforms, an expansion of Medicaid and its subsidies. The ACA has many provisions designed to generate the enough revenues to fund the expanding coverage and to lower the costs of Medicare and Medicaid. The ACA also included provisions that created programs requiring all individuals to have health insurance with limited exceptions, and imposed increased taxes, shifting the industry to value-based care. One of these taxes is a 2.3% excise tax on United States sales of most medical devices.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act of 2011, as amended, resulted in the imposition of 2% deductions in Medicare (but not Medicaid) payments to providers in 2013 and, except for a suspension from May 1, 2020 through December 31, 2020, will remain in effect through 2030 unless additional Congressional action is taken. Significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

VI. Quality system and Post-market Requirements

Quality System Regulation

Putting a medical device onto the U.S. market, from a manufacturer perspective, is legally bonded with quality system compliance to Part 820 of Title 21 CFR, the QSR. Similar as ISO13485 but as a high level regulation, QSR covers the typical operation functions including design control, document control, purchasing control, production and process control and etc. All the applicable requirements shall be fulfilled according to the functions of the entity for the marketed devices.

As one of the initiator of Medical Device Single Audit Program ("MDSAP"), FDA accepts compliance to the QSR if the manufacturer passes the MDSAP audit.

Factory inspection for Quality system compliance

FDA performs on-site inspection of factories if necessary. FDA categorizes the results of its on-site inspection as follows:

- No action indicator ("**NAI**") which means no observations are found during the inspection;

- Voluntary action indicator which represents non-conformity(ies) in Form 483 requiring the manufacturer's response;

- Official action indicator ("**OAI**") which means systematic issues usually caused by major findings or multiple findings, in case of OAI, the manufacturer will receive a warning letter.

The recent FDA inspection to OrbusNeich was a pre-PMA inspection at the end of December of 2020 with the result of NAI.

Establishment Registration and Device Listing

Establishment registration and device listing typically happen after either 510(k) clearance or PMA approval, or for devices exempted from premarket notification, before placing the products onto market. Besides the manufacturer, certain companies will also be required for the registration including the contract manufacturer, contract sterilizer, initial importer and among others. This registration enables the agency to keep track of the establishment information for medical devices that are being marketed in the United States. Foreign manufacturers will need a U.S. agent as the liaison with FDA. All facilities must renew their registrations between October 1 and December 31 of each fiscal year.

Device listing as part of the establishment registration will need the manufacturer to provide the cleared/approved product information and the products exempted from premarket notification.

The online system which is known as FDA Unified Registration and Listing System will then return a Firm Establishment Identifier number for the entity and a listing number(s) for the device which will be used for the Unique Device Identifier ("**UDI**") system uploading in the Global Unique Device Identification Database ("**GUDID**").

Labeling and Packaging

Part 801 of Title 21 CFR outlines the requirements to labeling including general requirements and special requirements for specific devices, as well as the UDI requirements.

UDI includes a Device identifier, a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and a Production identifier, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

– Lot or batch number within which a device was manufactured;

– Serial number of a specific device;

– Expiration date of a specific device;

– Date a specific device was manufactured;

– Distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

The FDA Unique Device Identification System final rule (UDI Rule) requires device labelers (typically, the manufacturer) to:

– Include a unique device identifier (UDI) on device labels and packages, except where the rule provides for an exception or alternative.

  • If a device is intended for more than one use and intended to be reprocessed before each use, the device labeler must also mark the UDI directly on the device.

– Submit device information to the GUDID.

Promotion and advertising materials are considered as part of the product labeling and subjected to regulatory control.

Medical Device Reporting

FDA requires certain parties to report to FDA adverse events and product problems if the adverse events and product problems meet certain requirements. This mandatory requirement applies to manufacturers, importers, and device user facilities. In particular, manufacturers must submit a Medical Device Report ("**MDR**") to FDA within 30 days of receiving or otherwise learning of information that reasonably suggests that their devices may have caused or contributed to a death or serious injury, or malfunctioned and the device or a similar device that the manufacturer markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to occur again. In addition, manufacturers must provide a five-day report to FDA within five working days once becoming aware from any source that remedial action is necessary for preventing an unreasonable risk of substantial harm to the public health, or if FDA requests such a written report. Similar requirements exist for importers and device user facilities.

MDR may be submitted through FDA's electronic Medical Device Reporting database, and must include known or reasonably known information such as patient information (e.g., name, gender, etc.), outcomes of the adverse event, date of the event, date of the report, device information including the brand name, product code, and model number, and any remedial action taken. There is also a requirement to file Supplemental Reports upon learning information that would have been included in the MDR, had it been known at the time of filing. FDA considers a Supplemental Report to be required when new facts prompt the company to alter or supplement any information or conclusions contained in the original MDR or in any prior supplemental reports. The supplemental information must be submitted within one month (30 calendar days) following receipt of the information.

VII. Advertisements of Medical Devices in the U.S.

A product can be subject to different regulatory schemes (drug, device, food, cosmetic, consumer product, etc.) depending on how the FDA categorizes them based on their intended use. The FDA regulates the labels, labelling and advertising of over-the-counter, prescription and restricted medical devices. Labels and labelling of medical devices must contain specific information, including but not limited to:

- statement of identity;
- manufacturer, packer and/or distributor;
- net quantity;
- directions for usage;
- frequency and duration of administration or application;

- statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used;

- warning statements (if any);

- indication for use;

- Risks (if applicable);

Labels, labeling and advertisement of medical devices cannot claim that a device is safe and effective for uses which that FDA has not reviewed and approved. Non-compliance or violation of these advertising and promotion requirements may render the products misbranded or adulterated for lack of a cleared premarket notification or premarket approval, and subject the product and/or the company to enforcement actions. Off-label promotion violations may too render a device adulterated or misbranded, and subject the company, its employees, and officers to significant civil and criminal liabilities including fines and incarceration, and may also constitute a violation of the False Claims Act.

VIII. Registration and Listing

Under the FDCA, all person and parties that own or operate any establishment which engages in manufacturing, preparing, propagating, compounding or processing a medical device, needs to be registered with the FDA, in order to allow the FDA to keep track of the establishment information for medical devices that are being marketed and sold in the United States. All facilities must renew their registrations between October 1 and December 31 of each fiscal year, failures of which constitutes a violation of the FDCA.

The FDA also requires a list of the medical devices in commercial distribution from the owner of operator of the establishment (including specification developers, medical device sterilizers, medical device repackagers or relabelers, reprocessors of a single use device, manufacturers of components or accessories that are packaged for commercial distribution, or initial importers of medical devices), or if applicable, the parent, subsidiary, or affiliate of the owner or operator. The list must be provided at the time of registering the establishment. Any changes must be reflected on FDA's database within 30 days of such change, failures of which constitutes a violation of the FDCA.

HONG KONG REGULATORY OVERVIEW

In Hong Kong, an entity involving medical device distribution and sales are subjected to regulatory controls including the requirements to the entity, and the listing requirements. Regulatory requirements to the entity include commercial registration, company listing, medical device listing and other applicable corporation laws and regulations.

Regulatory Requirements to Medical Device Company in Hong Kong

Regulatory requirements to a medical device company can be divided into general corporation laws and regulations, and then the laws and regulations issued by Medical Device Division (formerly known as Medical Device Control Office) under Department of Health ("**DOH**").

Laws and Regulations on the General Business in Hong Kong

Business Registration and other General Regulations

All companies incorporated or registered in Hong Kong (including "shelf" companies and Hong Kong companies carrying out business outside Hong Kong) are required to register. In addition, every person carrying on any business in Hong Kong has to apply for business registration.

Where the business of a company or person is carried out through a branch of the business, application for branch registration is also required.

Once registered, the corporation shall comply with other applicable social and financial regulations, including employment, fund schemes, occupational and health safety, tax etc.

Listing Requirements under Medical Device Administrative Control System

Per the Guidance Notes: GN-01, Overview of the Medical Device Administrative Control System ("**MDACS**"), issued by DOH, the importer, local manufacturer and the distributor may be listed in the MDACS per GN-07, GN-08 and GN-09 respectively, though the requirements now is voluntary.

If an oversea manufacturer of the medical devices does not have an office in Hong Kong, a Local Responsible Person ("**LRP**") is required, and will need to take the obligations of application for listing medical devices, complaint handling, reporting of adverse events and other field actions as per GN-01. LRP will need to be listed while a device listing which will be required for the usage of a device in public hospital as explained in the section below.

Listing and Classification of a Medical Device

As per GN-01, listing of a device is voluntary. However, since using a medical device in public hospital will need the approval from Hospital Authority ("**HA**"). The application to HA will reference the listing number of the device, which makes the listing of a device as necessary.

Medical device classification in Hong Kong adopts the classification rules promulgated by the International Medical Device Regulator Forum. According to TR-003, Classification Rules for Medical Devices, Medical Devices are classified as Class I, II, III, IV for low risk devices, low-moderate risk devices, moderate-high risk devices and high risk devices.

Class I devices are free from the listing. Other devices shall follow GN-02: Guidance Notes for Listing Class II/III/IV General Medical Devices to prepare the application with supporting documents, and then submit to Medical Device Division. Medical Device Division will review the application and issue a Certificate of Listing after the completeness of review. The certificate will be valid for 5 years and renewal of the certificate shall be started at least 3 months before the expiry date as per GN-01.

Product Quality and Liability

The contract sale of medical devices in Hong Kong are governed by the Sale of Goods Ordinance (Cap. 26) ("SOGO"). SOGO provisions impose certain implied terms, conditions and/or warranties on the goods sold, including goods supplied must be of merchantable quality; reasonably fit for the purpose for which the purpose made known to the seller; and corresponds with the description and sample (if applicable).

The Consumer Goods Safety Ordinance (Cap. 456) imposes a statutory duty on manufactures, importers and suppliers of consumer goods, medical devices included, to ensure the reasonable safety having considered all the relevant circumstances of their products. Under the Consumer Goods Safety Ordinance (Cap. 456), it is an offence for a person to supply, manufacture or import into Hong Kong consumer goods which fail to meet the general safety requirements or product-specific safety requirements. Failure of compliance may result in product withdrawal, fines and/or imprisonment. The Consumer Goods Safety Regulations (Cap. 456A) requires that any warning or caution related to the safe keeping, use, consumption or disposal of any consumer goods must be given in both English and Chinese. The warning or caution label must be legible and placed in a conspicuous position on the consumer goods, or any package of the consumer goods, or on a label securely affixed to the packaging or a document enclosed in the package.

Packaging, Advertising and Promotion

Under the Trade Descriptions Ordinance (Cap. 362), false trade descriptions, false, misleading or incomplete information, false marks and misstatements in respect of goods supplied are prohibited. The Trade Descriptions Ordinance (Cap. 362) requires information or instructions related to the good to be marked, accompanied with the goods, or to be included in advertisements.

The Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits the use of any advertisements that will likely lead to the use of any surgical appliance or treatment, including the use of medicine and surgical appliances, of certain diseases or conditions, including, among others, any disease of the heart or cardiovascular system, including rheumatic heart disease, arteriosclerosis, coronary artery disease, arrythmias, hypertension, cerebrovascular disease, congenital heart disease, thrombosis, peripheral artery disease, oedema, retinal vascular change and peripheral venous disease.

Transfer Pricing Laws and Regulations in Hong Kong

Regulations concerning transfer pricing between associated enterprises can be found in the Inland Revenue Ordinance (Chapter 112 of the Laws of Hong Kong) (the "**IRO**") and the comprehensive double taxation agreements (the "**DTAs**") between Hong Kong and other countries or territories, including the Mainland China.

Under section 60 of the IRO, where it appears to an assessor that for any year of assessment any person chargeable with tax has not been assessed or has been assessed at less than the proper amount, the assessor may, within the year of assessment or within six years after the expiration thereof, assess such person at the amount or additional amount which, according to his judgment, such person ought to have been assessed, and, provided that where the non-assessment or under-assessment of any person for any year of assessment is due to fraud or wilful evasion, such assessment or additional assessment may be made at any time within 10 years after the expiration of that year of assessment.

Section 61A of the IRO stipulates that where it would be concluded that person(s) entered into or carried out transactions for the sole or dominant purpose to obtain a tax benefit (which means the avoidance or postponement of the liability to pay tax or the reduction in the amount thereof), liability to tax of the relevant person(s) will be assessed (a) as if the transaction or any part thereof had not been entered into or carried out; or (b) in such other manner as the supervising authority considers appropriate to counteract the tax benefit which would otherwise be obtained.

The DTAs contain provisions mandating the adoption of arm's length principle for pricing transactions between associated enterprises. The arm's length principle uses the transactions of independent enterprises as a benchmark to determine how profits and expenses should be allocated for the transactions between associated enterprises. The basic rule for DTA purposes is that profits tax charged or payable should be adjusted, where necessary, to reflect the position which would have existed if the arm's length principle had been applied instead of the actual price transacted between the enterprises.

The Departmental Interpretation and Practice Notes No. 45–Relief from Double Taxation due to Transfer Pricing or Profit Reallocation Adjustments issued by the Inland Revenue Department in April 2009 makes it available that where double taxation arises as a result of transfer pricing adjustments made by the tax authorities of another jurisdiction, a Hong Kong taxpayer may potentially claim relief under the tax treaty between Hong Kong and that country (jurisdictions that entered into tax arrangements with Hong Kong includes the Mainland China).

The Inland Revenue Department also issued Departmental Interpretation and Practice Notes No. 46 ("**DIPN 46**") in December 2009 on Transfer Pricing Guidelines – Methodologies and Related Issues. As stated in DIPN 46, transfer pricing documentation is not mandatory under the IRO and the taxpayers are not expressly required to create specific documents showing compliance with the arm's length principle. The Inland Revenue Department further issued Departmental Interpretation and Practice Notes No. 48 in March 2012 which provides a mechanism for taxpayers to pre-agree their transfer pricing arrangements with the Inland Revenue Department.

In July 2018, the Inland Revenue (Amendment) (No. 6) Ordinance 2018 (the "**Amendment Bill**") was enacted to introduce a legislative framework to codify how the pricing for the supply of goods and services between associated parties should be determined and implemented. Codified international transfer pricing principles include, amongst others, the arm's length principle for provision between associated persons, the separate enterprises principle for attributing income or loss of non-Hong Kong resident person, and the three-tier transfer pricing documentation relating to the master file, local file and country-by-country reporting. Based on the Amendment Bill, a person who have a Hong Kong tax advantage if taxed on the basis of a non-arm's length provision (the "**advantaged person**") will have income adjusted upwards or loss adjusted downwards. The advantaged person's income or loss is to be computed as if arm's length provision had been made or imposed instead of the actual provision. If the advantaged person fails to prove to the satisfaction of the assessor of the Inland Revenue Department ("**IRD**") that the amount of the person's income or loss as stated in the person's tax return in an arm's length amount, the assessor of the IRD must estimate an amount as the arm's length amount and, taking into account the estimated amount (a) make an assessment or additional assessment on the person; or (b) issue a computation of loss, or revise a computation of loss resulting in a smaller amount of computed loss, in respect of that person pursuant to section 50AAF of the IRO. In July 2019, the Inland Revenue Department further issued the Departmental Interpretation and Practice Notes No. 58 ("**DIPN 58**"), No. 59 ("**DIPN 59**") and No. 60 ("**DIPN 60**") to set out interpretations to the Amendment Bill.

PRC REGULATORY OVERVIEW

Laws and Regulations Relating to Medical Devices Administration

Our business operations in the Mainland China are subject to a number of laws and regulations relating to the medical devices administration. The main regulatory authorities of the PRC's medical devices industry are National Medical Products Administration (國家藥品監督管理局) ("**NMPA**") and its local counterparts, whose predecessor were China Food and Drug Administration (國家食品藥品監督管理總局) ("**CFDA**") and its local counterparts.

Classification of Medical Devices

According to the Regulation on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) ("**Regulation on Medical Devices**") which was promulgated on January 4, 2000 and latest amended on February 9, 2021 by the State Council, the PRC implements classified administration of medical devices which are classified as Class I, Class II and Class III based on the degree of risks from low to high. Class III medical devices are those with high risks, such as life sustaining, life-supporting or implantable devices, whose safety and effectiveness shall be ensured through special measures for strict control and management.

The classification of a medical device, among others, determines (i) whether a manufacturer or a seller needs to obtain a production license or an operation license in order to manufacture or sell this medical device in the PRC and which level of regulatory authority has jurisdiction over such license and (ii) which type of registration requirements is applicable to such medical device.

During the Track Record Period and as of the Latest Practicable Date, our finished medical products were all registered as Class III medical devices with NMPA.

Registration of Medical Devices

According to the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法) promulgated by the State Administration for Market Regulation ("**SAMR**") on August 26, 2021 and effective from October 1, 2021, Class III medical devices are subject to product registration-based administration. NMPA is responsible for reviewing the registration of both domestic and imported Class III medical devices and issuing the relevant registration certificates.

A. Technical requirements and registration testing

As stipulated by the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法), prior to applying for the registration of Class III medical devices, the registrant shall draw up the product technical requirements applicable to such medical devices. The product technical requirements shall mainly include the functional and safety indicators that can be objectively assessed for the finished medical devices products and testing methods.

Furthermore, it is required to conduct registration testing in accordance with the product technical requirements and submit a testing report to apply for the registration of Class III medical devices. The testing report of such medical device products submitted for registration can be self-testing report issued by the applicant itself or the testing report issued by a qualified medical device testing institution. Only those medical devices testing as qualified can be further submitted to conduct clinical trials or apply for registration.

B. Clinical evaluation

Clinical evaluation is required for the registration of Class III medical devices, with some specific exceptions. According to the Regulation on Medical Devices and the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法), in the clinical evaluation, the safety and effectiveness of medical devices can be proved through (i) clinical trials or (ii) the analysis of clinical literatures and materials, by taking into account the product feature, clinical risk, existing clinical data, etc., and medical devices may be exempt from clinical evaluation under any of the following circumstances: (i) the medical device has clear working mechanisms, finalized design and mature manufacturing process, and the medical devices of the same type that are available on the market have been used in clinic for years without any record of serious adverse event, and the medical device will not change the general purposes thereof; (ii) the safety and effectiveness of such medical device can be proved through other non-clinical evaluation methods. NMPA has the authority to formulate, adjust and publish the catalog of the medical devices exempt from clinical evaluation (the "**Exemption Catalog**").

As of the Latest Practicable Date, the latest version of the Exemption Catalog was the Notice on Publishing Medical Device Catalog Exempted from Clinical Evaluation (關於發布免於臨床評價醫療器械目錄的通告) promulgated by NMPA on September 16, 2021 and effective on October 1, 2021.

During the Track Record Period and as of the Latest Practicable Date, certain of our balloons and microcatheter products have been listed in the Exemption Catalog and therefore had been exempted from clinical evaluation.

C. Registration process

The registrant shall apply for medical devices registration after completing the safety and effectiveness research of the medical devices, and shall be well prepared to accept the the quality management system verification. The application documents shall include the applicable technical requirements, registration testing report and clinical trial evaluation report (if applicable) and other documents as required by the regulators. For medical devices which meet the requirements of safety, effectiveness, and quality control, the medical devices regulatory authority will issue a medical device registration certificate.

The medical device registration certificate is valid for 5 years. In the event of any substantial change of the design, raw material, production process, scope of application or use methods, etc., that may affect the safety and effectiveness of the registered Class III medical devices, the registrant shall apply for the registration of such change; in the event of any other change of the registered Class III medical devices thereof, registrant shall apply for filing of such change. If the medical device registration certificate needs to be renewed upon expiration, the registrant shall make the application for registration renewal at least 6 months prior to the expiry date of the medical device registration certificate.

We obtained the Class III medical device registration certificates for our stents and angioplasty balloons in the PRC, which are within the validity term as of the Latest Practicable Date.

Production Supervision and Quality Management

Medical Devices Production License

According to (i) the Regulation on Medical Devices, (ii) the Measures for the Supervision and Administration of the Production of Medical Devices (醫療器械生產監督管理辦法) promulgated by CFDA on July 30, 2014 and latest amended on November 17, 2017 and (iii) the measures of the same name of (ii) which was promulgated by SAMR on March 10, 2022 and was effective and replaced (ii) on May 1, 2022, the enterprises which intend to engage in the production of Class III medical devices shall apply for medical devices production license (醫療器械生產許可證) at the provincial level of the medical product regulatory authority which will issue to the applicant a medical device production license if the relevant requirements are satisfied. The medical device production license is valid for five years. In the event of a change to the content of the medical device production license, the manufacturer shall make an application to license-issuing authority for change of licensed items or change of registered items (as the case may be). If medical device production license needs to be renewed upon expiration, the manufacturer shall make the application for renewal within the prescribed time limit prior to the expiry date of the medical device production license.

As of the Latest Practicable Date, ONM Shenzhen held the medical device production license with the expiry date of July 17, 2024, which was issued by Guangdong Medical Product Administration on May 15, 2020.

Quality Assurance

As stipulated by the Regulation on Medical Devices and the Measures for the Supervision and Administration of the Production of Medical Devices (醫療器械生產監督管理辦法), the medical device manufacturing enterprises shall comply with the standards of medical devices production and quality assurance, establish a quality assurance system and maintain its effective operation. The medical device manufacturing enterprises shall conduct comprehensive self-inspection on the performance of the quality assurance system on a regular basis. A medical device manufacturer shall record the process for procurement, manufacturing or inspection of raw materials and shall assure the record to be true, accurate and complete and be traceable.

The Medical Devices Good Manufacturing Practice (醫療器械生產質量管理規範) which was promulgated by CFDA on December 29, 2014 and came into effect on March 1, 2015, sets out the detailed requirements for the medical device production enterprises to establish and effectively maintain a quality control system commensurate with the medical devices produced and to integrate the risk management into the whole process of medical device design, development, production, sale and after-sales service where the measures to be taken shall be compatible with the risk relating to the products.

Post-Market Quality Surveillance

In accordance with the Administration Measures for Medical Device Adverse Events Monitoring and Re-evaluation (醫療器械不良事件監測和再評價管理辦法), the holder of medical device registration certificate is obliged to collect information with respect to medical device adverse events and report to the monitoring technical regulators timely. The medical device adverse events are classified as individual medical device adverse events and group medical device adverse events. In the event an individual medical device adverse event occurs, the holder is required to conduct investigations immediately and report within 7 days in case of death or within 20 days in case of serious injury, possible serious injury or possible death. In the event a group medical device adverse event occurs, the holder, other business operator or user who is aware of the group medical device adverse event shall report to the competent regulators within 12 hours.

The Administrative Measures for Medical Device Recalls (醫療器械召回管理辦法), which was promulgated on January 25, 2017 and came into effect on May 1, 2017, regulates that a medical device manufacturer, as the responsible person for controlling and eliminating product defects, shall take the initiative to recall defective products. Medical device manufacturers shall determine the level of recall based on the specific situation and properly formulate and implement the recall plan based on the recall level and the sale and use of the medical devices.

According to the Regulation on Medical Devices, the medical devices regulatory authorities have the authority to conduct onsite supervision and inspection on product samples. In practice, NMPA and its local counterparts may publish the results of inspection on the product samples on their websites.

Product Liability

According to the Civil Code of the PRC (中華人民共和國民法典) which was passed by the National People's Congress (全國人民代表大會) on May 28, 2020 and effective on January 1, 2021, if a patient suffers damages due to defects of medical devices, the patient is entitled to claim compensation against the manufacturer of such medical devices or the medical institution. If a patient claims compensation against the medical institution, the medical institution has the right to recover the compensation from the manufacturer of such medical devices after it pays the compensation to the patient.

The Product Quality Law of the PRC (中華人民共和國產品質量法), which was passed by the Standing Committee of the National People's Congress (the "**SCNPC**") on February 22, 1993 and latest amended on December 29, 2018, applies to all production and marketing activities within the territory of the PRC. Pursuant to this law, a manufacturer shall be responsible for the quality of products it manufactures and shall be liable for compensation for damages (including personal injuries and property damages) caused by its products with defects. In addition, the enterprise, which manufactures or sells the products failing to meet the national or industry standards for ensuring human health, personal safety and property safety, may face the administrative liabilities, such as suspension of production or sales activities, payment of penalties and confiscation of illegal income, and, in serious scenario, revocation of business license, and it may even face the criminal liabilities if such act constitutes a crime.

Sales or Distribution of Medical Devices

Medical Device Operation License

Under the Measures for the Supervision and Administration of the Operation of the Medical Devices (醫療器械經營監督管理辦法) promulgated on July 30, 2014 and latest amended on November 17, 2017 by CFDA and the measures of the same name of the former which was promulgated by SAMR on March 10, 2022 and was effective and replaced the former on May 1, 2022, the enterprise to engage in the operation activities of Class III medical devices shall obtain the medical device operation license (醫療器械經營許可證) from the municipal level of medical product regulatory authority and operation activities of medical devices include wholesale and retail of medical devices in which the enterprises engaging are required to establish the sales record system. The medical device operation license is valid for five years. In the event of a change to the medical device operation license, the enterprise shall make an application to license-issuing authority for change of the license. If medical device operation license needs to be renewed upon expiration, the enterprise shall make the application for renewal within the prescribed time limit prior to the expiry date of the medical device operation license.

As of the Latest Practicable Date, ONM Shenzhen held the medical device operation license with the expiry date of July 26, 2023, which was issued by Shenzhen Administration for Market Regulation on July 27, 2018 and re-issued on February 8, 2021.

Centralized Procurement of Medical Devices

In the PRC, the public medical institutions are required to, implement the centralized procurement for their purchase of the high-value medical consumables which are brought into the centralized procurement scope. The Code on Centralized Procurement of High Value Medical Consumables (Trial) (高值醫用耗材集中採購工作規範(試行)) issued on December 17, 2012, provides that (i) the provincial level government should establish and maintain the online centralized procurement platform of high value medical consumables and formulate the centralized procurement catalog for its administrative region; (ii) all public medical institutions in that administrative region should purchase through the centralized procurement platform the high value medical consumables listed in the centralized procurement catalog and cannot purchase, in principle, the ones not listed in the above catalog; and (iii) the manufacturer of the high value medical consumables (including the deemed manufacturer, such as the PRC general agent for imported products) should directly bid on the centralized procurement platform.

In recent years, the PRC governments strengthened the implementation of centralized procurement system of high-value medical consumables with the aim of improving the pricing mechanism and reducing the inflated prices of the high-value medical consumables.

On July 19, 2019, the General Office of the State Council of the PRC promulgated the Notice on Printing and Distributing the Reform Plan on Managing High-value Medical Consumables (關於印發《治理高值醫用耗材改革方案》的通知). One of the key tasks of the reform plan is to improve the methods of classified and centralized procurement by, among others, (i) requiring all the public medical institutions to purchase the high-value medical consumables on the procurement platforms via public trading or "sunlight" procurement; and (ii) encouraging the provincial governments to carry out the centralized procurement of the high-value medical consumables, which are in large clinical demand, high purchase amount, mature clinical use and produced by multiple enterprises, by means of collecting or combining the demand from multiple hospitals in one provincial region or even several provincial regions and having volume-based negotiations with bidders. The above task was scheduled to start in the second half of 2019 with continuous improvement. After the issuance of the above reform plan, vascular interventional balloon products were gradually brought into the scope of the centralized procurement (also known as volume-based procurement and/or the centralized volume-based procurement, hereinafter referred to as "centralized procurement") in Jiangsu, Hubei, Zhejiang, Sichuan, Shanxi, Liaoning, Jilin, Heilongjiang, Guangdong, Beijing, Tianjin, Hebei and other regions from the second half of 2019 to 2021 according to their centralized procurement notices and were expected to be implemented across the PRC.

On April 30, 2021, eight departments of the State Council jointly promulgated the Guidance on Centralized Volume-based Procurement and Use of High-Value Consumables Organized by the State (關於開展國家組織高值醫用耗材集中帶量採購和使用的指導意見), which provides the overall norms and requirements on the centralized procurement by specifying that, among others, (i) the scope of centralized procurement will include the high-value medical consumables that are in large clinical demand, high purchase amount, mature clinical use, fully competitive market and high level of homogenization; and (ii) the enterprises eligible to participate in the centralized procurement shall be the registrant of medical device in the scope of centralized procurement and shall meet the relevant requirements on quality standards, production capacity, supply stability and enterprise credit.

The above policies influenced the PRC sales environment of the high-valued medical consumables in the scope of centralized procurement mainly in the following respects: (i) the manufacturers (including the deemed manufacturer, such as the general agent of the imported products) or the holders of the medical device registration certificate are required to directly participate in the bidding or tender process of the centralized procurement, and (ii) the end prices of the high-value medical consumables within the scope of centralized procurement generally drop significantly caused by the pricing mechanism of the bidding or tender process and volume-based negotiations for preferential price.

As of the Latest Practicable Date, seven out of 13 products we sold in the PRC market were included in the scope of centralized procurement. Our sales activities in the PRC market was affected by the implementation of the above policies and, as a result, starting from 2021 we started to directly participate in the sales activities in the PRC and changed our distribution model in the PRC from the exclusive distributorship for the entire PRC market to the combination of direct sales (mainly for our products in the scope of centralized procurement) and regional distributors (mainly for our products outside the scope of centralized procurement).

Two-Invoice System

In the PRC, some provinces or regions implement the "Two-Invoice System" in the procurement of the medical consumables. According to the rules mentioned below, the "Two-Invoice System" (兩票制) means that in the distribution chains of the medical consumables only two value-added tax invoices (增值税發票) can be issued when the medical consumables are ultimately sold to the public medical institutions, one is the value-added tax invoice issued by a manufacturer or a deemed manufacturer (such as the PRC domestic general agent of the imported medical devices) to its distributor, the other one is the value-added tax invoice issued by such distributor to a public medical institution.

On June 24, 2016, the National Health and Family Planning Commission together with other ministries issued the Main Points of Special Governance to Correct Medical Malpractice in the Sale of Drugs and the Process of Providing Medical Services in 2016 (2016年糾正醫藥購銷和醫療服務中不正之風專項治理工作要點), which stipulates that the provinces (regions and municipalities) for pilot comprehensive medical reform and the cities for pilot public

hospital reform shall implement the "Two-Invoice System" in procurement of medical consumables. Some provincial governmental authorities also issued local regulations to require public medical institutions in their respective administrative regions to implement the "Two-Invoice System" in the procurement process of medical consumables, such as Two-invoice System Implementation Opinions on the Procurement of Medical Consumables in Public Medical Institutions in Anhui Province (Trial) (安徽省公立醫療機構醫用耗材採購"兩票制"實施意見(試行)) promulgated on November 20, 2017 and the Notice on Further Promoting the "Two Invoice System" for Medicines and Medical Consumables (關於進一步推進藥品和醫用耗材"兩票制"的通知) in Shaanxi promulgated on July 23, 2018, according to which, if the manufacturers or distributors of medical consumables fail to implement the "Two-Invoice System", they may lose the qualification to bid for, win a bid of or distribute medical consumables and they may also be included in the bad credit record for medical consumables procurement.

Advertisements of Medical Devices

SAMR promulgated on December 24, 2019 the Interim Measures for the Review and Administration of Advertisements for Pharmaceuticals, Medical Devices, Health Foods, and Formulas for Special Medical Purposes (藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法) effective from March 1, 2020 (the "**Interim Measures for Advertisements**"), according to which the provincial market supervision and regulation authorities and medical product regulatory authorities are responsible for the review of advertisements for medical devices. No advertisements for medical devices may be published without approval and the approval number shall be conspicuously indicated on the advertisements.

The contents of an advertisement on a medical device shall be subject to the contents of the registration certificate or the registered product instructions approved by the medical product regulatory authorities. The validity term of the approval number of advertisement conforms to the earliest expiry date of the registration certificates or production licenses for the relevant medical devices. If no validity term specified in the above documents, the validity term of approval number would be two years.

As of the Latest Practicable Date, ONM Shenzhen had obtained approvals for publishing advertisements for certain medical devices from Guangdong Medical Products Administration, and the approvals of the advertisements that were material to our current business operation were all within the valid period.

Foreign Exchange

Under the Foreign Exchange Administration Regulations of the PRC (中華人民共和國外匯管理條例), promulgated on January 29, 1996 and latest amended on August 5, 2008 by the State Council, from the perspective of administration on the foreign exchange, the international receipts and payments shall be classified into current account items and capital account items. The current account item refers to a transaction involving goods, services, gains or frequent

transfers in the international receipts and payments. The capital account item refers to a transaction which causes the changes in external assets and liabilities in international receipts and payments, including capital transfers, direct investments, investments in securities, derivatives and loans, etc.. No prior approval from or registration with SAFE is required for the international receipts and payments under current account items, however, certain procedural requirements should be followed and the handling banks in the PRC should verify whether the international receipts and payments are based on true and legal transactions. Compared to the current account items, the international receipts and payments under capital account items are subject to a deeper supervision by SAFE and it is normally required to register with SAFE or its local counterparts before such international receipts and payments are made.

As the cross-border capital flows are common to us based on our business model, the PRC laws and regulations in relation to the foreign exchange are material to our Group's business.

Environmental Protection

Environmental Impact Assessment

According to the Environmental Impact Assessment Law of the PRC (中華人民共和國環境影響評價法) which was passed by the SCNPC on October 28, 2002 and latest amended on December 29, 2018, and the Regulations on the Administration of Construction Project Environmental Protection (建設項目環境保護管理條例) which was promulgated on November 29, 1998 and latest amended on July 16, 2017 by the State Council, the PRC implements an environmental impact assessment system for construction projects and the administration of construction projects are classified into three types in accordance with the degree of their respective environmental impact. On December 28, 2020, Shenzhen Ecology and Environment Bureau promulgated the Environment Assessment Approval and Filing Administration Catalog of Construction Projects in Shenzhen (2021 Version) (深圳市建設項目環境影響評價審批和備案管理名錄(2021年版)) to further clarify the classified administration of the environment impact assessment on the construction projects in Shenzhen, according to which, a medical devices manufacturing project equipped with pollution prevention and control facilities for waste water and gas should be administrated by means of the environmental impact form (環境報告表), which means, according to the Environmental Impact Assessment Law of the PRC, the environmental impact of the construction project is mild and the construction enterprise should submit an environmental impact form containing the analysis or a specialized assessment on its environmental impact to the competent environmental authority and obtain the approval from the same.

Our Shenzhen production facility was administrated by means of the environmental impact form. ONM Shenzhen had submitted the environmental impact form regarding our Shenzhen facility to the competent environmental authorities and obtained the relevant environmental impact approval.

Pollutant Discharge

According to the Regulation on the Administration of Permitting of Pollutant Discharges (排污許可管理條例) which was promulgated by the State Council on January 24, 2021 and came effective on March 1, 2021 and Measures for Pollutant Discharge Permitting Administration (Trial)(排污許可管理辦法(試行) promulgated by the Ministry of Ecology and Environment of the PRC on January 10, 2018 and amended on August 22, 2019, the PRC implements the classified administration on pollutant discharges of enterprises in line with the amount of pollutants produced, emissions, the environmental impact and other factors, which means (i) a pollutant discharger who generates large amount of pollutants or emissions or has material impact on the environment should be under the key administration of pollutant discharge permit, (ii) a pollutant discharger who generates relatively small amount of pollutants and emissions and has mild impact on the environment should be under the simplified administration of pollutant discharge permit, and (iii) a pollutant discharger who generates very small amount of pollutants and emissions and has very small impact on the environment should be under the administration of pollutant registration.

ONM Shenzhen has been included the scope of simplified administration of pollutant discharge permit since November 9, 2021 and it obtained the relevant pollutant discharge permit on the same day with the validity period of 5 years. Prior to that, ONM Shenzhen was under the administration of pollutant registration and it completed the submission of the relevant pollutant discharge registration form on the national pollutant discharge permit administration information platform.

Employment

Labor Law

The Labor Law of the PRC (中華人民共和國勞動法), which was passed by the SCNPC on July 5, 1994 and was latest amended December 29, 2018, provides that employees are entitled to equal opportunities in employment, selection of occupations, receiving labor remuneration, rest days and holidays, protection of occupational safety and healthcare, social insurance and welfare, etc.. Employers must establish and improve the system for occupational safety and healthcare, provide training on occupational safety and healthcare to employees, comply with national local regulations on occupational safety and healthcare, and provide necessary labor protective supplies to employees.

Labor Contract Law

The Labor Contract Law of the PRC (中華人民共和國勞動合同法) (the "**Labor Contract Law**") which was passed by the SCNPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and the Implementation Regulations on the Labor Contract Law (勞動合同法實施條例) which was promulgated by the State Council on September 18, 2008, and came into effect on the same day, provide that the labor contracts must be executed in order to establish the labor relationship between employers and

employees. The Labor Contract Law stipulates that an employer shall inform the employees truthfully the scope of work, working conditions, workplace, occupational hazards, production safety conditions, labor remuneration and other information requested by the employees. The Labor Contract Law also stipulates that employer and employee shall fully perform their respective obligations in accordance with the terms set forth in the labor contract. In addition, employer shall pay employees the labor remuneration timely and in full amount in accordance with terms in the labor contract. The Labor Contract Law also provides for the scenario of rescission and termination, except the situation explicitly stipulated in the Labor Contract Law which will not subject to economic compensation, the economic compensation shall be paid to the employees by the employer for the illegally rescission or termination of the labor contract.

Social Insurance and Housing Provident Funds

Under the Social Insurance Law of the PRC (中華人民共和國社會保險法), promulgated by the SCNPC on October 28, 2010 and amended on December 29, 2018, the Regulations on Work-Related Injury Insurance (工傷保險條例), promulgated by the State Council on April 27, 2003 and amended on December 20, 2010, the Regulations on Unemployment Insurance (失業保險條例), promulgated by the State Council on January 22, 1999, and took effective on the same day, the Provisional Measures on Maternity Insurance of Employees (企業職工生育保險試行辦法), promulgated on December 14, 1994 and came into effective on January 1, 1995, and the Interim Regulations on Collection of Social Insurance Premiums (社會保險費徵繳暫行條例), promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. Employers are also required to withhold and remit to the social insurance schemes the social insurance premiums payable by the employees. If the employer fails to make social insurance contributions in full and on time, the social insurance authorities may demand the employer to make payments or supplementary payments for the unpaid social insurance within a specified period together with a 0.05% per day surcharge of the unpaid social insurance from the date on which the payment is due. If the employer fails to settle the overdue payment within a specified period, the relevant regulatory authorities may impose on such employer a fine equivalent to one to three times of the amount of the overdue payment.

Under the Administrative Regulations on Housing Provident Funds (住房公積金管理條例), which was promulgated by the State Council on April 3, 1999 and latest amended on March 24, 2019, employers are required to make contribution to housing provident funds for their employees. Employers are also required to withhold and remit the contributions payable by the employees to the housing provident funds. Where an employer fails to pay up housing provident funds due in full within the prescribed time limit, the housing fund administration center shall order it to make payment within a specified period. If the employer still fails to do so, the housing fund administration center may apply to the court for enforcement of the unpaid amount.

Intellectual Property

Trademark Law

The Trademark Law of the People's Republic of China (中華人民共和國商標法), which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019, and the Regulations for the Implementation of the Trademark Law of the People's Republic of China (中華人民共和國商標法實施條例), which was promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014, provides for the application, review and approval, renewal, alteration, transfer, use, and invalidity cases of trademark registration, and protects the trademark registrant's right to exclusive use of trademark. According to the above-mentioned laws and regulations, the validity period of a registered trademark is 10 years, starting on the day when the registration is approved. If the valid period of a registered trademark has expired and further use is required, the renewal procedures must be completed in accordance with the regulations within 12 months before the expiration date. If the procedures cannot be completed within the time limit, it can be extended further for six months. The validity period of each renewal of registration is 10 years, starting from the day after the expiration date of the previous validity period of the trademark. A trademark registrant can authorize others to use his or her registered trademark by entering into a trademark license contract.

Our Group has registered certain trademarks in the PRC which are protected and regulated by the Trademark Law of the PRC and its implementation rules above.

Patent Law

According to the Patent Law of the People's Republic of China (中華人民共和國專利法), which was promulgated by the SCNPC on March 12, 1984 and last amended on October 17, 2020, and the Regulations for the Implementation of the Patent Law of the People's Republic of China (中華人民共和國專利法實施細則), which was promulgated by the State Council on June 15, 2001 and latest amended by the State Council on January 9, 2010, invention-creations refer to inventions, utility models and designs. Inventions refer to new technical solutions proposed for products, methods or improvements. Utility model refers to a new technical solution suitable for practical use proposed for the shape, structure or combination of the product. Design patents refer to a new design that is esthetically pleasing and suitable for industrial applications based on the overall or partial shape, pattern, or combination of the product, as well as the combination of color, shape, and pattern. The term of patent right for inventions is 20 years, the term of patent right for utility models is 10 years, and the term of patent right for designs is 15 years. All the terms of patent right start on the date of filing.

Our Group has been granted, by the PRC patent regulatory authority, certain invention patents and utility model patents which are protected and regulated by the Patent Law of the PRC and its implementation rules above.

Property

The Land Administration Law of the PRC (中華人民共和國土地管理法), which was promulgated by the SCNPC on June 25, 1986 with effect from January 1, 1987 and latest amended on August 26, 2019, and the Implementation Regulations of the Land Administration Law of the PRC (中華人民共和國土地管理法實施條例), which was promulgated by the State Council on January 4, 1991 and latest amended on July 2, 2021 and took effective on September 1, 2021, provide that the land-use regulation system and the land registration and certification system are implemented in the PRC. Enterprises or individuals must use land in strict accordance with the purposes of land use as specified in the overall land utilization plan. Any change to the ownership and/or the use of the land requires the relevant approvals to be obtained from and the relevant registrations to be made with the competent governmental authorities according to the relevant laws and regulations. Under the Civil Code of the PRC (中華人民共和國民法典), the creation, alteration, transfer or termination of the title of an immovable property shall be subject to registration in accordance with the PRC laws.

Our Group has self-owned properties located in Shenzhen, the PRC, which are protected and regulated by the PRC laws in relation to the properties.

Customs

Pursuant to the Customs Law of the PRC (中華人民共和國海關法), which was adopted by the SCNPC on January 22, 1987 and latest amended on April 29, 2021, all conveyance, goods and articles entering or leaving the territory shall be subject to customs control, including declaration, examination and supervision. Duties shall be levied accordingly. Unless otherwise exempted or reduced by the laws or regulations, the consignee of import goods, the consignor of export goods and the owner of inward and outward articles shall be the obligatory customs duty payer. A fine may be imposed for acts which violate the regulations on customs control prescribed in the Customs Law of the PRC, such as, the failure to make accurate declaration of the import or export goods to the PRC customs authority, the failure to accept, in accordance with relevant regulations, the checking and examination by the PRC customs authority of the conveyance, goods or articles entering or leaving the territory, and to open or break seals affixed by the PRC customs authority without authorization.

The State Council promulgated the Regulations on the Customs Supervision in Bonded Areas (保稅區海關監管辦法) on January 8, 2011 which took effect on the same day. According to the regulations, the bonded areas within the territory of the PRC are special areas under the supervision of the PRC customs authorities and the flow of goods between the bonded areas and abroad is subject to the administration and supervision with simple, convenient and effective principle. The enterprise incorporated and located in the bonded areas shall set account book and make statements and accounting based on the valid proof and shall record the storage, transfer, relocation, sales, processing, use and loss of the goods and articles into and out of the bonded areas. The goods brought from abroad into the bonded areas can be bonded if they are raw materials, spare parts, primary components or packing materials. When the finished product or the leftover materials produced by the processing enterprise in bonded

areas are transported abroad, such enterprise shall complete the relevant customs procedures and, unless otherwise provided by the laws and regulations, the export duties will be exempted. The import procedures shall be completed when the goods brought from the bonded areas into non-bonded areas in the PRC. When the finished products or the leftover materials produced by the processing enterprise in bonded areas are transported into the non-bonded areas in the PRC, such enterprise shall complete the import procedures and pay the tax in accordance with laws.

Our Shenzhen factory is located in Futian Bonded Area and the flows of raw materials and products of ONM Shenzhen between Futian Bonded Area and abroad or non-bonded areas in the PRC shall be subject to the special customs rules under the Regulations on the Customs Supervision in Bonded Areas and the related PRC regulations.

Transfer Pricing

According to the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得税法) which was promulgated on March 16, 2007 and most recently amended on December 29, 2018, the Implementation Regulations of the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得税法實施條例), which was promulgated on December 6, 2007 and amended on April 23, 2019 and the Law on the Administration of Tax Collection of the PRC (中華人民共和國税收徵收管理法), which was promulgated on September 4, 1992 and amended on April 24, 2015, (i) the related party transactions shall comply with the arm's length principle (獨立交易原則) and if the related party transactions fail to comply with the arm's length principle which results in the reduction of the enterprise's taxable income, the PRC tax authority has the power to make adjustments with reasonable methods within 10 years from the taxable year when such related party transaction occurred; (ii) an enterprise shall fill in and submit an annual related party transactions form (年度關聯業務往來報告表) along with its submission of the annual enterprise income tax returns to its competent tax authority; and (iii) an enterprise which has related party transactions shall prepare the contemporaneous documentation (同期資料) (such as the standards, calculation methods and explanation of the pricing and expenses in respect of the related party transactions) and submit to the PRC tax authority if requested. According to the Announcement on Promulgating the Administrative Measures for Special Tax Investigation Adjustments and Mutual Agreement Procedures (關於發佈《特別納税調查調整及相互協商程序管理辦法》的公告), which was issued by the State Taxation Administration (the "SAT") on March 17, 2017 and became effective on May 1, 2017, if an enterprise receives a special tax adjustment risk warning from tax authorities or detects in itself any special tax adjustment risk, it may carry out voluntary adjustments regarding tax payment matters and the relevant tax authority may still proceed with special tax investigation adjustment procedures according to the relevant provisions. In the event that the tax authority determines to implement the special tax adjustment after investigations, the relevant enterprise may be required to pay up the relevant tax. Besides, pursuant to the tax treaties signed by the PRC with other jurisdictions, the SAT may activate mutual consultation procedures either upon application by an enterprise or upon request by the competent tax authority of the contracting counterparty of a tax treaty to consult and negotiate with the latter, so as to avoid or eliminate international double taxation triggered by special tax adjustment.

OVERVIEW

We are a major global medical device manufacturer specialized in interventional instruments for PCI/PTA procedures. 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. Our Group's history traces back to 2000 when Mr. Teddy CHIEN, our Chairman Emeritus and founder, commenced our cardiovascular interventional medical devices business through OrbusNeich Medical Company Limited (業聚醫療有限公司) (under its former name, Top Charter Investments Limited) ("**ONM HK**"), which primarily engages in the import and distribution of medical devices manufactured by our Group, and subsequently other group companies. As the founder and the then chairman of ONM HK, Mr. Teddy CHIEN was primarily responsible for making key decisions on business strategies and plans of ONM HK. He also injected funds to our Group to meet capital needs when required. Mr. Teddy CHIEN has worked with the medical community over the past 50 years in various capacities at pharmaceutical and medical device companies. Mr. Teddy CHIEN first launched Cordis Neich, an exclusive distributor of medical devices for diagnostics and interventional procedures for Cordis Corporation in Asia. After Cordis Corporation and assets of Cordis Neich were acquired by Johnson & Johnson in 1996, Mr. Teddy CHIEN founded our Group to focus on the development and manufacturing of endovascular interventional devices. Mr. Teddy CHIEN also established the Chien Foundation to provide young interventional cardiologists with financial resources and opportunities for training in enhanced techniques in interventional cardiology, with an overall objective to raise the standard of healthcare for the benefit of the general public in countries in Asia-Pacific region.

Under Mr. Teddy CHIEN's leadership, in addition to balloons, we further expanded our capacity to the research and development and the manufacturing of stents, as balloons and stents are complementary devices in cardiovascular interventional procedures. In 2005, we acquired Orbus Medical Technologies Inc., which primarily focused on developing and manufacturing of stents. Through the acquisition, we established our manufacturing base and operations in the Netherlands, and expanded our sales network in Europe. Mr. Teddy CHIEN maintained a controlling interest in our Group through Belinfer Corporation until December 2017 when he transferred his entire equity interest in Belinfer Corporation to Mr. David CHIEN, Mr. Teddy CHIEN's son and the chairman of our Board, an executive Director and the chief executive officer of our Company for family succession planning purpose. On February 1, 2021, Mr. David CHIEN procured Belinfer Corporation to transfer all of its shareholding in Cosmic Ascent Limited ("**COSMIC**"), representing its indirect interest in our Group, to himself. On February 16, 2021, Mr. David CHIEN transferred all of his shareholding in COSMIC to Harmony Tree Limited ("**HART**"), which was jointly owned by Mr. David CHIEN and Ms. Kwai Ching Denise LAU as to 55% and 45%, respectively. Subsequent to the foregoing transfer, HART, Mr. David CHIEN and Ms. Kwai Ching Denise LAU became a group of Controlling Shareholders of our Group.

HART was incorporated in BVI in September 2020. For family asset planning purpose, in January 2021, Mr. David CHIEN transferred 45% of the equity interest in HART to Ms. Kwai Ching Denise LAU, Mr. David CHIEN's spouse and an executive Director of our Company. As of the date of this document, Mr. David CHIEN and Ms. Kwai Ching Denise LAU jointly hold a controlling interest of 67.46% in our Group through HART, please refer to the section headed "Relationship with Our Controlling Shareholders" and the paragraph headed "– Capitalization of our Company" for more details.

For the purpose of the [**REDACTED**], we incorporated our Company in the Cayman Islands on July 22, 2021, which became the holding company of our Group as a result of the Reorganization. Please refer to the paragraph headed "– Pre-[**REDACTED**] Investments" and "– Reorganization" for further details of our historical financing.

KEY DEVELOPMENT MILESTONES

The following table sets forth certain key development milestones of our Group:

Year	Milestone
2001	Our Group launched our R&D, product development and manufacturing base in Shenzhen, the PRC.
	Our Group received our first regulatory approval for our balloon catheter from PMDA in September.
2005	Our Group acquired Orbus Medical Technologies Inc. and its subsidiaries for a research and development center in the United States and a manufacturing base in the Netherlands, and expanded our sales network in Europe.
2007	Our first generation "Sapphire" received CE Mark in April, marking the beginning of our Sapphire balloon catheter product family.
2008	Our first generation "ScoreFlex" obtained CE Mark in May.
2016	Mr. David CHIEN became our CEO, resetting the business strategy of our Group.
	We launched our second generation COMBO Plus dual therapy stent with an advanced delivery system in June.
2017	We commenced selling our balloon products in the United States.

Year	Milestone
2018	Jade PTA received FDA 510(k) clearance in February.
	Sapphire II Pro received FDA 510(k) clearance in March and became the first 1.0mm diameter balloon in the United States.
	Teleport, our first microcatheter product, obtained CE Mark and FDA 510(k) clearance in March and November, respectively.
	We commenced worldwide distribution of coronary artery and peripheral orbital atherectomy products for a United States medical device developer and manufacturer.
2019	Our latest generation Sapphire 3 obtained approval from PMDA in January.
	ScoreFlex PTA received FDA 510(k) clearance in May.
	COMBO Plus dual therapy stent obtained approval from PMDA.
2020	Sapphire 3 and Sapphire NC 24 received CE Mark in March.
	We acquired our distributor in Switzerland in August to actively expand our direct sales network.
	COMBO dual therapy stent obtained NMPA approval in August.
	We formed a strategic joint venture with Products & Features International, LDA for the development, manufacturing and distribution of structural heart products in certain countries in Asia Pacific regions in October.
	Sapphire II Pro OTW version and Jade PTA 14"/18"/35" OTW series were launched in the United States.
2021	We first opened to third party investments and completed two rounds of financing within a few months, raising US$202.5 million in aggregate from well-known institutional investors and family offices.
	We expanded our direct sales network and established our direct sales team in Mainland China.
2022	Scoreflex NC was launched in Mainland China and the United States.

OUR PRINCIPAL SUBSIDIARIES

As of the Latest Practicable Date, we had 28 subsidiaries and one joint venture. The following table sets forth details of (i) the significant intermediate holding company of our Group through which we received two rounds of equity financing and (ii) subsidiaries of our Group which made material contribution to our results of operations during the Track Record Period and up to the Latest Practicable Date (the "**Material Subsidiaries**"):

Name	Place of incorporation	Date of incorporation	Authorized share capital/ Registered capital	Principal business activities
OrbusNeich Medical Group Limited (業聚醫療集團有限公司) ("**ONM Group Ltd.**")	Cayman Islands	June 8, 2017	US$600,000	Investment holding
OrbusNeich Medical Company Limited (業聚醫療有限公司) ("**ONM HK**")	Hong Kong	February 23, 1998	HK$10,000	Trading, sales and marketing
OrbusNeich Medical (Shenzhen) Company Limited (業聚醫療器械(深圳)有限公司) ("**ONM Shenzhen**")	PRC	May 29, 2000	US$5,000,000	Research and development, manufacturing and sales
OrbusNeich Medical K.K. ("**ONM Japan**")	Japan	September 13, 2001	JPY90,000,000	Trading, sales and marketing
Orbus International B.V. ("**OIBV**")	Netherlands	March 10, 1999	EUR45,320,279	Trading, sales and marketing
OrbusNeich Medical B.V. ("**ONM BV**")	Netherlands	July 13, 2006	EUR18,000	Manufacturing

CORPORATE DEVELOPMENT

The following sets forth the major corporate history and shareholding changes of our Company and our Material Subsidiaries.

Our Company

Incorporation and Initial Issuance of Shares

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on July 22, 2021, with its share capital of US$50,000 divided into 500,000,000 Shares with par value of US$0.0001 each and one Ordinary Share issued to the initial subscriber. On the same day, the initial subscriber transferred one Ordinary Share at par value to HART.

Acquisition of COSMIC through Share Swap

On September 28, 2021, HART, our then sole Shareholder, resolved to increase the authorized share capital from US$50,000 to US$600,000, which is divided to 6,000,000,000 Shares comprising 5,018,814,933 Ordinary Shares, 234,784,854 Series A Preferred Shares and 746,400,213 Series A-2 Preferred Shares, with par value of US$0.0001 each.

As part of the Reorganization, pursuant to instruments of transfer dated September 28, 2021, HART, the Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU underwent the First Share Swap with our Company pursuant to which COSMIC became a wholly-owned subsidiary of our Company, and HART, the Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU became our direct Shareholders. Please refer to the paragraph headed "– Reorganization – Step 1: Share Swap between our Company and COSMIC" for further details.

Acquisition of ONM Group Ltd. through Share Swap

As part of the Reorganization, the Series A Investors and the Series A-2 Investors underwent the Second Share Swap with COSMIC, pursuant to which ONM Group Ltd. became a wholly-owned subsidiary of COSMIC, a direct wholly-owned subsidiary of our Company, and the Series A Investors and the Series A-2 Investors became our direct Shareholders. Please refer to the paragraph headed "– Reorganization – Step 2: Share Swap between our Company and ONM Group Ltd." for further details.

Please refer to the paragraphs headed "– Capitalization of our Company" and "– Our Structure Immediately Prior to the [**REDACTED**]" for the shareholding structure of our Company and our corporate structure, respectively, upon completion of the Reorganization and as of the date of this document.

ONM Group Ltd.

Incorporation and Initial Issuance of Shares

ONM Group Ltd. was incorporated in the Cayman Islands as an exempted company with limited liability on June 8, 2017 with one ordinary share issued to the initial subscriber, an Independent Third Party.

Transfer of shares to the Controlling Shareholders

On the same day, the initial subscriber transferred one ordinary share of ONM Group Ltd. to ONM BVI, which held subsidiaries of our Group through ONM Investment Holdings at the time. The then majority equity interest of ONM BVI was held by Belinfer Corporation, and the then remaining shares of ONM BVI held by other minority shareholders were either redeemed and cancelled by ONM BVI in May and July 2020 or transferred to Belinfer Corporation in June and November 2020 (in respect of the shares held by the Initial COSMIC Shareholders). After the foregoing shareholding changes, ONM BVI became wholly owned by Belinfer Corporation. Belinfer Corporation was wholly owned by Mr. Teddy CHIEN as of June 8, 2017, being the date of incorporation of ONM Group Ltd. and was subsequently transferred to Mr. David CHIEN on December 19, 2017.

In return for ONM BVI's transfer of the total issued share capital of ONM Investment Holdings to ONM Group Ltd. on April 26, 2019, ONM Group Ltd. allotted and issued one ordinary share to ONM BVI on September 20, 2019, upon which the then subsidiaries in our Group became indirectly wholly owned by ONM Group Ltd., which was in turn wholly owned by ONM BVI.

Transfer of shares between holding entities of the Controlling Shareholders

Pursuant to a sale and purchase agreement dated July 30, 2020, as an intra-group transfer, ONM BVI transferred the total issued share capital of ONM Group Ltd. to COSMIC, which was wholly-owned by Belinfer Corporation and the Initial COSMIC Shareholders before the foregoing sale and purchase agreement was signed, at a consideration of US$187,827,882.30.

The consideration of the foregoing transfer was settled by COSMIC's issuance of promissory notes (the "**COSMIC Promissory Notes**") to the shareholders of ONM BVI (comprising Belinfer Corporation and the Initial COSMIC Shareholders) in proportion to their respective shareholdings in ONM BVI. On July 31, 2020, the COSMIC Promissory Notes were applied to set off the outstanding subscription price of shares of COSMIC held by Belinfer Corporation and the Initial COSMIC Shareholders in full, which was payable by the shareholders of ONM BVI (comprising Belinfer Corporation and the Initial COSMIC Shareholders) for issuance of shares in COSMIC.

Upon completion of the transfer of shares of ONM Group Ltd. and the settlement of the COSMIC Promissory Notes on July 31, 2020, ONM Group Ltd. became wholly owned by COSMIC, the fully-paid shares of which were held by the then shareholders of ONM BVI (comprising Belinfer Corporation and the Initial COSMIC Shareholders).

Redenomination of share capital

Prior to the following changes in authorized share capital of ONM Group Ltd., the authorized share capital of ONM Group Ltd. was HK$380,000 divided into 38,000,000 ordinary shares with par value of HK$0.01 each, and two ordinary shares with par value of HK$0.01 each were held by COSMIC.

On October 29, 2020, the director and shareholder of ONM Group Ltd. resolved to (i) increase the authorized share capital of ONM Group Ltd. by US$600,000, (ii) issue 1,878,278,823 ordinary shares of ONM Group Ltd. with par value of US$0.0001 each to COSMIC, (iii) repurchase two ordinary shares with par value of HK$0.01 each from COSMIC, and (iv) diminish and cancel the authorized share capital of HK$380,000. The subscription price of 1,878,278,823 ordinary shares with par value of US$0.0001 each offsets the repurchase price of two ordinary shares with par value of HK$0.01 each.

As a result of the foregoing resolutions, the denomination of ONM Group Ltd. was changed from Hong Kong dollars to U.S. dollars. As of October 29, 2020, the authorized share capital of ONM Group Ltd. consists of US$600,000 divided into 6,000,000,000 ordinary shares with par value of US$0.0001 each, amongst which 1,878,278,823 ordinary shares were issued to COSMIC.

Series A Financing

Pursuant to a share subscription agreement dated April 23, 2021, CICC Biomedical Fund L.P. (中金啟德(廈門)創新生物醫藥創業投資合夥企業(有限合夥) (formerly known as 中金啟德(廈門)創新生物醫藥股權投資基金合夥企業(有限合夥))) ("**CICC Biomedical Fund**"), Bliss Moment Limited ("**Bliss Moment**") and Shenzhen Share Zeshan Precision Medical Limited Partnership (深圳市分享擇善精準醫療創業投資合夥企業(有限合夥)) ("**Shenzhen Share Zeshan**") (collectively the "**Series A Investors**") subscribed for 100,622,080, 67,081,387 and 67,081,387 series A preferred shares of ONM Group Ltd. at a consideration of US$15,000,000, US$10,000,000 and US$10,000,000, respectively (the "**Series A Financing**"). The consideration was determined after arms' length negotiation between ONM Group Ltd. and the Series A Investors with reference to the development status of our Group's products, the scale of business and development prospect of our Group.

Upon completion of the initial closing and the subsequent closing of Series A Financing on April 27, 2021 and June 18, 2021, respectively, the shareholding structure of ONM Group Ltd. is as follow:

Name of shareholders of ONM Group Ltd.	Class of shares of ONM Group Ltd.	Number of shares of ONM Group Ltd.	Percentage
COSMIC	Ordinary	1,878,278,823	88.89%
CICC Biomedical Fund	Series A preferred	100,622,080	4.76%
Bliss Moment	Series A preferred	67,081,387	3.17%
Shenzhen Share Zeshan	Series A preferred	67,081,387	3.17%
Total		2,113,063,677	100.00%

Issuance of Shares as a result of Injection of ON HV

OrbusNeich P+F Company Limited ("**ON P&F**") was incorporated on May 15, 2017 as a company within our Group. After an intra-group transfer, OrbusNeich HeartValve Company Limited ("**ON HV**"), an entity wholly owned by COSMIC and accounted for as a subsidiary of our Group, holds one share of ON P&F, representing the then total issued share capital of ON P&F as of September 29, 2020. ON P&F is the sole shareholder of OrbusNeich P&F (Hong Kong) Company Limited (業聚培福(香港)有限公司) ("**ON P&F (HK)**"), which is in turn the sole shareholder of OrbusNeich P&F MedTech (Shenzhen) Company Limited (業聚培福醫療技術(深圳)有限公司) ("**ON P&F (SZ)**").

In October 2020, ON HV entered into a joint venture arrangement with Products & Features International, LDA ("**P&F Int'l**"), pursuant to which ON P&F allotted and issued 49 new shares to ON HV and 50 new shares to P&F Int'l at par. As a result, ON P&F was owned by ON HV and P&F Int'l as to 50% and 50%, respectively. The consideration was fully settled and the shares of ON P&F were credited as fully paid in October 2020. P&F Int'l is an Independent Third Party principally engaged in the development, manufacturing, commercialization and distribution of heart valve products. Pursuant to the joint venture arrangement, ON P&F have the right to distribute certain heart valve products including the TricValve Bicaval System in certain countries of the APAC region. Please refer to the paragraph headed "Business – Our Collaborations with P&F Int'l" for further details.

As of July 6, 2021, ON HV was wholly owned by COSMIC. Pursuant to a sale and purchase agreement dated July 7, 2021, COSMIC transferred the total issued share capital of ON HV to ONM Group Ltd. (the "**ON HV Transfer**"), and in return, ONM Group Ltd. allotted and issued an aggregate of 1,006,220,798 ordinary shares to COSMIC.

Subsequent to the ON HV Transfer, ON HV became wholly owned by ONM Group Ltd.

Series A-2 Financing

Pursuant to a share subscription agreement dated June 10, 2021 (the "**Series A-2 Subscription Agreement**"), the following investors subscribed for 746,400,213 series A-2 preferred shares of ONM Group Ltd. to be issued to themselves or their respective offshore affiliates (the "**Series A-2 Investors**") at a total consideration of US$167,500,000 (the "**Series A-2 Financing**"):

Series A-2 Investors	**Consideration** *(US$)*	**Number of series A-2 preferred shares of ONM Group Ltd.**
Suzhou Red Earth Yeju Venture Capital Investment LLP (蘇州紅土業聚創業投資合夥企業(有限合夥)) ("**Suzhou Red Earth**")*	78,500,000	349,805,473
Kinetic Creation Global Investments Limited (建成開元投資有限公司) ("**Kinetic**")	30,000,000	133,683,620
Shenzhen Red Earth Healthcare Industry Investment Fund Partnership (LP) (深圳紅土醫療健康產業股權投資基金合夥企業(有限合夥)) ("**Shenzhen Red Earth**")*	17,500,000	77,982,112
Shenzhen Capital Group Company, Ltd. (深圳市創新投資集團有限公司) ("**SCGC**")*	14,000,000	62,385,689
Worldstar Global Holdings Limited ("**Worldstar**")	10,000,000	44,561,207
Galaxy Capital International Limited (星河資本國際有限公司) ("**Galaxy Capital**")	10,000,000	44,561,207
Bliss Moment	5,000,000	22,280,603
B.W. Holding Limited ("**B.W. Holding**")	2,500,000	11,140,302
Total	**167,500,000**	**746,400,213**

Note:

* The initial closing of Series A-2 Financing, which involves an aggregate investment of US$110 million by SCGC, Suzhou Red Earth and Shenzhen Red Earth, was completed on July 20, 2021. Pursuant to deeds of joinder dated July 20, 2021, SCGC, Suzhou Red Earth and Shenzhen Red Earth, the initial subscribers in the Series A-2 Share Subscription Agreement, directed ONM Group Ltd. to issue its series A-2 preferred shares to their offshore affiliates, namely SCGC Capital Holding Company Limited ("**SCGC Capital**"), Suzhou Red Earth Yeju Investment Ltd. ("**SZYJ**") and HTYL Investment Holdings Limited ("**HTYL**"), respectively.

The consideration was determined after arms' length negotiation taking into account the injection of ON HV, the development status of our Group's products, the scale of business and development prospect of our Group.

Upon completion of the initial closing and the subsequent closing of Series A-2 Financing on July 20, 2021 and August 10, 2021, respectively, the shareholding structure of ONM Group Ltd. was as follow:

Name of shareholders of ONM Group Ltd.	Class of shares of ONM Group Ltd.	Number of shares of ONM Group Ltd.	Percentage
COSMIC	Ordinary	2,884,499,621	74.62%
SCGC Entities			
– SZYJ	Series A-2 preferred	349,805,473	9.05%
– HTYL	Series A-2 preferred	77,982,112	2.02%
– SCGC Capital	Series A-2 preferred	62,385,689	1.61%
Sub-total of SCGC Entities		490,173,274	12.68%
Kinetic	Series A-2 preferred	133,683,620	3.46%
CICC Biomedical Fund	Series A preferred	100,622,080	2.60%
Bliss Moment	Series A preferred	67,081,387	1.74%
	Series A-2 preferred	22,280,603	0.58%
Shenzhen Share Zeshan	Series A preferred	67,081,387	1.74%
Worldstar	Series A-2 preferred	44,561,207	1.15%
Galaxy Capital	Series A-2 preferred	44,561,207	1.15%
B.W. Holding	Series A-2 preferred	11,140,302	0.29%
Total		**3,865,684,688**	**100.00%**

Share Swap between our Company and ONM Group Ltd.

As part of the Reorganization, the Series A Investors and the Series A-2 Investors underwent the Second Share Swap with COSMIC pursuant to which ONM Group Ltd. became a wholly-owned subsidiary of COSMIC and the Series A Investors and the Series A-2 Investors became our direct Shareholders. Please refer to the paragraph headed "– Reorganization – Step 2: Share Swap between our Company and ONM Group Ltd." for further details. Subsequent to the Second Share Swap, ONM Group Ltd. reclassified and redesignated all of its shares to ordinary shares on September 28, 2021.

Upon completion of the share swap between our Company and ONM Group Ltd. and as of the date of this document, ONM Group Ltd. is a wholly-owned subsidiary of COSMIC.

ONM HK

ONM HK was incorporated in Hong Kong as a limited company on February 23, 1998 with one ordinary share held by each of Snatch Prize Limited and Boxing Company Limited, which are Independent Third Parties. Each of the initial shareholders of ONM HK subsequently transferred one ordinary share of ONM HK to Mr. Teddy CHIEN and his spouse on August 27, 1998 at nominal consideration, respectively.

On February 18, 2000, prior to the commencement of business by ONM HK in late February 2000, each of Mr. Teddy CHIEN and his spouse transferred one ordinary share of ONM HK (under its former name, Top Charter Investments Limited) to ONM BVI (then operating under its former name, Multi-Well Development Limited) and Apex Score Limited, respectively, at the par value of HK$1.00 per ordinary share. As the predecessor Companies Ordinance requires a limited liability company incorporated in Hong Kong to have at least two shareholders, Apex Score Limited held one ordinary share of ONM HK as a nominee shareholder on behalf of ONM BVI.

On August 7, 2017, as the Companies Ordinance no longer requires a limited liability company incorporated in Hong Kong to have at least two shareholders, ONM BVI directed its nominee shareholder, Apex Score Limited, to transfer one ordinary share of ONM HK to itself at nil consideration.

On July 13, 2018, ONM BVI transferred two ordinary shares of ONM HK to OrbusNeich Medical Manufacturing Holdings (APAC) Company Limited ("**ONM Manu Hold's (APAC)**"), in exchange for the allotment and issuance of one share of ONM Manu Hold's (APAC) to ONM BVI. After the foregoing transfer, ONM HK became wholly owned by ONM Manu Hold's (APAC), which was wholly owned by ONM BVI. On April 26, 2019, as an intra-group transfer, ONM BVI transferred two ordinary shares of ONM Manu Hold's (APAC) to ONM Investment Holdings, which is directly wholly owned by ONM Group Ltd.

Subsequent to the foregoing transfers and as of the Latest Practicable Date, ONM HK was wholly owned by ONM Manu Hold's (APAC), which was indirectly wholly owned by ONM Group Ltd. and our Company.

ONM Shenzhen

ONM Shenzhen was incorporated in the PRC on May 29, 2000 with an initial registered capital of US$3,000,000, which was fully paid and wholly owned by ONM HK.

On February 26, 2001, ONM HK resolved to increase the registered capital of ONM Shenzhen to US$5,000,000, which was fully paid by ONM HK.

As of the Latest Practicable Date, ONM Shenzhen was wholly owned by ONM HK.

ONM Japan

ONM Japan was incorporated in Japan as a stock company with limited liability on September 13, 2001 with a total issued share capital of JPY10 million divided into of 200 shares, 199 shares of which were held by ONM HK and the remaining 1 share was held by Mr. Takeshi OHBA, the president and representative director of ONM Japan and a nominee shareholder on behalf of ONM HK.

On July 7, 2006, the share capital of ONM Japan was increased to JPY90 million divided into 1,800 shares, with an additional 1,600 fully-paid shares allotted and issued to ONM HK.

On June 25, 2021, the share capital of ONM Japan was further increased to JPY644,450,000 divided into 21,800 shares, with an additional 20,000 fully-paid shares allotted and issued to ONM HK.

On September 3, 2021, the share capital of ONM Japan was reduced to JPY90 million.

Since the foregoing transfer and as of the Latest Practicable Date, ONM HK and Mr. Takeshi OHBA were the registered shareholders of ONM Japan as to 99.995% and 0.005%, respectively, with ONM HK holding 100.00% beneficial interest of ONM Japan.

OIBV

OIBV was incorporated in the Netherlands with limited liability on March 10, 1999, with its share capital divided into 99,875 shares. As of the date of its incorporation, OIBV issued 40 ordinary shares and was wholly owned by OrbusNeich Medical Inc., a company incorporated in Delaware, the United States and wholly owned by our Group.

On December 18, 2017, as an intra-group transfer, OrbusNeich Medical Inc. transferred 40 ordinary shares of OIBV to OrbusNeich Medical Investments Limited B.V. ("**ONM Investment BV**"), a wholly-owned subsidiary of ONM HK, at a consideration of US$20,039. Immediately following the intra-group transfer, OIBV was wholly owned by ONM Investment BV.

On August 31, 2021, OIBV issued 94,371 ordinary shares to ONM HK to fully set off an outstanding intra-group loan of EUR42,822,731 owed to ONM HK.

On March 31, 2022 OIBV issued 5,464 ordinary shares to ONM HK to fully settle an outstanding intra-group loan of EUR2,479,399 owed to ONM HK.

As of the Latest Practicable Date, OIBV is owned by ONM HK and ONM Investment BV as to 99.96% and 0.04%, respectively.

ONM BV

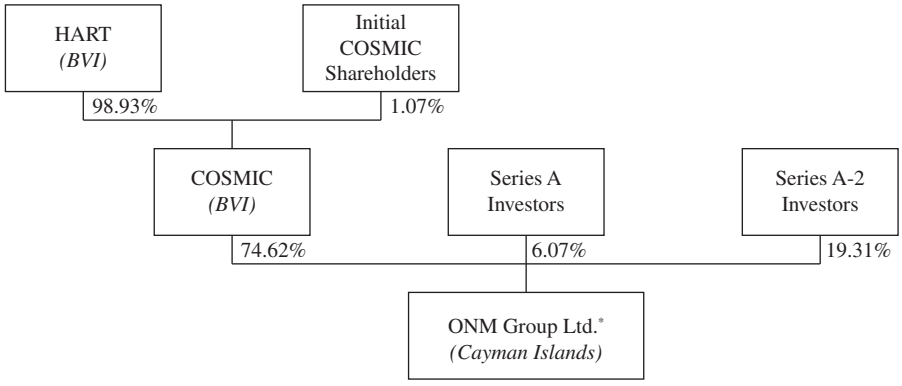
ONM BV was incorporated in the Netherlands with limited liability on July 13, 2006 and was wholly owned by OrbusNeich Medical Holding B.V. ("**ONM Holding BV**"), a company within our Group since incorporation. As of the Latest Practicable Date, ONM BV was wholly owned by ONM Holding BV, an indirect wholly-owned subsidiary of our Company.

ACQUISITION DURING THE TRACK RECORD PERIOD

During the Track Record Period, to strengthen our overseas direct sales network in Europe and in light of the potential of the Swiss medical device market, we strategically expanded our direct sales network into Switzerland and acquired the total issued share capital of ON AG from two Independent Third Parties at a consideration of US$4,019,000, which was determined through arms' length negotiation between the parties after taking into account factors including the customers and distribution network of ON AG and business prospect of the Swiss medical device market. Upon completion of the acquisition in August 2020, ON AG became a direct wholly owned subsidiary of ONM HK and its financial information has been reflected in our consolidated financial statements for the Track Record Period. Our Directors have confirmed that none of the applicable percentage ratios as stipulated under the Listing Rules of the above-mentioned acquisition of ON AG exceeds 25%. Accordingly, the acquisition of ON AG during the Track Record Period does not amount to a major acquisition under Rule 4.05A of Listing Rules, and is not required to be disclosed pursuant to Rule 4.05A of the Listing Rules. Please refer to Note 38 to the Accountant's Report in Appendix I to this document for more details.

REORGANIZATION

In preparation for the [**REDACTED**], we incorporated our Company in the Cayman Islands as an exempted company with limited liability on July 22, 2021 and underwent the following steps of Reorganization. Prior to the Reorganization, ONM Group Ltd. was the ultimate holding vehicle of our subsidiaries. Set forth below is our simplified shareholding chart immediately prior to the Reorganization:



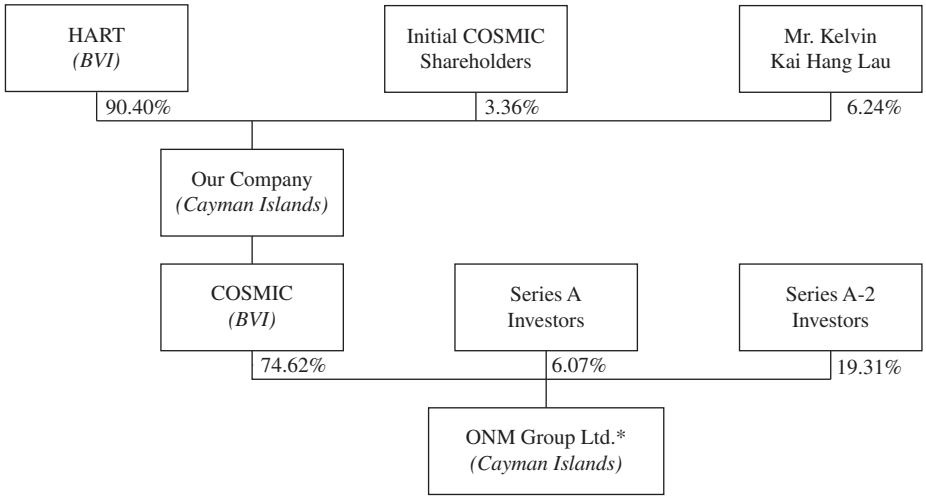
* Please refer to the paragraph headed "– Our Structure Immediately Prior to the [**REDACTED**]" for shareholding structure of our Material Subsidiaries.

Step 1: Share Swap between our Company and COSMIC

COSMIC was incorporated in the BVI with limited liability on July 7, 2020. Prior to the Reorganization, COSMIC was held by HART and the Initial COSMIC Shareholders as to 98.93% and 1.07%, respectively. Please refer to the paragraph headed "Transfer of shares between holding entities of the Controlling Shareholders" for details. Prior to the Reorganization, COSMIC was a shareholder of ONM Group Ltd., through which our Group holds its subsidiaries. On August 20, 2021, Mr. David CHIEN and Ms. Kwai Ching Denise LAU procured HART to transfer (i) 117,210,115 shares of COSMIC to Mr. Kelvin Kai Hang LAU (劉啟衡), the brother of Ms. Kwai Ching Denise LAU, for family asset planning and succession planning purposes; and (ii) 42,977,042 shares of COSMIC to Ms. Pik Lin Barbara WONG (黃璧璉), one of the Initial COSMIC Shareholders and a former senior management of our Group in recognition and for award of her 14 years of service in overseeing the overall corporate and financial functions of our Group. The foregoing transfers were made by way of gift at nil consideration. Neither Mr. Kelvin Kai Hang LAU nor Ms. Pik Lin Barbara WONG is given any special rights granted to the Series A Investors and/or the Series A-2 Investors. In relation to the foregoing transfers, each of Mr. Kelvin Kai Hang LAU (with respect to 23,442,023 Ordinary Shares as adjusted by Share Consolidation) and Ms. Pik Lin Barbara WONG (with respect to 8,595,408 Ordinary Shares as adjusted by Share Consolidation) will be subject to a lock-up period of six months from the [**REDACTED**]. Upon completion of the foregoing transfers, HART, the Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU hold 1,697,984,609, 63,084,099 and 117,210,115 shares of COSMIC, representing approximately 90.40%, 3.36% and 6.24% of the total issued share capital of COSMIC, respectively.

On September 28, 2021, HART, the Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU transferred the total issued share capital of COSMIC to our Company. In consideration of the foregoing transfer, on September 28, 2021, our Company allotted and issued Ordinary Shares to HART, the Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU based on a ratio of 1 share of COSMIC in exchange for approximately 1.54 Ordinary Shares of our Company (the "**First Share Swap**"). The basis for determining the First Share Swap ratio is to maintain effective percentage equity interest of the HART, Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU. As a result of the First Share Swap, COSMIC became wholly owned by our Company, of which 2,607,619,220, 96,879,152 and 180,001,248 Ordinary Shares were held by HART, the Initial COSMIC Shareholders and Mr. Kelvin Kai Hang LAU, representing approximately 90.40%, 3.36% and 6.24% of the then total issued share capital of our Company, respectively. Save for 8,595,408 Ordinary Shares as adjusted by Share Consolidation held by Ms. Pik Lin Barbara WONG as a result of the share transfer on August 20, 2021 mentioned above, all Ordinary Shares held by the entire group of Initial COSMIC Shareholders will not be subject to a lock-up period of six months from the [**REDACTED**].

Set forth below is our simplified shareholding chart subsequent to the share swap between our Company and COSMIC:



Note:

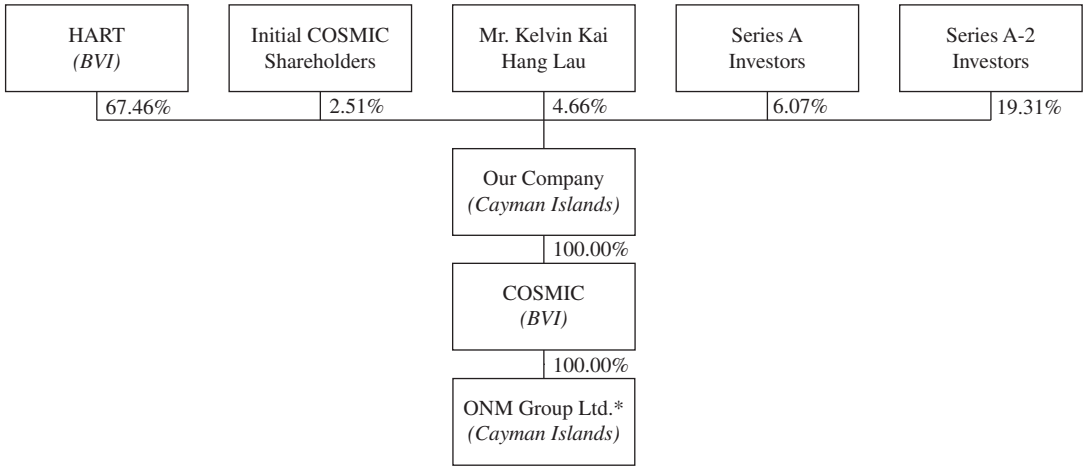
* Please refer to the paragraph headed "– Our Structure Immediately Prior to the [**REDACTED**]" for shareholding structure of our Material Subsidiaries.

Step 2: Share Swap between our Company and ONM Group Ltd.

Upon completion of Series A-2 Financing on August 10, 2021, ONM Group Ltd. was owned by COSMIC, the Series A Investors and the Series A-2 Investors as to 74.62%, 6.07% and 19.31%, respectively. Please refer to the paragraph headed "– Corporate Development – ONM Group Ltd. – Series A-2 Financing" for further details.

Pursuant to a share exchange agreement dated September 28, 2021, (i) the Series A Investors and the Series A-2 Investors transferred their shareholdings in ONM Group Ltd. to COSMIC in exchange for issuance of their corresponding classes of Shares by our Company on 1:1 basis (the "**Second Share Swap**"), and (ii) in consideration of the foregoing issuance of Shares by our Company, one share of COSMIC was issued to our Company (the "**Share Contribution**"). Upon completion of the Second Share Swap and Share Contribution, ONM Group Ltd. became wholly owned by COSMIC, a direct wholly-owned subsidiary of our Company.

Set forth below is our simplified shareholding chart as of September 28, 2021 immediately after the Reorganization:



Note:

* Please refer to the paragraph headed "– Our Structure Immediately Prior to the [**REDACTED**]" for shareholding structure of our Material Subsidiaries.

PRE-[REDACTED] INVESTMENTS

The Pre-[**REDACTED**] Investments include Series A Financing and Series A-2 Financing.

Principal Terms of the Pre-[REDACTED] Investments

The principal terms of the Pre-[**REDACTED**] Investments are set out as below:

	Series A Financing	**Series A-2 Financing**
Date of agreement	April 23, 2021	June 10, 2021
Date of which investment was fully settled	June 18, 2021	August 10, 2021
Cost per Share paid by each of the Pre-[REDACTED] Investors (in approximation)[(1)]	US$0.75 (equivalent to approximately HK$5.87)	US$1.12 (equivalent to approximately HK$8.76)
Post-money valuation	Approximately US$315 million	Approximately US$868 million

	Series A Financing	Series A-2 Financing
Bases of consideration and valuation	The consideration of Series A Financing was determined after arms' length negotiation between ONM Group Ltd. and the Series A Investors conducted in late 2020 with reference to the development status of our Group's products, the scale of business and development prospect of our Group, taking into account the then market sentiment and uncertainty to the economic recovery in the midst of the COVID-19 pandemic.	The consideration of Series A-2 Financing was determined after arms' length negotiation taking into account the ON HV Transfer, the development status of our Group's products, the scale of business and development prospect of our Group. Our valuation increased from approximately US$315 million post Series A Financing to approximately US$868 million post Series A-2 Financing due to (i) the then financial performance of our Company; (ii) nine new product registration approvals being obtained for in jurisdictions across four continents, including major markets such as the PRC and the United States in the first quarter of 2021; (iii) developing our own direct sales team to further strengthen our market presence in the PRC; and (iv) the product portfolio of ON P&F.
Discount to the [REDACTED] (in approximation)[(2)]	[**REDACTED**]%	[**REDACTED**]%
Amount of consideration paid	US$[**REDACTED**]	US$[**REDACTED**]
Lock-up Period	The equity interest of our Company acquired by the Pre-[**REDACTED**] Investors in the Pre-[**REDACTED**] Investments [will be] subject to a lock-up period of six months from the [**REDACTED**].	
Use of proceeds from the Pre-[REDACTED] Investments	The proceeds have been used to repay the outstanding bank loans of approximately US$39.0 million, purchase financial assets with pre-determined coupon at maturity of US$20.0 million and deposited as short-term bank deposit of US$129.0 million, respectively. As of the Latest Practicable Date, approximately [93]% of the net proceeds from the Pre-[**REDACTED**] Investments by the Pre-[**REDACTED**] Investors were utilized.	

	Series A Financing	Series A-2 Financing
Strategic benefits of the Pre-[REDACTED] Investors brought to our Company	At the time of the Pre-[**REDACTED**] Investments, our Directors were of the view that our Company could benefit from the additional capital that would be provided by the Pre-[**REDACTED**] Investors' investments in our Company and the Pre-[**REDACTED**] Investors' knowledge and experience. The investments by our Pre-[**REDACTED**] Investors, who are reputable investors in the PRC, also increases our brand awareness in the PRC and facilitates our marketing efforts. The Directors nominated and appointed by our Pre-[**REDACTED**] Investors complement our Board to support good corporate governance.	

Notes:

1. The cost per Share paid by each of the Pre-[**REDACTED**] Investors is calculated based on the consideration paid by each of Pre-[**REDACTED**] Investors divided by the number of Shares held by each of the Pre-[**REDACTED**] Investors after Share Consolidation.

2. The discount to the [**REDACTED**] is calculated based on the [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the [**REDACTED**] and the exchange rate of US$1 to HK$7.8250.

3. For further details of accounting treatment of the Series A Preferred Shares and Series A-2 Preferred Shares, please refer to the paragraph headed "Financial Information – Indebtedness – Convertible Redeemable Preferred Shares" in this document.

Special Rights of the Pre-[REDACTED] Investors

All Preferred Shares shall be converted into Ordinary Shares of our Company immediately before the completion of the [**REDACTED**] on a 1:1 ratio. All the shareholders (including the Pre-[**REDACTED**] Investors) of our Company are bound by shareholders' agreement dated September 28, 2021 (as amended from time to time) (the "**SHA**") and the articles of association of our Company which superseded all previous agreements among the contracting parties in respect of the shareholders' rights in our Company.

The Pre-[**REDACTED**] Investors were granted customary special rights, including protective provisions and information rights, etc. Except for the redemption right which has been waived, all other special rights (including the conversion right, the conversion adjustment right and the director nomination right as set out below) shall cease to be effective and be discontinued upon [**REDACTED**].

Redemption Right

Each Pre-[**REDACTED**] Investor is given a redemption right to, upon occurrence of specified events, sell to HART all or a portion of the Preferred Shares it then holds in accordance with the terms of the SHA at a specified redemption price. Each of the relevant Pre-[**REDACTED**] Investors has executed a waiver undertaking by September 28, 2021 to terminate the aforementioned redemption right with effect from the date of the waiver undertaking. The redemption right is only exercisable if the [**REDACTED**] does not take place and shall be automatically restored upon the earlier of, among others, (i) failure on the part of our Company to complete its [**REDACTED**] before a specified deadline, or (ii) upon the earlier of the rejection, withdrawal or lapse of the Company's [**REDACTED**].

Conversion Right

Each Pre-[**REDACTED**] Investor is given a conversion right to convert, at its option, its Preferred Shares to Ordinary Shares at an initial conversion ratio of 1:1. The conversion from Preferred Shares to Ordinary Shares will automatically take place upon an [**REDACTED**] of shares of the Company and commencement of [**REDACTED**] of the Shares of the Company on the [**REDACTED**] at the pre-[**REDACTED**] market capitalization that (i) implies a valuation of Preferred Shares held by the Pre-[**REDACTED**] Investors immediately prior to the [**REDACTED**] at no less than 100% of the aggregate purchase price paid by such Pre-[**REDACTED**] Investors for the issuance of their respective Preferred Shares if the [**REDACTED**] is consummated within twenty four months from July 20, 2021; or (ii) is equal to or exceed US$1,000,000,000 if the [**REDACTED**] is consummated after the second anniversary of July 20, 2021 ((i) or (ii) referred to as "**Qualified** [**REDACTED**]"). The [**REDACTED**] [is] a Qualified [**REDACTED**] and all Preferred Shares will be automatically converted into Ordinary Shares upon [**REDACTED**].

Director Nomination Right

Pursuant to the Series A share subscription agreement, so long as the outstanding Series A Preferred Shares represent no less than 5% of the total issued share capital of the Company (on a fully-diluted and as-converted basis) in aggregate, CICC Biomedical Fund shall be entitled to nominate a Director (the "**Series A Director**"). The Series A Director was appointed as a director of ONM Group Ltd. from June 23, 2021 to September 28, 2021, and was appointed as a Director of our Company on September 2021. Pursuant to the resolutions of the Board dated September 29, 2021, the Series A Director will resign effective before the date of this document. Both CICC Biomedical Fund and the SCGC Entities enjoy director nomination right pursuant to the relevant subscription agreements. As such director nomination right will be terminated upon [**REDACTED**], the Company has discussed with CICC Biomedical Fund and the SCGC Entities as to whether the directors they nominated would remain on the Board upon [**REDACTED**]. It was agreed by the Company and the relevant parties (including the directors nominated by CICC Biomedical Fund and the SCGC Entities) that the Series A Director will resign with effect before the date of this document whilst Dr. Yi Zhou, being the director nominated by the SCGC Entities, will remain on our Board upon [**REDACTED**], having taken into account considerations such as the respective shareholding of CICC Biomedical Fund and the SCGC Entities.

Information about the Pre-[REDACTED] Investors

Our Pre-[**REDACTED**] Investors include certain well-known and experienced institutional investors. Set out below is a description of our Pre-[**REDACTED**] Investors.

SCGC Entities

Each of SCGC Capital Holding Company Limited ("**SCGC Capital**"), Suzhou Red Earth Yeju Investment Ltd. ("**SZYJ**") and HTYL Investment Holdings Limited ("**HTYL**") (collectively the "**SCGC Entities**") is a company incorporated under the laws of the BVI. The SCGC Entities are affiliates of Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司), which was established in 1999 by the Shenzhen Municipal Government with a focus on venture capital investment to nurture entrepreneurship and innovation and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of the Shenzhen Municipal Government (深圳市人民政府國有資產監督管理委員會). The SCGC Entities focus, among other things, on investments in innovative growth-oriented enterprises. We became acquainted with the SCGC Entities through our then financial advisor, CITIC Securities Company Limited, a company listed on the Main Board of the Stock Exchange (stock code: 6030) ("**CITIC Securities**"). As of the date of this document and immediately following completion of the [**REDACTED**], the SCGC Entities are interested in 12.68% and [**REDACTED**]% of the total issued share capital of the Company (without taking into account any Shares which may be allotted and issued under the Share Incentive Schemes), respectively. Accordingly, Shenzhen Capital Group Co., Ltd. is a substantial shareholder of our Company.

Kinetic

Kinetic is a limited liability company incorporated under the laws of Hong Kong and is an investment holding company indirectly wholly owned by CCB International (Holdings) Limited (建銀國際(控股)有限公司), which is in turn an indirect wholly-owned subsidiary of China Construction Bank Corporation (中國建設銀行股份有限公司). China Construction Bank Corporation is a joint stock company incorporated in the PRC with limited liability and the shares of which are listed on the Main Board of the Stock Exchange (stock code: 00939) and Shanghai Stock Exchange (stock code: 601939), which offers banking, corporate financing and sales and trading services. We were introduced to Kinetic by the SCGC Entities upon their decision to proceed with their investments. Kinetic has invested in companies which are listed on the Main Board of the Stock Exchange, such as Bison Finance Group Limited (stock code: 0888) and Tongcheng Travel Holdings Limited (stock code: 0780). To the best of the Directors' knowledge, each of Kinetic, CCB International (Holdings) Limited and China Construction Bank Corporation is an Independent Third Party.

CICC Biomedical Fund

CICC Biomedical Fund L.P. (中金啟德(廈門)創新生物醫藥創業投資合夥企業(有限合夥) (formerly known as 中金啟德(廈門)創新生物醫藥股權投資基金合夥企業(有限合夥))) ("**CICC Biomedical Fund**") is a private equity fund managed by CICC Capital Management Co., Ltd. as the general partner and is focused on world-leading innovative medicines and technologies. CICC Capital Management Co., Ltd. is a wholly-owned subsidiary of China International Capital Corporation Limited, a company listed on the Main Board of the Stock Exchange (stock code: 3908) and Shanghai Stock Exchange (stock code: 601995). China International Capital Corporation Hong Kong Securities Limited is wholly owned by China International Capital

Corporation (Hong Kong) Limited, which is a wholly-owned subsidiary of China International Capital Corporation Limited. We were introduced to CICC Biomedical Fund by China Merchants Securities Investment Co., Ltd., a wholly-owned subsidiary of China Merchant Securities Co., Ltd (a company listed on the Main Board of the Stock Exchange (stock code: 6099) and Shanghai Stock Exchange (stock code: 600999)) ("**CMS**"), which is the indirect holding company of Bliss Moment, upon their decision to proceed with their investments. CICC Biomedical Fund has 30 limited partners, none of them is holding 30% or more partnership interests. To the best of the Directors' knowledge, each of the general partner and limited partners of CICC Biomedical Fund is an Independent Third Party.

Bliss Moment

Bliss Moment Limited is a company incorporated in the BVI and is wholly owned by China Merchants Securities Investment Management (HK) Co., Ltd. (招商證券投資管理(香港)有限公司) ("**CMSHK**"), an Independent Third Party. CMSHK is a wholly-owned subsidiary of China Merchants Securities International Company Limited, a company incorporated in Hong Kong in July 1999 acting as the main overseas business platform of CMS, and offers security brokerage, corporate financing, sales and trading, asset management, private equity, and commodities trading services. We became acquainted with Bliss Moment through CITIC Securities.

Shenzhen Share Zeshan

Shenzhen Share Zeshan Precision Medical Limited Partnership (深圳市分享擇善精準醫療創業投資合夥企業(有限合夥)) ("**Shenzhen Share Zeshan**") is a limited partnership managed by Shenzhen Share Growth Investment Management Co., Ltd. (深圳市分享成長投資管理有限公司). The general partner of Shenzhen Share Zeshang is Shenzhen Share Growth Investment Management Co., Ltd. (深圳市分享成長投資管理有限公司), which is in turn owned as to 62.08% by Mr. Bai Wentao (白文濤), an Independent Third Party. Shenzhen Share Zeshang has four limited partners, with Ningbo Meishan Port Share Zeshang Precision Medical Investment Partnership (Limited Partnership) (寧波梅山保稅港區分享擇善精准醫療投資合夥企業(有限合夥)) and Shenzhen Yindao Fund Investment Co., Ltd. (深圳市引導基金投資有限公司) holding partnership interests of 45.67% and 30.00%, respectively, and the two other limited partners holding less than 30% partnership interests. We were introduced to Shenzhen Share Zeshan by China Merchants Securities Investment Co., Ltd., a wholly-owned subsidiary of CMS, which is the indirect holding company of Bliss Moment, upon their decision to proceed with their investments. Founded in 2007, the Share Capital Fund (分享投資) has its headquarters in Shenzhen, a professional investment team of over 50 members, and its assets under management exceeding RMB8 billion. It specializes in structuring strategic investments in early-to-mid stage start-ups, and has an extensive investment portfolio including biotech and breakthrough drug research start-ups. To the best of the Directors' knowledge, each of the general partner and limited partners of Shenzhen Share Zeshan is an Independent Third Party.

Worldstar

Worldstar Global Holdings Limited ("**Worldstar**") is a company incorporated in the BVI on December 9, 2005, which focuses on equity investment opportunities in emerging industries, such as medicine and food technology. We were introduced to Worldstar by the SCGC Entities upon their decision to proceed with their investments. The total issued share capital of Worldstar is held by Mr. Lui Yiu Wah Alexander, an Independent Third Party. Worldstar has invested in Akeso, Inc., a company listed on the Main Board of the Stock Exchange (stock code: 9926).

Galaxy Capital

Galaxy Capital International Limited (星河資本國際有限公司) ("**Galaxy Capital**") is a company incorporated in Hong Kong on November 29, 2019. We were introduced to Galaxy Capital by the SCGC Entities upon their decision to proceed with their investments. Galaxy Capital is ultimately held by Mr. Huang Chu-long (黃楚龍) and his spouse, Ms. Mo Jinli (莫錦禮) as to 75% and 25%, respectively. Mr. Huang Chu-long is the chairman of Galaxy Holding Group Company Limited* (星河控股集團有限公司) and one of the controlling shareholders of E-Star Commercial Management Company Limited, a company listed on the Main Board of the Stock Exchange (stock code: 6668). To the best of the Directors' knowledge, each of Galaxy Capital and its two ultimate shareholders is an Independent Third Party.

B.W. Holding

B.W. Holding Limited is a company incorporated in the BVI on June 21, 2018, of which the total issued share capital is held by Mr. Wong Wai Yue, an Independent Third Party. Mr. Wong Wai Yue is the chairman and an executive director of Nameson Holdings Limited, a company listed on the Main Board of the Stock Exchange (stock code: 1982). He has been investing in the healthcare industry locally and overseas, such as aggregation-induced emission technology, in-vitro diagnostics solutions and elderly homes. Mr. Wong Wai Yue is a family friend of our Controlling Shareholders.

Compliance with Interim Guidance and Guidance Letter

The Joint Sponsors confirm that the investments by the Pre-[**REDACTED**] Investors are in compliance with the Guidance Letter HKEX-GL29-12 issued in January 2012 and updated in March 2017 by the Stock Exchange, the Guidance Letter HKEX-GL43-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange and the Guidance Letter HKEX-GL44-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange.

CAPITALIZATION OF OUR COMPANY

The following table illustrates the capitalizations of the Company as of the Latest Practicable Date and upon completion of the [**REDACTED**] (assuming that all the Preferred Shares have been converted to Ordinary Shares on a 1:1 basis, and without taking into account any Shares which may be allotted and issued under the Pre-[**REDACTED**] Share Option Scheme and after taking into account the Share Consolidation of every five Shares with par value of US$0.0001 into one share of the corresponding class with par value of US$0.0005):

Shareholder	Ordinary Shares	Series A Preferred Shares	Series A-2 Preferred Shares	Ownership percentage as of the date of this document	Number of Ordinary Shares held upon [REDACTED]	Ownership percentage as of the [REDACTED]
HART	2,607,619,221	–	–	67.46%	[**REDACTED**]	[REDACTED]%
Initial COSMIC Shareholders[(1)]	96,879,152	–	–	2.51%	[**REDACTED**]	[REDACTED]%
Mr. Kelvin Kai Hang LAU[(2)]	180,001,248	–	–	4.66%	[**REDACTED**]	[REDACTED]%
Bliss Moment[(2)]	–	67,081,387	22,280,603	2.31%	[**REDACTED**]	[REDACTED]%
CICC Biomedical Fund[(2)]	–	100,622,080	–	2.60%	[**REDACTED**]	[REDACTED]%
Shenzhen Share Zeshan[(2)]	–	67,081,387	–	1.74%	[**REDACTED**]	[REDACTED]%
SZYJ	–	–	349,805,473	9.05%	[**REDACTED**]	[REDACTED]%
Kinetic[(2)]	–	–	133,683,620	3.46%	[**REDACTED**]	[REDACTED]%
HTYL	–	–	77,982,112	2.02%	[**REDACTED**]	[REDACTED]%
SCGC Capital	–	–	62,385,689	1.61%	[**REDACTED**]	[REDACTED]%
Worldstar[(2)]	–	–	44,561,207	1.15%	[**REDACTED**]	[REDACTED]%
Galaxy Capital[(2)]	–	–	44,561,207	1.15%	[**REDACTED**]	[REDACTED]%
B.W. Holding[(2)]	–	–	11,140,302	0.29%	[**REDACTED**]	[REDACTED]%
Total	2,884,499,621	234,784,854	746,400,213	100.00%	[**REDACTED**]	[REDACTED]%

Notes:

(1) The [**REDACTED**] Shares ([**REDACTED**] Shares as adjusted by Share Consolidation) held by Mr. Ching Chung John CHOW, our executive Director, and the [**REDACTED**] Shares ([**REDACTED**] Shares as adjusted by Share Consolidation) held by Mr. Takeshi OHBA, the president and representative director of ONM Japan, will not count towards the [**REDACTED**] and the remaining [**REDACTED**] Shares ([**REDACTED**] Shares as adjusted by Share Consolidation) held by the other Initial COSMIC Shareholders will count towards the [**REDACTED**].

(2) These Shareholders are not our core connected persons and the [**REDACTED**] Shares ([**REDACTED**] Shares as adjusted by Share Consolidation) they hold will count towards the [**REDACTED**].

[**REDACTED**]

Upon completion of the [**REDACTED**], HART will hold [**REDACTED**] Shares, approximately [**REDACTED**]% of the total issued Shares; therefore, it is our Controlling Shareholder and its Shares will not count towards the [**REDACTED**]. In addition, SCGC Capital, SZYJ and HTYL (collectively the "**SCGC Entities**", our substantial shareholders) are each controlled by Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司), and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of the Shenzhen Municipal Government (深圳市人民政府國有資產監督管理委員會). The SCGC entities will collectively hold [**REDACTED**] Shares, approximately [**REDACTED**]% of the total issued Shares; therefore, the SCGC Entities are our substantial shareholders and their Shares will not count towards the [**REDACTED**]. Furthermore, Mr. Ching Chung John CHOW is our executive Director and the [**REDACTED**] Shares he holds will not count towards the [**REDACTED**]. Moreover, Mr. Takeshi OHBA is the president and representative director of ONM Japan, a subsidiary of our Company. As the role of president in entities incorporated in Japan is equivalent to the role of director under the Listing Rules, the [**REDACTED**] Shares he holds will not count towards the [**REDACTED**]. As a result, the [**REDACTED**] Shares held by our core connected persons, representing a total of approximately [**REDACTED**]% of our Company's total issued Shares, will not count towards the [**REDACTED**].

Save as disclosed above, to the best of our Directors' knowledge, all other investors and shareholders of our Company are not core connected persons of our Company. As a result, approximately [**REDACTED**]% of our Company's total issued Shares, inclusive of a total of approximately [**REDACTED**]% of the Shares held by the other existing Shareholders, will count towards the [**REDACTED**] upon completion of the [**REDACTED**] (without taking into account the Shares which may be allotted and issued under the Share Incentive Schemes and assuming the [**REDACTED**] are allotted and issued to [**REDACTED**]). Accordingly, over 25% of our Company's total issued Shares will be held by the [**REDACTED**] upon completion of the [**REDACTED**] in accordance with 8.08(1)(a) of the Listing Rules.

PRC LEGAL COMPLIANCE

M&A Rules

Under the Rules on the Merger and Acquisition of Domestic Enterprises by Foreign Investors in the PRC (關於外國投資者併購境內企業的規定) (the "**M&A Rules**"), which was jointly promulgated by the Ministry of Commerce of the PRC ("**MOFCOM**") and other departments of the State Council on August 8, 2006 and came into effective on the same day and latest amended on June 22, 2009, the merger and acquisition of the PRC domestic enterprises by foreign investors, which means that the foreign investors purchase or subscribe for the equity or shares of a non-foreign invested PRC enterprise (also known as a PRC domestic enterprise) or that the foreign investors establish a foreign invested PRC enterprise to acquire or operate the assets of a non-foreign invested PRC enterprise by agreement, should comply with the PRC laws and regulations. The approval from MOFCOM is required to be obtained in some specific circumstances including but not limited to: (i) a PRC individual or

a PRC enterprise acquires its affiliated PRC domestic enterprise through its controlled foreign company ("**Acquisition of the Affiliated PRC Company**"); (ii) a foreign investor acquires a PRC domestic enterprise at the consideration of the equity interests in foreign companies ("**Exchange of Shares**"); and (iii) the establishment of an offshore special purpose vehicle (the "**SPV**"), which is directly or indirectly controlled by the PRC individuals or the PRC companies for the purpose of offshore listing of the interests in the PRC enterprises actually owned by those PRC individuals or the PRC companies. Moreover, under the M&A Rules, for the offshore listing of the shares of the SPV, it is also required to obtain the approval from the China Securities Regulatory Commission.

Our PRC legal advisors are of the opinion that no approval from MOFCOM or China Securities Regulatory Commission under the M&A Rules is required for the Pre-[**REDACTED**] Investments or the [**REDACTED**], for the reasons that (i) our Group was not affiliated with the Pre-[**REDACTED**] Investors who are PRC enterprises prior to the Pre-[**REDACTED**] Investments and such Pre-[**REDACTED**] Investors paid the share subscription price in cash rather than by means of shares of a PRC company and thus the Pre-[**REDACTED**] Investments did not constitute the Acquisition of the Affiliated PRC Company or the Exchange of Shares mentioned above; and (ii) our Controlling Shareholders are not PRC individuals or PRC companies under the M&A Rules and thus our Company did not constitute an SPV under the M&A Rules.

SAFE Circular 37

According to the Circular of the State Administration of Foreign Exchange on Issues Concerning the Administration of Foreign Exchange in Offshore Investments and Financing and Return Investments by Domestic Residents through Special Purpose Vehicles (國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知) (the "**SAFE Circular 37**"), which was promulgated and became effective on July 4, 2014, the PRC resident individuals are required to register with the State Administration of Foreign Exchange ("**SAFE**") or its local counterparts in connection with their investments in a special purpose vehicle before they make contribution to the same in accordance with the provisions of SAFE Circular 37 ("**SAFE 37 Registration**"). Under SAFE Circular 37, "special purpose vehicle" refers to an offshore entity directly established or indirectly controlled by the PRC residents with their legally owned assets or equity interests in PRC enterprises or their offshore assets or interests for the purpose of the offshore investment and financing; and a "PRC resident individual" refers to a Chinese citizen with a resident identification card, servicemen identification card or armed police identification card, or a foreign individual who has no legal identification card of the PRC but habitually resides in the Mainland China for economic interests. The Guidelines on the Foreign Exchange Business for Capital Accounts (2020 Version) (資本項目外匯業務指引(2020年版)) which was promulgated by the Comprehensive Department of SAFE on November 13, 2020, further provides that the foreign individuals are not required to make the SAFE 37 Registration if they invest in the special purpose vehicle with their offshore assets or interests.

Our Controlling Shareholders are not the PRC resident individuals under SAFE 37 Circular and they used their offshore funds to establish and invest in our Company. Based on the foregoing, our PRC legal advisors are of the view that our Controlling Shareholders are not required to make SAFE 37 Registration for their incorporation of or investment in our Company or the [**REDACTED**] under SAFE Circular 37.

ODI Procedures

NDRC Procedure

According to Measures for the Administration of Outbound Investment of Enterprises (企業境外投資管理辦法) promulgated by National Development and Reform Commission of the PRC ("**NDRC**") on December 26, 2017 and effective from March 1, 2018, a PRC enterprise shall obtain the approval from NDRC or complete the filing with NDRC or its local counterparts (as the case may be) in connection with its outbound investment before it makes capital contribution to such outbound investment project and after completion of the outbound investment, the PRC enterprise shall submit the project completion report via the on-line system to the NDRC or its local counterparts ("**NDRC ODI Procedure**").

MOFCOM Procedure

According to the Outbound Investment Administration Rules (境外投資管理辦法) promulgated by the MOFCOM on September 6, 2014 and effective from October 6, 2014, a PRC enterprise shall complete the approval or filing procedure at MOFCOM or its local counterparts (as the case may be) in connection with its outbound investment and obtain a corresponding outbound investment certificate before it makes capital contribution to such outbound investment project ("**MOFCOM ODI Procedure**"). In the event of changes to the items specified on the outbound investment certificate obtained, the PRC enterprise shall go through the alteration procedure at MOFCOM or its local counterparts which issued the original outbound investment certificate to obtain a revised certificate.

SAFE Procedure

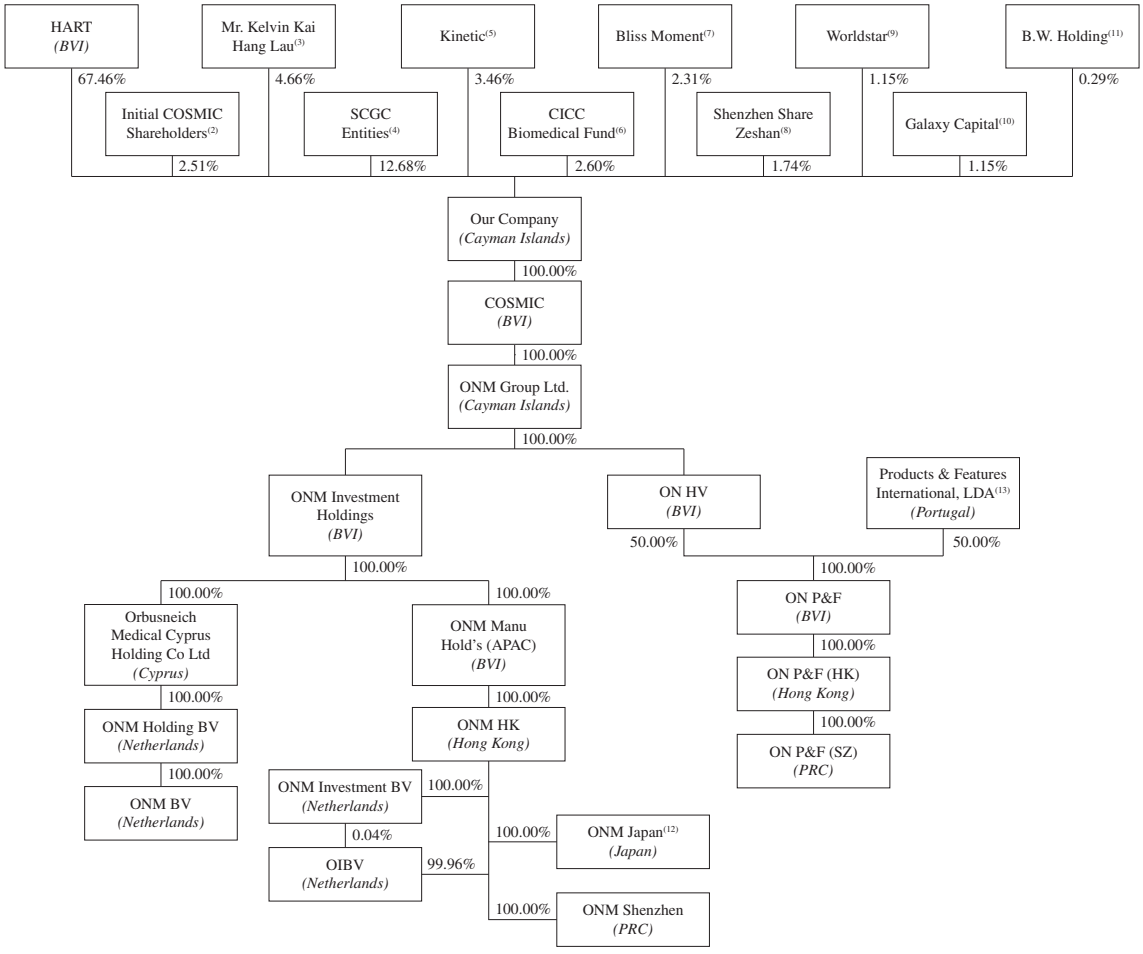
According to (i) Foreign Exchange Administration Rules on Outbound Direct Investment of PRC Organizations (境內機構境外直接投資外匯管理規定) promulgated by SAFE on July 13, 2009 and effective from August 1, 2009 and (ii) the SAFE Notice of the Policies on Further Simplifying and Improving the Foreign Exchange Administration of Direct Investment (國家外匯管理局有關進一步簡化和改進直接投資外匯管理政策的通知) promulgated on February 13, 2015 and effective from June 1, 2015, a PRC enterprise which has completed the approval or filing procedures at the outbound investment regulatory authorities shall make the registration with SAFE through its designated banks in connection with its outbound direct investment and obtain a corresponding SAFE registration certificate ("**SAFE ODI Procedure**", together with NDRC ODI Procedure and MOFCOM ODI Procedure, "**ODI Procedures**"). With the approval or filing certificate issued by the outbound investment regulatory authorities and the SAFE registration certificate, the PRC enterprise can remit funds outside the PRC through the designated banks for the purpose of outbound direct investment. In the event of changes to certain basic information of the offshore company registered at SAFE's system, the PRC enterprise shall make the alteration registration with SAFE through its designated banks.

Among the Pre-[**REDACTED**] Investors, CICC Biomedical Fund and Shenzhen Share Zeshan are PRC enterprises and SCGC Entities made their Pre-[**REDACTED**] Investments with the domestic funds remitted from their PRC parent enterprises (i.e. Suzhou Redearth, Shenzhen Redearth and SCGC). As advised by our PRC legal advisors, the Pre-[**REDACTED**] Investments made by CICC Biomedical Fund, Shenzhen Share Zeshan and SCGC Entities were subject to ODI Procedures. Based on the review of the relevant regulatory documentation, our PRC legal advisors were of the view that CICC Biomedical Fund, Shenzhen Share Zeshan and the PRC parent enterprises of SCGC Entities (collectively "**PRC Pre-**[**REDACTED**] **Investors**") had completed the ODI Procedures with respect to their Pre-[**REDACTED**] Investments before they paid the subscription price to us. As the Second Share Swap in the Reorganization caused the changes to (i) the information set out in outbound investment certificate obtained by the PRC Pre-[**REDACTED**] Investors and (ii) the registered information in SAFE's system in connection with CICC Biomedical Fund and Shenzhen Share Zeshan's outbound direct investments, the PRC Pre-[**REDACTED**] Investors should go through the alteration filing with the competent local counterpart of MOFCOM and, after receiving the revised outbound investment certificate, CICC Biomedical Fund and Shenzhen Share Zeshan should make the alteration registration with SAFE through the relevant bank. As of the Latest Practicable Date, as advised by our PRC legal advisors based on their view of the relevant documentation, the above-mentioned alternation filing with the competent local counterpart of MOFCOM and alternation registration with SAFE had both been completed.

Our PRC legal advisors confirmed that all relevant material registrations, approvals and permits required under PRC laws and regulations in relation to the establishment, increases of registered capital, equity transfers (if any) in respect of the PRC subsidiaries of our Group as described above had been completed and obtained.

OUR STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

A simplified corporate structure of our Group immediately prior to the [**REDACTED**] is as follows [(1)]:



Notes:

(1) Based on the assumption that all Preferred Shares will be converted into Shares on a 1:1 basis upon the [**REDACTED**] becoming unconditional and without taking into account any Shares to be allotted and issued under the Share Incentive Schemes.

(2) The Initial COSMIC Shareholders comprise the following:

Name	**Role and responsibilities**	**Number of Shares held**
Pik Lin Barbara WONG	Former senior management, responsible for overseeing the overall corporate and financial functions of our Group	81,989,864 Shares (16,397,973 Shares as adjusted by Share Consolidation)
Robert John COTTONE JR	Chief technical officer, responsible for overseeing the overall technology and product research and development and the global intellectual property strategies and protection of our Group	5,673,368 Shares (1,134,674 Shares as adjusted by Share Consolidation)
GJB Investments, LLC	The holding vehicle of Dr. Gary BECKER, our consultant and co-founder of Orbus Medical Technologies Inc., who is responsible for providing general advice in relation to products on vascular diseases	2,394,068 Shares (478,814 Shares as adjusted by Share Consolidation)
Elyse B. DAVIS	Sister of Dr. Gary BECKER	165,089 Shares (33,018 Shares as adjusted by Share Consolidation)
Wai Keung LEUNG	Senior director of corporate finance, responsible for overseeing the finance of our Group	2,303,571 Shares (460,713 Shares as adjusted by Share Consolidation)
Clarence Craig EDEWAARD	Co-founder of Orbus Medical Technologies Inc.	1,819,264 Shares (363,853 Shares as adjusted by Share Consolidation)
Ching Chung John CHOW	Executive Director, responsible for overseeing overall business development activities of our Group	1,535,714 Shares (307,143 Shares as adjusted by Share Consolidation)
Takeshi OHBA	President and representative director of ONM Japan, responsible for overseeing commercial activities and managing the development and the implementation of commercial strategies of our Group in Japan	998,214 Shares (199,643 Shares as adjusted by Share Consolidation)

The 1,535,714 Shares (307,143 Shares as adjusted by Share Consolidation) held by Mr. Ching Chung John CHOW, our executive Director, and the 998,214 Shares (199,643 Shares as adjusted by Share Consolidation) held by Mr. Takeshi OHBA, the president and representative director of ONM Japan, will not count towards the [**REDACTED**] and the remaining 94,345,224 Shares (18,869,045 Shares as adjusted by Share Consolidation) held by the other Initial COSMIC Shareholders will count towards the [**REDACTED**].

(3) Mr. Kelvin Kai Hang LAU is the brother of Ms. Kwai Ching Denise LAU, an executive Director and the chief operating officer of our Company. Mr. Kelvin Kai Hang LAU holds 180,001,248 Shares (36,000,250 Shares as adjusted by Share Consolidation). Mr. Kelvin Kai Hang LAU is not our core connected person and his Shares will count towards the [**REDACTED**].

(4) The SCGC Entities are Series A-2 Investors of our Group and consist of SCGC Capital, SZYJ and HTYL, which hold 62,385,689 Shares (12,477,138 Shares as adjusted by Share Consolidation), 349,805,473 Shares (69,961,095 Shares as adjusted by Share Consolidation) and 77,982,112 Shares (15,596,422 Shares as adjusted by Share Consolidation), respectively.

(5) Kinetic is a Series A-2 Investor of our Group, which holds 133,683,620 Shares (26,736,724 Shares as adjusted by Share Consolidation). Kinetic is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

(6) CICC Biomedical Fund is a Series A Investor of our Group, which holds 100,622,080 Shares (20,124,416 Shares as adjusted by Share Consolidation). CICC Biomedical Fund is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

(7) Bliss Moment is a Series A Investor and a Series A-2 Investor of our Group, which holds 89,361,990 Shares (17,872,398 Shares as adjusted by Share Consolidation). Bliss Moment is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

(8) Shenzhen Share Zeshan is a Series A Investor of our Group, which holds 67,081,387 Shares (13,416,277 Shares as adjusted by Share Consolidation). Shenzhen Share Zeshan is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

(9) Worldstar is a Series A-2 Investor of our Group, which holds 44,561,207 Shares (8,912,241 Shares as adjusted by Share Consolidation). Worldstar is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

(10) Galaxy Capital is a Series A-2 Investor of our Group, which holds 44,561,207 Shares (8,912,241 Shares as adjusted by Share Consolidation). Galaxy Capital is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

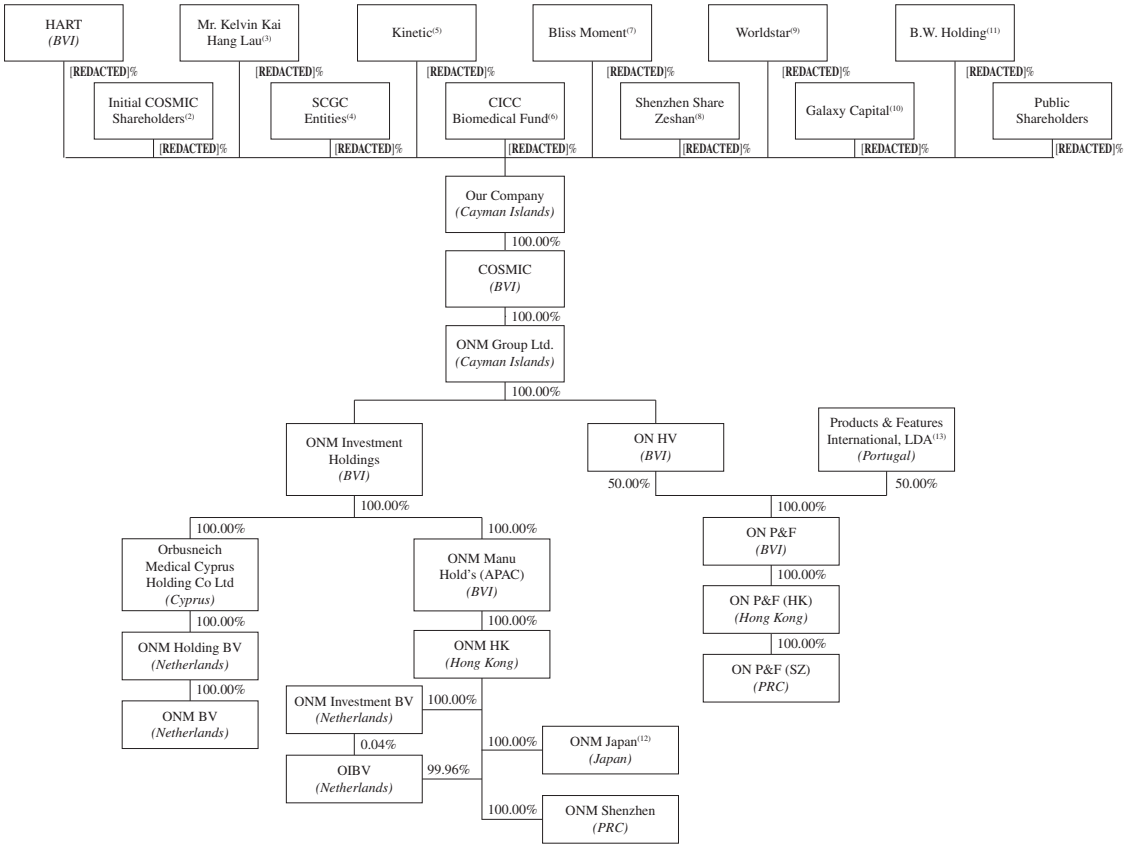
(11) B.W. Holding is a Series A-2 Investor of our Group, which holds 11,140,302 Shares (2,228,060 Shares as adjusted by Share Consolidation). B.W. Holding is not our core connected person and such Shares will count towards the [**REDACTED**]. Please refer to "– Pre-[**REDACTED**] Investments – Information about the Pre-[**REDACTED**] Investors" for further details.

(12) ONM HK and Mr. Takeshi OHBA are the registered shareholders of ONM Japan as to 99.995% and 0.005%, respectively, with ONM HK holding 100.00% beneficial interest of ONM Japan.

(13) ON P&F is owned by ON HV and Products & Features International, LDA ("**P&F Int'l**"), as to 50% and 50%, respectively. P&F Int'l is a company incorporated in Portugal and an Independent Third Party.

OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

A simplified corporate structure of our Group immediately following the [**REDACTED**] is as follows [(1)]:



Note:

Please refer to notes (1)-(13) to "– Our Structure Immediately Prior to the [**REDACTED**]".

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 a 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 a 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 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 1.75 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 product (DEB) 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	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
	Endobental 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. Endo-bentall 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 endobental 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.

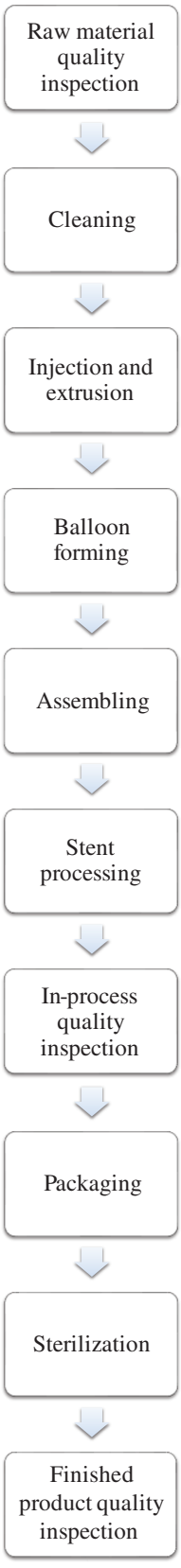
We believe that having production facilities both in the PRC and the Netherlands also gives us a competitive advantage over our international competitors in terms of labor cost management and operational flexibility. Typically, we require our employees to undergo health checks before they start producing 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.

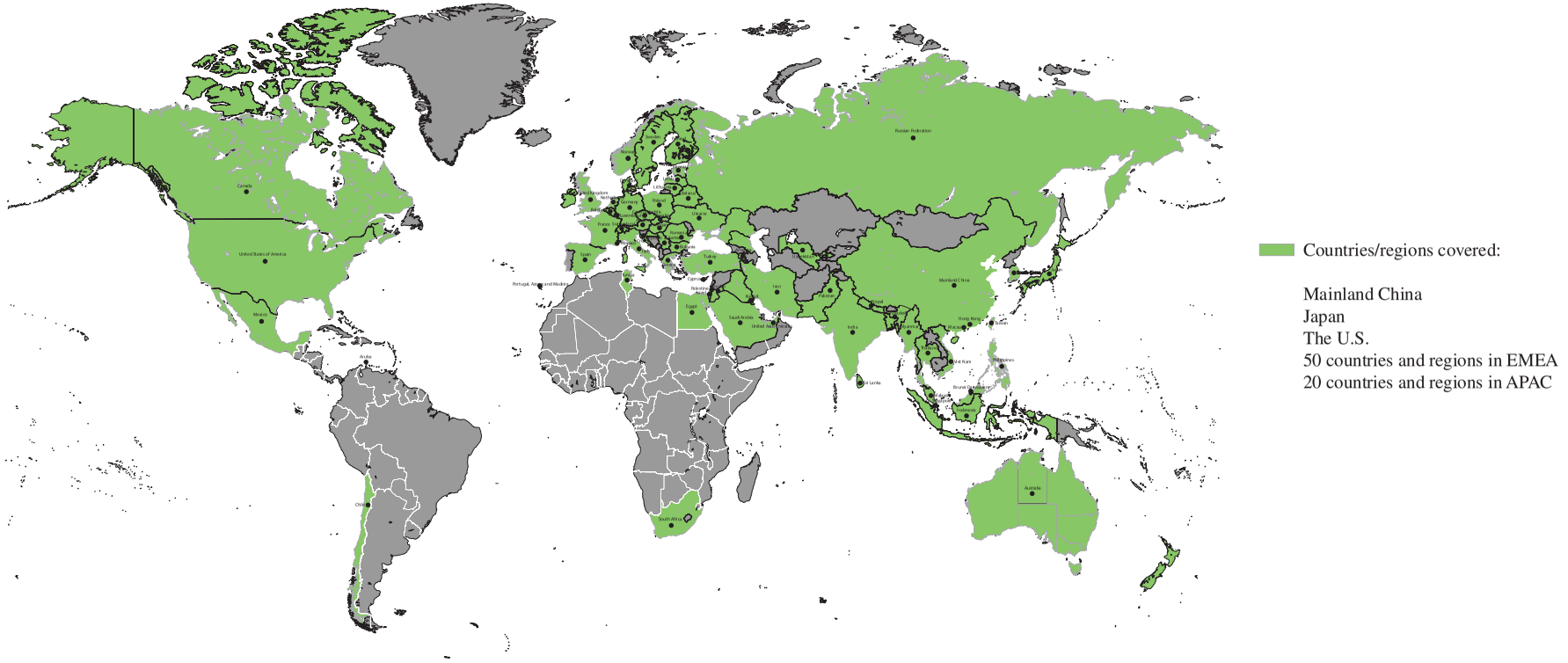
To the best knowledge of our Directors, there has been no material disruption of operations with our production facilities during the Track Record Period.

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

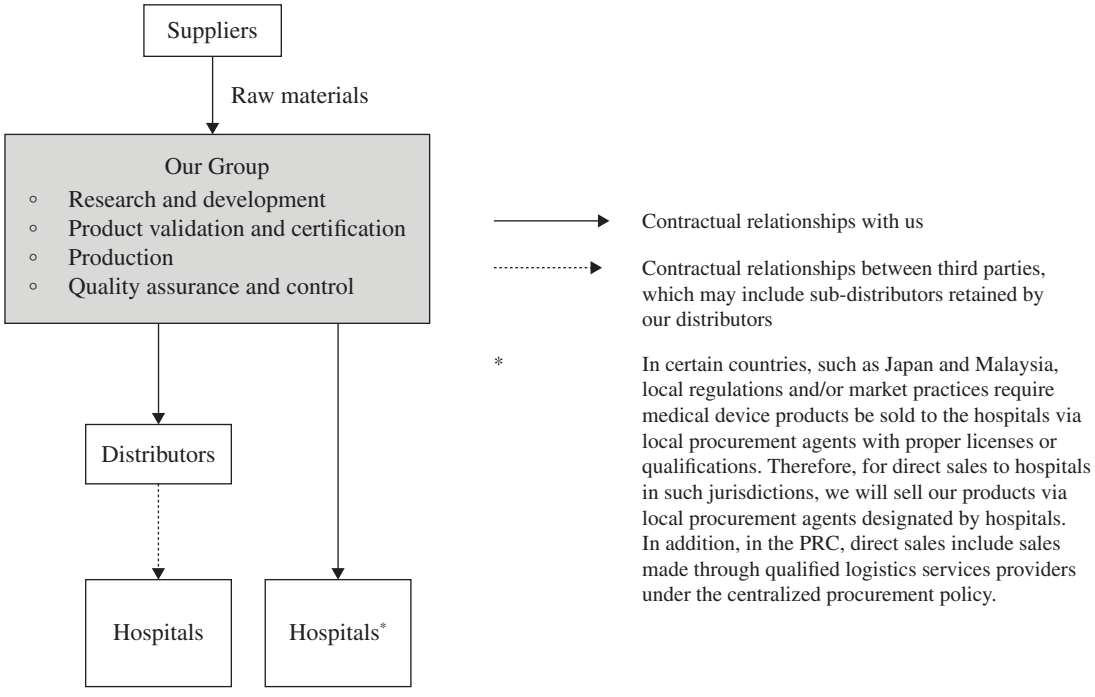
- *Internal marketing*: we seek to ensure that all multidisciplinary teams across our global operations are constantly aware and informed of our marketing efforts and updates to market trends

- *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.

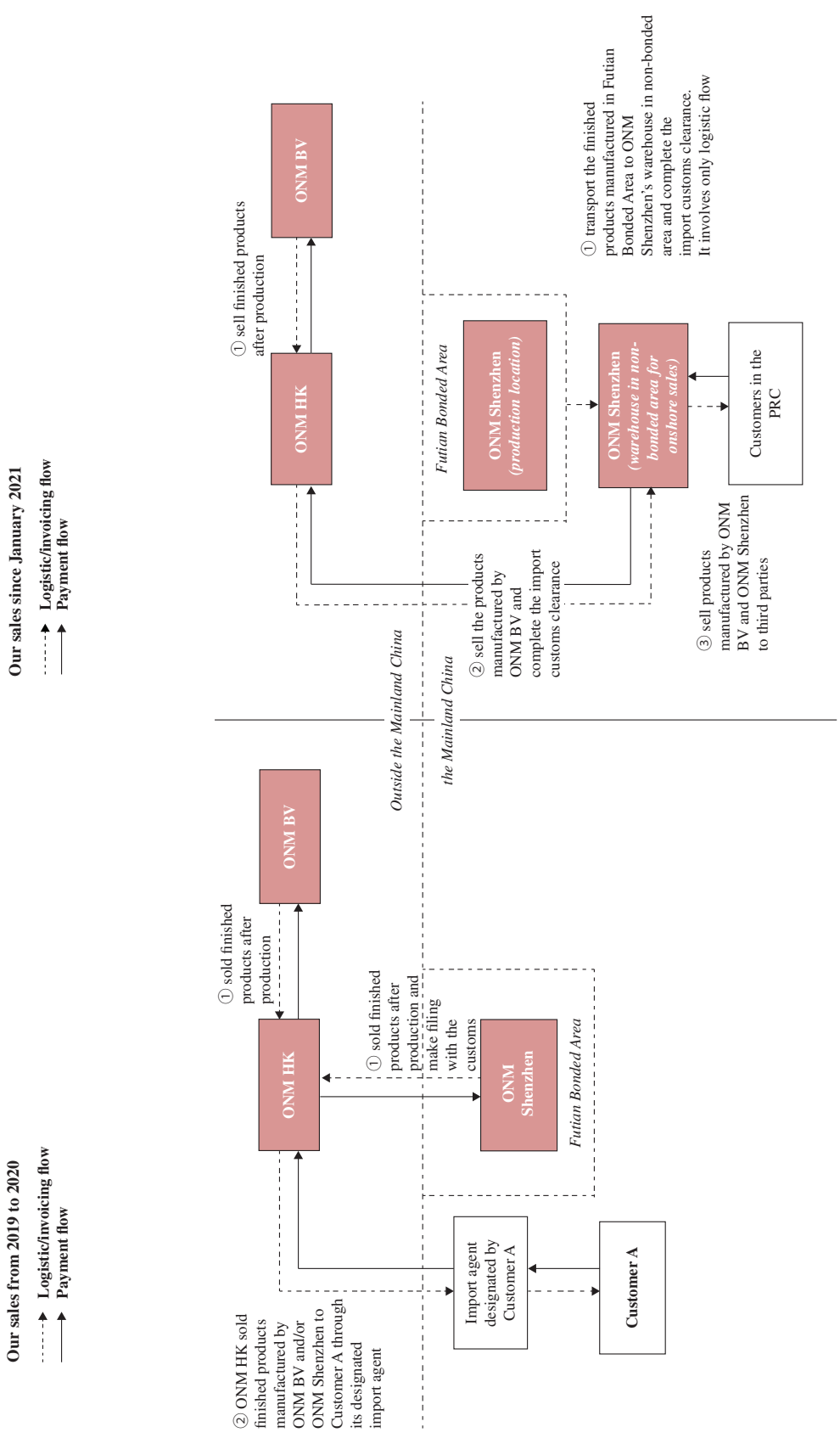
Since we may only possess limited market knowhow and offer limited products in new markets, we tend to enter new markets through distributors, which do not require us to set up a sales office in the new market immediately. Instead, our existing internal sales force will manage the distributors and provide 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

		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 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
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.

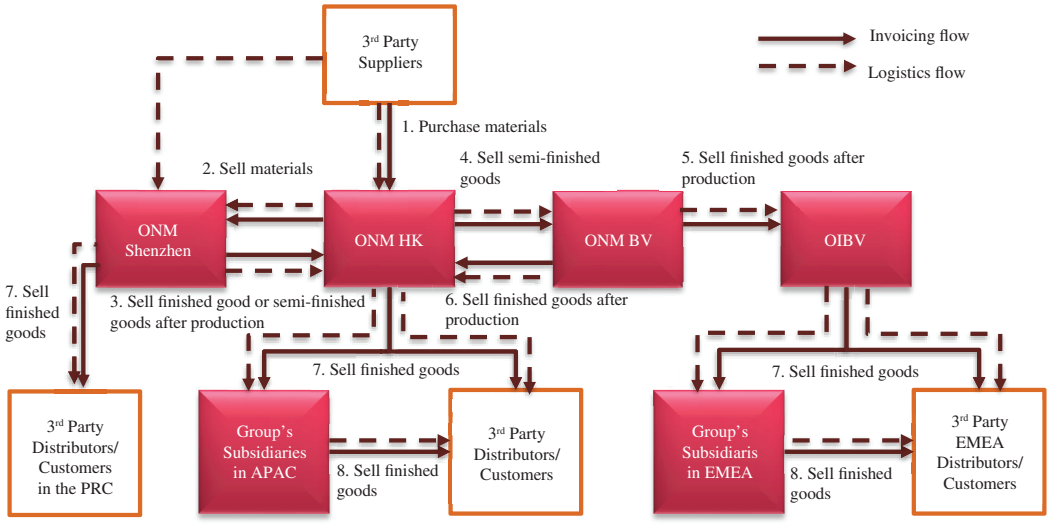
- Finished balloon/stent products by ONM BV were sold to OIBV for distribution of our Netherlands originated products to our distribution subsidiaries in Europe and third-party distributors.

- 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

		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 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, ISO014971:2019. 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.

ESG topics	Materiality	Potential Risks, Opportunities and Impacts
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."

	Our actions
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."
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

Climate related risks	Possible financial impacts	Mitigation measures
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
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
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

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) 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
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

License/Permit	License/Permit No.	Validity Period	Authority
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
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

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)	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
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

License/Permit	License/Permit No.	Validity Period	Authority
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:

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

  - 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

  - 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.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements as included in Appendix I to this document, which were prepared in accordance with HKFRS, together with the accompanying notes. The following discussion and analysis include forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements due to various factors, including those set forth in the sections headed "Forward-Looking Statements", "Risk Factors" in this document and elsewhere in this document.

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.

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. 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 know how 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 an around 40 products under development.

We maintain an established global sales network which consists of both distributorship and direct sales. 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 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 direct sales team covered an aggregate of nine countries/regions as of June 30, 2022 and works closely with each other to facilitate physician education and product promotions among different jurisdictions. For the six months ended June 30, 2022, sales generated from our direct sales was US$33.6 million, representing 48.9% of our total revenue in such period.

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 products per year, thereby enabling us to supply large-scale and stable high-quality products to customers around the world.

BASIS OF PRESENTATION

Immediately prior to and after the our Reorganization, we conducted our business through OrbusNeich Medical Group Limited and its subsidiaries (collectively, the "[**REDACTED**]"). Pursuant to the Reorganization, the [**REDACTED**] was transferred to and held by our Company.

Our Company has not been involved in any other business prior to the Reorganization and do not meet the definition of a business. The Reorganization is merely a reorganization of the [**REDACTED**] with no change in management of such business and the ultimate owners of the [**REDACTED**] remain the same. Accordingly, the Group resulting from the Reorganization is regarded as a continuation of the [**REDACTED**] conducted through our Company and its subsidiaries.

For the purpose of this document, our financial information has been prepared and presented as a continuation of the consolidated financial information of the [**REDACTED**], with the results, assets and liabilities recognized and measured at the carrying amounts of the [**REDACTED**] under the consolidated financial statements for all the years/periods presented.

Inter-company transactions, balances and unrealized gains/losses on transactions between our group companies were eliminated on combination.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION

During the Track Record Period, the following factors have significantly affected our results of operations and financial condition:

Growth and Competitive Landscape of the Global PCI/PTA Instrument Market

Our financial performance and future growth depend on the overall growth of the global PCI/PTA instrument market, as well as changes in their respective competitive landscape. In major markets, such as the PRC, Japan, the United States, Europe and APAC region, the PCI/PTA instrument market continue to grow at a steady pace. With the escalating prevalence of cardiovascular diseases, increasing preference of PCI procedures over traditional open-chest surgeries, and growing physician awareness and hospital adoption of transcatheter procedures, PCI/PTA instrument market is expected to experience continuous growth in the future, according to the CIC Report. For details, see section headed "Industry Overview" in this document.

In addition, changes in the competitive landscape in the PCI/PTA instrument market globally will also impact our results of operations. Our PCI balloon products achieved a 20%, 11%, 8% and 3% market share in terms of sales volume in 2021 in Japan, Europe, the PRC and the United States, respectively. However, potential competitors or faster-than-expected development of their products may affect our market position and demand for our products, which may in turn affect our results of operations.

We believe that by leveraging on our market position in the global PCI/PTA instrument market, we are well-positioned to capture the expected growth of the market through our innovative and robust product portfolio, which will further drive our results of operation and financial performance in the future.

Changes in Regulatory Environment

The medical device industry is highly regulated. Government policies and regulations, and their implementation and enforcement, significantly impact the supply, demand and pricing of medical devices, as well as on the cost of compliance for medical device companies in countries/regions where they operate. Medical devices must be filed or registered with the FDA, EMA, PMDA, NMPA or other similar regulatory authorities before they can be manufactured or sold in relevant markets, and some of such filings and registrations must be renewed periodically. The regulatory requirements in connection with such filing and registrations may change, which could significantly increase the resources and time required to launch new products and renew registrations for existing products.

In recent years, the government in the PRC, the U.S. and many other countries have promulgated policies to encourage the development of innovative medical devices, which have contributed to the growth of the medical devices industry. Changes in policies and regulations may also affect our results of operations. For example, in light of the PRC government's key policy objective to regulate pricing in the healthcare industry, legislations have been proposed or enacted. One of such efforts is the public tender processes that we are responsible for participating in under regional centralized procurement regimes for the right to sell our products to many public hospitals and other not-for-profit medical institutions within a particular region. We will constantly adjust our operations and sales practices in order to comply with any changes in the regulatory environment in the countries and/or regions where our products are sold to.

Our Ability to Develop and Successfully Market New Products

Our ability to develop and successfully market new products is one of the most important factors affecting our results of operations and financial condition. Our success depends on our ability to anticipate industry trends and identify, develop and market innovative products that meet our customers' evolving demand in a timely and cost-effective manner. Although we have a variety of existing products and have covered most of the cardiovascular interventional procedural instruments, new products are expected to continue to significantly influence our revenue and gross profit margins as new products generally have higher gross profit margins. We intend to expand our product portfolio by strengthening our research and development of new or enhanced products, expanding product lines and improving our existing products.

Moving forward, we will target our product development efforts on increasing our portfolio of cardiovascular interventional medical devices and expanding our product lines to include products such as medical devices for neuro-interventional and structural heart diseases. Nonetheless, any potential delays in our research and development activities or expected commercial launches relating to our pipeline products may significantly affect our future revenue growth and business prospects.

Our Ability to Expand and Efficiently Manage Our Distributor Network and Sales Force

We generate a substantial portion of our total revenue from sales to distributors. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, revenue 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. As a result, our ability to expand and efficiently manage our distribution network remains critical to our business and financial performance. In 2019, 2020, 2021 and for the six months ended June 30, 2022, our distribution network consisted of approximately 69, 62, 174 and 207 distributors globally, respectively.

In addition, we generate a large portion of our total revenue from sales to hospitals. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, revenue from direct sales to hospitals 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. Accordingly, our ability to expand and efficiently manage our sales force also remains critical to our business and financial performance.

Product Pricing

For our products sold directly to customers, our product prices are based on the public biddings set by hospitals and health care agencies and our negotiation with relevant customers pursuant to applicable regulations, which may put downward pressure on our selling prices. For our products sold to distributors, our product prices are affected by our negotiation with the distributors with reference to their selling price to the hospitals. Decreases in the selling prices of our products may materially and adversely affect our revenue and gross profit margin. We seek to enhance our pricing bargaining power by investing in product development, design capabilities and new product initiatives that respond to customer needs. We seek to maintain the average selling prices of our products despite pricing pressure. However, to the extent our cost reductions do not sufficiently offset price reductions, our profit margins could decline.

Our Ability to Expand Manufacturing Capacity

Our manufacturing capacity affects our results of operations. Since our inception, the overall production capacity of our production facilities in Shenzhen, the PRC and Hoevelaken, the Netherlands have grown from approximately 1,066,000 units per year for balloon products and approximately 56,400 units per year for stent products in 2019 to approximately 1,352,000 units per year for balloon products and approximately 56,400 units per year for stent products for the six months ended June 30, 2022. We need to expand our manufacturing capacity over time to satisfy increased demand for our products. The expansion of our manufacturing capacity requires time to (i) construct the facilities, (ii) obtain the necessary permits and certifications for operations, (iii) recruit and train the new employees for the new manufacturing facility and (iv) purchase our replacement machine and equipment. We plan to increase our capacity by adding additional production lines in our facilities in the PRC. For details, please refer to the section headed "Future Plans and [**REDACTED**]" in this document.

Our Ability to Manage Our Costs and Expenses

Our profitability has benefited from our effective control of cost of sales and ability to improve operating efficiency. We recorded an adjusted net profit margin (non-HKFRS measure) of 7.2%, 8.0%, 18.3%, 19.2% and 19.8% for the year ended December 31, 2019, 2020 and 2021 and for the six months ended June 30, 2021 and 2022, respectively. As our production volume and revenue grow, our cost of sales as a percentage of revenue may further decrease due to economies of scale, which will drive our future business growth.

In addition, our business and results of operations are significantly affected by our operating cost structure, which primarily comprised cost of sales, selling and distribution expenses, general and administrative expenses and research and development expenses during the Track Record Period. We incur substantial selling and distribution expenses as we maintain a well-established sales and marketing team to conduct direct sales to hospitals in various countries and to support our marketing and physician education activities and customer services. As we expect to launch additional products when approvals are received and to further penetrate into existing and new markets, we will further increase our sales and marketing activities and expand our in-house sales and marketing team, and our selling and distribution expenses will increase accordingly.

Our general and administrative expenses primarily consist of employee benefit expenses, depreciation and amortization and legal and professional fees. We expect our general and administrative expenses to increase in the future to support our business expansion. We also anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company.

Our current research and development activities mainly relate to the advancement of our pipeline products. We expect that our research and development expenses will continue to contribute to a substantial proportion of our total operating expenses in the foreseeable future as we move pipeline products currently at earlier clinical stage into more advanced clinical trials and advance preclinical programs into clinical trials, as well as our continued clinical development of our pipeline products.

Fluctuations in Foreign Exchange Rates

During the Track Record Period, we generated some of our revenue from sales denominated in foreign currencies, while a substantial portion of our costs and expenses were denominated in Hong Kong dollars, Renminbi, Euro and Japanese Yen. In addition, we have a well-established global operations and generate revenue in multiple different currencies, and therefore the translation of local currencies into U.S. dollar, being our reporting currency, would also impact on our results of operations. Fluctuations in exchange rates, particularly the rate between Renminbi, Euro and Japanese Yen and the U.S. dollar, could significantly impact our financial condition and results of operations, affect our gross and net profit margins, and result in foreign exchange and operating gains or losses. For details of our sensitivity analysis, please refer to the paragraph headed "– Qualitative and Quantitative Disclosure about Market Risk" in this section.

Impact of the COVID-19 Outbreak

On January 30, 2020, the World Health Organization declared that the outbreak of COVID-19 constitutes a Public Health Emergency of International Concern (PHEIC). In February and March 2020, an increasing number of additional cases were confirmed in many countries and regions around the world. In March 2020, the World Health Organization declared COVID-19 as a pandemic. The outbreak of COVID-19 has endangered the health of many people, resulting in numerous confirmed cases and deaths and significantly disrupted travels and economies around the world.

In February 2020, we began to take precautionary measures to protect the health and safety of our employees and further assess the actual and potential impact of the COVID-19 pandemic on our business and operations. COVID-19 infections have been reported throughout the PRC, Japan, Europe and the U.S., along with various other jurisdictions in which our distributors and customers locate. In addition, COVID-19 has caused disruption and volatility in the global capital markets, and has led to an economic slowdown. We believe that our revenue for 2020 was negatively affected by decreased utilization of our products as a result of the COVID-19 pandemic. Nonetheless, the pandemic has not materially affected our liquidity as we maintain sufficient cash reserves.

In order to prevent and control the outbreak of COVID-19, many countries, including the PRC, Japan, Europe and the U.S. where we have operations, introduced various control measures. For example, the local governments of various countries adopted a series of continuous control measures, including but not limited to restrictions on hospitals from conducting surgeries without immediate needs, traffic control, travel bans, thereby leading to a lower number of PCI/PTA procedures performed.

As a result of the outbreak of COVID-19 pandemic, we experienced the following since 2020:

(i) Temporary reduction of our sales for certain products - we experienced a decrease in the sales of our PCI balloon products of approximately 66,000 units in 2020 as compared to the number of units sold in 2019.

(ii) Temporary suspension of our operations, and shortage of labor and raw materials - In February and March 2020, our operating results were adversely impacted by the salary expenses of our production staff of US$1.4 million in connection with the temporary suspension of our production facilities in Shenzhen, the PRC.

(iii) Increasing pressure on operational costs and expenses due to idled facilities - the utilization rate of our production facilities in Shenzhen, the PRC was adversely impacted by the COVID-19 outbreak, with depreciation and utility expenses for idled facilities and equipment of US$0.2 million in 2020.

(iv) Delays in our shipment generally ranging from one to two weeks in 2020 to 2022. We closely monitored the global logistics and shipment situation, and considered to place orders for raw materials two to three months in advance with our suppliers.

(v) Temporary suspension of production in our Shenzhen production facilities for about two weeks in March 2022.

Subsequent to the Track Record Period and up to the Latest Practicable Date, there has not been any further suspension of production in our Shenzhen production facilities as a result of the recurrences of COVID-19. The recurrences of COVID-19 in the PRC and other countries and regions did not result in any material adverse impact on the Group's financial performance during the Track Record Period and up to the Latest Practicable Date, given the durations of the delays in shipment and suspension of production were short. Our revenue increased by US$11.6 million from US$57.3 million in the first six months of 2021 to US$68.9 million in the first six months of 2022. Sales volume increased by 16.1% from approximately 678,000 units in the first eight months of 2021 to approximately 787,000 units in the first eight months of 2022.

The extent to which the COVID-19 pandemic impacts our results of operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures on our suppliers or relevant regulatory agencies, among others. We are constantly monitoring the situations of the COVID-19 outbreak as well as various regulatory and administrative measures adopted by the local governments to prevent and control the epidemics. If the situations deteriorate, we will continue to evaluate the impact from this outbreak on us and may enhance our measures such as strategically stock up raw materials that are crucial to our production, adjust buffer stock level to manage any potential increase in lead time and dedicate resources to take actions to mitigate any adverse effect on our business operations, results of operations, financial positions and prospects.

CRITICAL ACCOUNTING POLICIES

The Accountant's Report in Appendix I to this document sets forth significant accounting policies, which are important for understanding our financial condition and results of operations. Some accounting policies involve subjective assumptions, estimates and judgments related to assets, liabilities, income, expenses and other accounting items.

We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Our estimates during the Track Record Period were generally accurate as compared to actual results and our estimates are unlikely to change materially in the near future. Results may differ under different assumptions and conditions. Our management has identified below the accounting policies, estimates and judgments that are most critical to the preparation of our consolidated financial information.

Revenue Recognition

Our revenue is measured at the fair value of the consideration received or receivable, and represents amounts receivable for goods supplied, stated net of discounts, returns and value added taxes. Revenue is recognized when, or as, the control of the goods is transferred to the customer.

We base our estimates of return on historical results, taking into consideration the type of customers, the type of transactions and the specifics of each arrangement. Revenue is recognized as follows:

(a) Sales of goods

We manufacture and sell medical instruments in vascular therapies. Revenue from sales are recognized when control of the products has transferred to the customers, and there is no unfulfilled obligation that could affect the customers' acceptance of the products. There are two major channels of sales: (i) distributor sales and (ii) direct sales.

(i) Distributor sales

Revenue are recognized at point in time when control has been transferred to the customers, and either the customers have accepted the products in accordance with the sales contracts, the acceptance provisions have lapsed, or have objective evidence that all criteria for acceptance have been satisfied. Majority of such revenue are recognized when the products are dispatched from our warehouse. Revenue from these sales are recognized based on the price specified in the contract.

(ii) Direct sales

Our direct sales represent consignment sales of goods to private and public hospitals. Revenue are recognized at point in time when control has been transferred to customers, that is, at the time when the customer has actually consumed the goods.

Research and Development Expenses

Research costs are expensed as incurred. Costs incurred on development projects relating to the design and testing of new or improved products are recognized as an intangible asset when the technical feasibility and intention of completing the product under development has been demonstrated and the resources are available to do so, costs are identifiable and there is an ability to sell or use the asset that will generate probable future economic benefits. Such development costs are recognized as an asset and amortized on the straight-line basis to reflect the pattern in which the related economic benefits are recognized. Development costs that do not meet the above criteria are expensed as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period.

The research and development costs which do not meet these criteria and recognized in the consolidated statements of profit or loss are determined based on estimated budgeted costs, known services received and progress report from the service vendors. If the actual research and development expenses were different from the estimate, this would have an impact on the research and development expenses recognized in the following reporting period. Our Group regularly reviews and revises the estimation of the amounts of the research and development costs recognized in the consolidated statements of profit or loss as the project progresses. Management regularly reviews the progress of the projects and the corresponding cost budgets.

Property, Plant and Equipment

Buildings comprise mainly factories and offices. Property, plant and equipment other than construction in progress are stated at historical cost less accumulated depreciation and accumulated impairment losses. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to our Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to the consolidated statements of profit or loss during the financial period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost to their residual values over their estimated useful lives, as follows:

Buildings	20 years
Leasehold improvements	Shorter of 10 years or the lease term
Plant and machinery	5 to 10 years
Furniture, fixtures and equipment	4 to 10 years
Motor vehicles	3 to 5 years
Computer equipment	3 to 5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized within "other gains/(losses) net" in the consolidated statements of profit or loss.

Construction-in-progress represents plant and machinery, leasehold improvements, furniture, fixtures and equipment and computer equipment on which construction work has not been completed and which, upon completion, management intend to hold for the use of our Group. They are carried at cost which includes development and construction expenditure incurred and other direct costs attributable to the development less any accumulated impairment losses. On completion, the amounts are transferred to respective categories of property, plant and equipment and depreciated in accordance with the policy as stated above.

Trade Receivables

Trade receivables are amounts due from customers for goods sold in the ordinary course of business. They are generally due for settlement within 30 to 180 days and therefore are all classified as current.

Trade receivables are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value. We hold the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method.

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out (FIFO) method. The cost of finished goods and work in progress comprises design costs, raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity). It excludes borrowing costs. Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses.

Provision of Inventories

Our management reviews the condition of inventories at each reporting date and makes provision for inventories that are identified as obsolete, slow-moving or no longer recoverable or suitable for use in production. Our Group carries out the inventory review on a product-by-product basis and makes allowances by reference to the latest market prices and current market conditions.

Estimation of the Fair Value of the Level 3 Financial Instruments

Our level 3 financial instruments disclosed in Note 3.3, Note 29 and Note 30 of the Accountant's Report in Appendix I represented investment in life insurance assets, retirement benefit obligations and convertible redeemable preferred shares. As these instruments are not traded in active markets, their fair values have been determined by using applicable valuation techniques.

In respect of the valuation of level 3 fair value measurement financial assets and liabilities, with reference to the guidance under the "Guidance Note on Directors' Duties in the Context of Valuations in Corporate Transactions" issued by the SFC in May 2017 (the "Guidance") applicable to directors of companies [**REDACTED**] on the Stock Exchange, our Directors adopted, as appropriate, the following procedures: (i) reviewed the terms of insurance policies, post-employment schemes and the terms of the related agreement, as well as terms of the share subscription agreements in relation to Series A and Series A-2 Preferred Shares; (ii) selected qualified persons with adequate knowledge and conducted valuation on the financial assets without readily determinable fair value; (iii) carefully considered available information in assessing the financial data and assumptions including but not limited to discount rate, risk free interest rate, expected volatility and industry conditions; (iv) engaged independent valuer to appraise the fair value of certain financial assets and financial liabilities that are significant, provided necessary financial to the valuer for the valuer to assess our performed valuation procedures and discussed with the valuer on relevant assumptions; and (v) reviewed the valuation reports prepared by the valuer. Based on the above procedures, our Directors are of the view that the valuation analysis is fair and reasonable and our financial statements are properly prepared.

The details on the fair value measurement of the financial assets and liabilities, particularly the fair value hierarchy, the valuation techniques and key inputs, including significant unobservable inputs, the relationship of unobservable inputs to fair value are disclosed in Note 3.3, Note 29 and Note 30 of the Accountant's Report in Appendix I to this document which was issued by the Reporting Accountant in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 "Accountants' Report on Historical Financial Information in Investment Circulars" issued by the Hong Kong Institute of Certified Public Accountants. The Reporting Accountant's opinion on the Historical Financial Information, as a whole, of the Group for the Track Record Period is set out on page I-2 of Appendix I to this document. Our Directors are responsible for the underlying assumptions and bases in the preparation of the valuation of financial assets categorized within level 3 of fair value measurement in our historical financial information for the purpose of the preparation of the Accountant's Report as referred to in Appendix I to this document.

In relation to the valuation of the level 3 financial assets and liabilities, the Joint Sponsors have conducted, among others, the following due diligence work: (i) discussing with our management with a view to understanding the nature and terms of our financial assets and liabilities and the work done by the Company in fair value estimation and their assessment of the valuation of the financial assets and liabilities at fair value; (ii) reviewing the relevant notes in the Accountant's Report set out in Appendix I to this document; and (iii) discussing with the Reporting Accountant in respect of the audit procedures they have conducted for the purpose of expressing an opinion on the historical financial information of our Group as a whole.

Based on the due diligence work conducted as described above, and taking into account (i) the work done and representations by our Directors; and (ii) the unqualified opinion of the Reporting Accountant (see page I-2) that the Accountant's Report in Appendix I to this document gives a true and fair view of the financial position and performance of our Group taken as a whole, nothing has come to the attention of the Joint Sponsors that would lead them to cast doubts on our fair value estimation of our financial assets and liabilities.

DESCRIPTION OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

The following table sets forth selected items in our consolidated statements of profit or loss for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Revenue	96,342	88,472	116,462	57,339	68,851
Cost of sales	(30,895)	(30,452)	(35,290)	(16,790)	(21,137)
Gross profit	65,447	58,020	81,172	40,549	47,714
Other income – net	1,162	2,406	1,385	674	393
Other gains/(losses) – net	338	904	(1,020)	(513)	(2,854)
Selling and distribution expenses	(32,251)	(26,694)	(30,100)	(14,654)	(16,475)
General and administrative expenses	(15,707)	(14,295)	(19,958)	(8,187)	(10,738)
Research and development expenses	(9,593)	(12,578)	(12,148)	(5,827)	(6,720)
Net (impairment losses)/reversal of impairment losses on financial assets	(1,407)	931	109	158	(402)
Operating profit	7,989	8,694	19,440	12,200	10,918
Finance income	21	12	12	6	249
Finance costs	(503)	(1,405)	(5,607)	(1,048)	(1,407)
Finance costs – net	(482)	(1,393)	(5,595)	(1,042)	(1,158)
Fair value losses of convertible redeemable preferred shares	–	–	(14,397)	(6,030)	–
Loss on derecognition of financial liability in relation to convertible redeemable preferred shares	–	–	(559)	–	–
Share of losses of investment in a joint venture	–	(46)	(207)	(149)	(71)
Profit/(loss) before income tax	7,507	7,255	(1,318)	4,979	9,689
Income tax expense	(549)	(184)	(3,126)	(1,658)	(1,652)
Profit/(loss) for the year/period attributable to owners of the Company	6,958	7,071	(4,444)	3,321	8,037

Non-HKFRS Measures

To supplement our consolidated results, which are prepared and presented in accordance with HKFRS, we use certain additional financial measures which are not required by or presented in accordance with HKFRS. Such measures include adjusted profit for the year (non-HKFRS measure) and adjusted net profit margin (non-HKFRS measure). Our adjusted profit for the year/period (non-HKFRS measure) are not calculated in accordance with HKFRS, and they are considered non-HKFRS measures. We believe that adjusted profit for the year/period (non-HKFRS measure) are useful for investors in comparing our performance, and they allow investors to consider metrics used by our management in evaluating our performance.

We define adjusted profit for the year/period (non-HKFRS measure) as profit/(loss) for the year/period by adding back: (i) unwinding of interests on convertible redeemable preferred shares, (ii) share-based compensation expenses, (iii) fair value losses of convertible redeemable preferred shares, (iv) loss on derecognition of financial liability in relation to convertible redeemable preferred shares, (v) [**REDACTED**], and (vi) fair value loss of a Commodity Linked Fixed Rate Note. We also define adjusted net profit margin (non-HKFRS measure) as adjusted profit for the year/period (non-HKFRS measure) divided by total revenue. We elected to add back these items for the non-HKFRS measure primarily because (i) all outstanding Series A and Series A-2 Preferred Shares of our Company have been or will be reclassified to equity upon fulfillment of conditions attached in the relevant agreement and no later than the completion of the [**REDACTED**], and therefore, we will no longer incur any unwinding of interests, fair value losses or losses on derecognition of financial liability, in relation to the convertible redeemable preferred shares. In addition, unwinding of interests, fair value losses and losses on derecognition of financial liability in relation to the convertible redeemable preferred shares were non-cash items, (ii) our share-based compensation expenses were non-cash in nature, (iii) we incurred [**REDACTED**] in relation to the [**REDACTED**], and (iv) we will hold the Commodity Linked Fixed Rate Note till maturity and receive its face values plus predetermined coupon rate of 2.8% in December 2023, and the fair value loss was non-cash item and there will be fair value gain in subsequent period till maturity to completely offset the current fair value loss.

Our adjusted profit for the year (non-HKFRS measure) increased by 201.4% from US$7.1 million in 2020 to US$21.4 million in 2021, and our adjusted net profit margin (non-HKFRS measure) increased from 8.0% in 2020 to 18.3% in 2021, primarily due to the increase in gross profit as a result of increase in revenue, and our relatively stable expenses (excluding reconciling items under non-HKRFS measure) in 2021 as compared to 2020.

Our adjusted profit for the period (non-HKFRS measure) increased by 23.6% from US$11.0 million for the six months ended June 30, 2021 to US$13.6 million for the six months ended June 30, 2022, and our adjusted net profit margin increased from 19.2% for the six months ended June 30, 2021 to 19.8% for the six months ended June 30, 2022, primarily due to the increase in gross profit as a result of increase in revenue, and our relatively stable expenses (excluding reconciling items under non-HKRFS measure) for the six months ended of June 30, 2022 as compared to the same period in 2021.

Our Directors believe that the presentation of non-HKFRS measures when shown in conjunction with the corresponding HKFRS measures provides useful information to investors and management regarding financial and business trends relation to its financial condition and results of operations, by eliminating potential impacts of certain items.

The use of non-HKFRS measures has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for or superior to analysis of, our results of operations or financial conditions as reported under HKFRS. In addition, non-HKFRS measures used in this document may be defined differently from similar terms used by other companies.

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Non-HKFRS Measures					
Profit/(loss) for the year/period	6,958	7,071	(4,444)	3,321	8,037
Add:					
Unwinding of interests on convertible redeemable preferred shares	–	–	4,853	476	1,336
Share-based compensation expenses	–	–	1,339	670	368
Fair value loss of the Commodity Linked Fixed Rate Note	–	–	–	–	1,266
Fair value losses of convertible redeemable preferred shares	–	–	14,397	6,030	–
Loss on derecognition of financial liability in relation to convertible redeemable preferred shares	–	–	559	–	–
[REDACTED]	–	–	[REDACTED]	[REDACTED]	[REDACTED]
Adjusted profit for the year/period (non-HKFRS measure)	6,958	7,071	21,352	10,989	13,606

Revenue

The following table sets forth our revenue by business line, in absolute amount and as a percentage of total revenue, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Coronary interventional medical devices										
Balloon										
Semi-compliant	30,125	31.3%	25,875	29.2%	27,427	23.6%	14,153	24.7%	13,993	20.3%
Non-compliant	23,842	24.7%	20,670	23.4%	25,948	22.3%	12,826	22.4%	13,176	19.1%
Scoring	16,402	17.0%	14,352	16.2%	29,383	25.2%	12,154	21.2%	24,700	35.9%
Stent										
Dual therapy stents	11,619	12.1%	12,879	14.5%	13,591	11.7%	7,240	12.6%	6,259	9.1%
Bare metal stents	229	0.2%	71	0.1%	47	0.0%	23	0.0%	2	0.0%
Subtotal	82,217	85.3%	73,847	83.4%	96,396	82.8%	46,396	80.9%	58,130	84.4%
Peripheral interventional medical devices										
Balloon	6,963	7.2%	7,476	8.5%	11,683	10.0%	6,703	11.7%	5,581	8.1%
Other medical accessories	5,065	5.3%	4,810	5.4%	3,689	3.2%	1,469	2.6%	2,486	3.6%
Third party products	2,097	2.2%	2,339	2.7%	4,694	4.0%	2,771	4.8%	2,654	3.9%
Total	96,342	100.0%	88,472	100.0%	116,462	100.0%	57,339	100.0%	68,851	100.0%

We generate revenue from sales of coronary and peripheral interventional medical devices, other medical accessories (including certain products we produced for other medical device manufacturers) and third party products.

Our revenue decreased from 2019 to 2020, primarily due to a US$9.5 million decrease in revenue generated from coronary balloon products which was mainly the impact of the COVID-19 pandemic which led to a lower number of PCI surgeries performed and reduced the consumption of our products in 2020, partially offset by a US$1.1 million increase in revenue generated from coronary stent products in connection with the introduction of COMBO Plus products in Japan.

Our revenue increased from 2020 to 2021 primarily due to a US$21.9 million increase in revenue generated from coronary balloon products as demand for our products in most markets, including the PRC, APAC and EMEA recovered when the COVID-19 pandemic became more stable. To a lesser extent, the US$4.2 million increase in revenue generated from peripheral balloon products in connection with the introduction of our new Jade OTW series in the U.S. market also contributed to such increase in 2021.

Our revenue increased from the first six months of 2021 to the same period of 2022 primarily due to a US$12.7 million increase in revenue generated from our coronary balloon products, particularly our scoring balloon products, as a result of (i) the increase in sales volume of our Scoreflex NC series in the U.S. market, which was introduced to the U.S. market in 2022, (ii) increase in sales volume of our Scoreflex Trio series in the Japan market and (iii) the increase in sales volume and average selling price of our Scoreflex series in the PRC market in the first six months of 2022.

For further breakdown and analysis of average selling price and sales volume, please refer to the following tables and analysis for more details.

The following table sets forth the respective sales volume and the average selling price of our major product series for the periods indicated:

	For the year ended December 31,						**For the six months ended June 30,**			
	2019		**2020**		**2021**		**2021**		**2022**	
	Volume (thousand units)	*Average Selling Price US$*	*Volume (thousand units)*	*Average Selling Price US$*	*Volume (thousand units)*	*Average Selling Price US$*	*Volume (thousand units)*	*Average Selling Price US$*	*Volume (thousand units)*	*Average Selling Price US$*
Coronary										
Interventional medical devices										
Balloons										
Semi-compliant	379	79	347	74	359	76	187	76	203	69
Non-compliant	318	74	283	73	365	71	177	72	198	66
Scoring	73	223	75	191	151	195	62	198	114	216
Stents										
Dual therapy stents	24	492	23	550	23	587	12	598	11	546
Peripheral interventional medical devices										
Balloons	24	285	33	227	106	110	66	104	54	103

The above product categories all have different models, specifications and configurations in each product type. According to CIC Report, the average retail price of same model of standard PCI balloons is generally expected to decrease at approximately 2% per annum after its commercialization and product launch. However, the decrease in the average selling price is not an indication of our products reaching the end of their lifecycle or being replaced by other products.

The average selling price of semi-compliant balloons were relatively stable in 2019, 2020 and 2021, as the effect of the aforementioned decreasing price trend was partially offset by the launch of our new products, which were generally at higher average selling prices. The decrease in average selling price from the first six months of 2021 to the same period of 2022 was mainly due to the decrease in average selling price in the Japan markets as a result of the substantial depreciation of Japanese Yen against USD and the decrease in government reimbursement price in Japan in 2022.

The sales volume of semi-compliant balloons decreased from 2019 to 2020, primarily due to the decrease in the number of PCI surgeries performed as a result of the COVID-19 pandemic. As the demand recovered when the COVID-19 pandemic became more stable in 2021, our sales volume picked up accordingly. The sales volume of semi-compliant balloons increased from the first six months of 2021 to the same period of 2022, primarily due to the increase in sales of our Sapphire II Pro series in the U.S. market.

For non-compliant balloons, the average selling price in 2019 and 2020 were relatively stable. The decrease in average selling price from 2020 to 2021 was mainly due to the decrease in average selling price from 2020 to 2021 in the PRC market after our non-compliant balloons were brought into the scope of centralized procurement policies, and the decrease in average selling price in the Japan market as a result of the decrease in reimbursement to hospitals for medical products also contributed to the overall decrease in pricing of our non-compliant balloons. The decrease in average selling price from the first six months of 2021 to the same period of 2022 was mainly due to the decrease in average selling price in the Japan market as a result of the substantial depreciation of Japanese Yen against USD and the decrease in government reimbursement price in 2022.

Similar to our semi-compliant balloons above, the sales volume of non-compliant balloons decreased from 2019 to 2020 due to the COVID-19 pandemic. As the demand recovered when the COVID-19 pandemic became more stable in 2021, our sales volume picked up accordingly. The sales volume of semi-compliant balloons increased from the first six months of 2021 to the same period of 2022, primarily due to the increase in sales of our Sapphire NC Plus and Sapphire NC 24 series in the U.S. market.

The decrease in average selling price of our scoring balloons from 2019 to 2020 was mainly due to the decrease in pricing in our Japan market as a result of the decrease in government reimbursement price and also the increase of sales volume in the PRC market in 2020, where the selling price was lower than other markets. The average selling price in 2020 and 2021 were relatively stable. The increase in average selling price from the first six months of 2021 to the same period of 2022 was mainly due to the increase in average selling price in the U.S. market as a result of the introduction of our Scoreflex NC series, increase in sales volume of our Scoreflex Trio series with high average selling price in the Japan market and the increase in average selling price of our Scoreflex series in the PRC market in the first six months of 2022.

Sales volume of our scoring balloons remained relatively stable in 2019 and 2020 despite the impact of the COVID-19 pandemic, which was partially offset by the increase in demand in the PRC market for balloon products with high flexibility and cross-ability. The drastic increase in sales volume from 2020 to 2021 was primarily due to the increase in sales of our scoring balloons in the PRC market, as a result of our efforts in the expansion of sales network and the wide recognition of our products in the PRC. Sales volume further increased from the first six months of 2021 to the same period of 2022, primarily due to the introduction of our Scoreflex NC series in the U.S. market, increase in sales of our Scoreflex Trio series and Scoreflex series in the Japan and PRC markets respectively.

The average selling price of dual therapy stents increased from 2019 to 2020 and further increased in 2021 due to the introduction of COMBO Plus in Japan since late 2019, which had a relatively higher selling price. The decrease in average selling price from the first six months of 2021 to the same period of 2022 was mainly due to the decrease in average selling price in the Japan market as a result of the substantial depreciation of Japanese Yen against USD and the decrease in government reimbursement price in 2022.

Sales volume of our dual therapy stents remained relatively stable during the Track Record Period despite the impact of the COVID-19 pandemic, which was partially offset by the introduction of COMBO Plus in Japan in late 2019.

For peripheral balloons, the decrease in average selling price from 2019 to 2020 was mainly due to the increase of sales volume in APAC and EMEA markets, where the average selling prices in both markets are lower than our Japan market. The average selling price further decreased from 2020 to 2021 as a result of the launch of our Jade OTW series in the U.S., which had a lower selling price after taking into account the discount to the U.S. distributor.

The average selling price of our peripheral balloons were relatively stable for the first six months of 2021 and 2022.

The increase in sales volume of our peripheral balloons from 2019 to 2020 and further increase in 2021 was primarily due to our introduction of the Jade OTW series in the U.S. market in the second half of 2020. The decrease of sales volume of our peripheral balloons for the first six months of 2022 compared to that of the same period in 2021 was attributable to the decrease in sales in the U.S. market as a result of the launch of our coronary balloons, Scoreflex NC series and Sapphire NC 24 series in the U.S. market in the first half of 2022. The U.S. distributor planned to order more coronary balloons in the first half of 2022 and catch up the ordering of peripheral balloons in the second half of 2022 according to their sales and stock management.

As of June 30, 2022, we sold our products through distributors or directly to customers in around 70 countries and regions globally. The following table sets forth our revenue by geographic area, in absolute amount and as a percentage of our total revenue, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
EMEA										
Germany	3,437	3.6%	3,367	3.8%	5,371	4.6%	2,667	4.7%	2,572	3.7%
Russian Federation	2,965	3.1%	2,635	3.0%	2,042	1.8%	1,370	2.4%	281	0.4%
Switzerland	1,667	1.7%	2,138	2.4%	3,991	3.4%	2,198	3.8%	1,899	2.8%
Spain	2,925	3.0%	2,239	2.5%	3,305	2.8%	1,715	3.0%	1,808	2.6%
Others*	16,427	17.1%	14,049	15.9%	19,413	16.7%	9,951	17.4%	10,007	14.5%
EMEA Subtotal	27,421	28.5%	24,428	27.6%	34,122	29.3%	17,901	31.3%	16,567	24.0%
Japan	29,357	30.5%	28,164	31.8%	29,807	25.6%	14,748	25.7%	17,134	24.9%
APAC										
Hong Kong	5,932	6.2%	5,745	6.5%	7,723	6.6%	3,834	6.7%	3,454	5.0%
Singapore	3,742	3.9%	2,688	3.0%	4,275	3.7%	2,001	3.5%	1,828	2.7%
Malaysia	3,944	4.1%	3,981	4.5%	4,379	3.8%	1,750	3.1%	2,245	3.3%
Taiwan	3,111	3.2%	2,150	2.4%	2,224	1.9%	1,052	1.8%	1,568	2.3%
Vietnam	2,966	3.1%	2,402	2.7%	2,014	1.7%	1,467	2.6%	954	1.4%
Indonesia	1,699	1.8%	2,145	2.4%	2,366	2.0%	1,123	2.0%	1,661	2.4%
Others*	5,575	5.6%	4,434	5.2%	5,007	4.3%	2,394	4.0%	3,109	4.5%
APAC Subtotal	26,969	27.9%	23,545	26.7%	27,988	24.0%	13,621	23.7%	14,819	21.6%
The PRC	8,269	8.6%	5,047	5.7%	17,077	14.7%	6,940	12.1%	13,319	19.3%
United States	4,326	4.5%	7,288	8.2%	7,468	6.4%	4,129	7.2%	7,012	10.2%
Total	96,342	100.0%	88,472	100.0%	116,462	100.0%	57,339	100.0%	68,851	100.0%

* Included 39 or above EMEA countries/regions and 12 or above APAC countries/regions with individual contribution of less than 3% to the Group's revenue during the Track Record Period.

Our revenue decreased from 2019 to 2020, primarily due to an overall decrease in revenue generated from the PRC, Japan, EMEA and APAC which was mainly impacted by the COVID-19 pandemic, partially offset by a US$3.0 million increase in revenue generated from the U.S. in connection with the increased sales volume of coronary balloons and microcatheters along with our increased hospital coverage in the U.S..

Our revenue increased from 2020 to 2021 primarily due to a US$9.7 million increase in revenue generated from the EMEA market for coronary balloons, microcatheters and atherectomy devices as well as a US$12.0 million increase in revenue from the PRC primarily due to (i) the increase in average selling price due to the elimination of the intermediate layer of the previous exclusive distributor between us and the regional distributors/hospitals in the distribution process; (ii) the increase in the number of regional distributors to expand our hospital coverage; (iii) the success of the additional marketing efforts of our scoring coronary balloon which were not admitted under the centralized procurement policy and (iv) the wider market recognition of our products by physicians. The US$4.5 million increase in revenue generated from the APAC market, which was primarily due to the introduction of our Sapphire 3 series and Sapphire NC 24 series in Hong Kong and Singapore, along with a relatively high average selling prices, also contributed to the overall increase in revenue from 2020 to 2021.

Our revenue increased from the first six months of 2021 to the same period of 2022, primarily due to a US$2.9 million increase in revenue generated from the U.S. market for coronary balloons and microcatheters, primarily as a result of the increase in sales volume of our Scoreflex NC series, which was introduced in 2022; a US$2.4 million increase in revenue generated from the Japan market for coronary balloons and microcatheters, primarily as a result of the increase in sales volume of our Scoreflex Trio series; as well as a US$6.4 million increase in revenue generated from the PRC market, mainly because of the increase in sales volume and average selling price of our Scoreflex series, in connection with our continuous effort in the expansion of sales network to expand our hospital coverage and wider market recognition of our products by physicians. The US$1.2 million increase in revenue generated from the APAC market also contributed to the overall increase in revenue from the first six months in 2021 to the same period in 2022, which was mainly due to the increase in sales in the Malaysia market in connection with the introduction of our Sapphire 3 series. The overall increase in revenue from the first six months of 2021 to the same period in 2022 was slightly offset by the decrease in revenue in our EMEA market, as affected by the recent Russo-Ukrainian conflict which lead to a decrease in sales in the Russian Federation.

The following table sets forth our revenue generated from our major product series in the PRC in 2020, 2021 and for the six months ended June 30, 2021 and 2022, respectively:

	For the year ended December 31,		For the six months ended June 30,	
	2020	2021	2021	2022
	Revenue	Revenue	Revenue	Revenue
	US$'000	*US$'000*	*US$'000*	*US$'000*
			(Unaudited)	
Coronary interventional medical devices				
Semi-compliant balloon	1,900	1,359	805	607
Non-compliant balloon	1,715	1,512	880	526
Scoring coronary balloon	1,432	14,206	5,255	12,171
Subtotal	**5,047**	**17,077**	**6,940**	**13,304**
Peripheral interventional medical devices				
Balloon	–	–	–	7
Other medical devices	–	–	–	8
Total	**5,047**	**17,077**	**6,940**	**13,319**

We actively participated in tenders and won seven bids of centralized procurement covering 23 provincial regions in the PRC in 2021, and therefore a majority of our semi-compliant and non-compliant balloons were sold under the centralized procurement policy in 2021.

The increase in revenue in the PRC from 2020 to 2021 and from the first six months of 2021 to the same period of 2022 was due to: (i) the expansion of sales network in the PRC by increasing the number of regional distributors to expand our hospital coverage; (ii) the success of the additional marketing efforts of our scoring coronary balloon which were not under the centralized procurement policy; (iii) the wider market recognition of our products by physicians; and (iv) the increase in average selling price due to elimination of the previous exclusive distributor between us and the regional distributors/hospitals in the PRC in the distribution process. The overall gross profit margin for sales in the PRC increased from 52.1% in 2020 to 72.2% in 2021 and from 70.2% in the first six months of 2021 to 78.7% in the same period of 2022 as a result of the increase in the revenue and selling price of our scoring coronary balloon.

The following table sets forth our revenue by sales channels, in absolute amount and as a percentage of our total revenue, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Direct Sales*	50,464	52.4%	49,079	55.5%	63,944	54.9%	30,998	54.1%	33,643	48.9%
Sales to Distributors	44,778	46.5%	38,312	43.3%	52,267	44.9%	26,282	45.8%	35,202	51.1%
Others	1,100	1.1%	1,081	1.2%	251	0.2%	59	0.1%	6	0.0%
Total	96,342	100.0%	88,472	100.0%	116,462	100.0%	57,339	100.0%	68,851	100.0%

* Include sales in Japan and Malaysia markets, where sales are through local procurement agents designated by hospitals under applicable local regulations and/or market practice. For 2021 and the six months ended June 30, 2021 and 2022, direct sales included sales in the PRC market made through qualified logistics services providers under the centralized procurement policy.

During the years ended December 31, 2019, 2020 and 2021, revenue from sales to distributors and direct sales as a percentage to our total revenue remained relatively stable, and the fluctuations of our revenue numbers primarily reflects the continued growth of our Group, except that the decrease in 2020 primarily reflected the impact of the COVID-19 pandemic, which led to a lower number of PCI surgeries performed in 2020 compared to that of 2019.

Our direct sales increased from US$49.1 million in 2020 to US$63.9 million in 2021. Apart from the recovered demand for our products as the COVID-19 pandemic became more stable, the introduction of our new generation of products such as our Sapphire 3 series and Sapphire NC 24 series in markets including Hong Kong, Malaysia and Singapore with relatively high average selling prices also contributed to the increase. Moreover, sales in Switzerland increased from 2020 to 2021, as we acquired the previous exclusive distributor in August 2020 to eliminate the intermediate layer. Our direct sales increased from US$31.0 million in the first six months of 2021 to US$33.6 million in the same period in 2022. Such increase was mainly due to the increase in sales volume of our Scoreflex Trio series in the Japan market and also reflects the continuous growth of our Group.

Our sales to distributors increased from US$38.3 million in 2020 to US$52.3 million in 2021. Apart from the recovered demand for our products as the COVID-19 pandemic became more stable, the increase in revenue was mainly contributed by the increase in sales in the PRC market, as a result of (i) the increase in average selling price due to the elimination of the previous exclusive distributor layer between us and the regional distributors, (ii) the increase in the number of regional distributors to expand our hospital coverage, (iii) the success of the additional marketing efforts of our scoring coronary balloons which were not admitted under the centralized procurement policy and (iv) the wider market recognition of our products by

physicians. Our sales to distributors increased from US$26.3 million in the first six months of 2021 to US$35.2 million in the same period in 2022. Such increase was primarily due to (i) the increase in sales volume of our Scoreflex NC series in the U.S. market, which was introduced to the U.S. market in 2022, and (ii) a US$6.1 million increase in the PRC market through the increase in sales volume and average selling price of our Scoreflex series.

Cost of Sales

Our cost of sales consists of raw material, manufacturing and direct labor costs. Our cost of sales accounted for 32.1%, 34.4%, 30.3%, 29.3% and 30.7% of our total revenue in 2019, 2020, 2021 and the first six months of 2021 and 2022, respectively. The following table sets forth the components of our cost of sales, in absolute amount and as a percentage of our total cost of sales, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Costs of self-developed products										
Raw material costs	14,656	47.4%	14,990	49.2%	15,479	43.9%	6,905	41.1%	9,260	43.8%
Manufacturing costs	7,824	25.3%	7,051	23.2%	7,658	21.7%	3,727	22.2%	4,359	20.6%
Direct labor costs	5,905	19.1%	5,655	18.6%	7,369	20.9%	3,619	21.6%	4,677	22.1%
Others*	1,057	3.5%	1,182	3.8%	1,789	5.0%	802	4.8%	1,025	4.9%
Subtotal	29,442	95.3%	28,878	94.8%	32,295	91.5%	15,053	89.7%	19,321	91.4%
Purchase costs of third party products	1,453	4.7%	1,574	5.2%	2,995	8.5%	1,737	10.3%	1,816	8.6%
Total	30,895	100.0%	30,452	100.0%	35,290	100.0%	16,790	100.0%	21,137	100.0%

* Others include royalty expenses, delivery and warehouse charges.

Raw material costs constituted the largest component of our cost of sales during the Track Record Period. The principal raw materials used in our production are medical grade stainless steel stent frame, polyester and nylon. Our raw material costs increased from 2020 to 2021 and from the first six months of 2021 to the same period of 2022, primarily due to the increased sales volume. Our raw material costs increased from 2019 to 2020, mainly due to the launch of our COMBO Plus products in Japan, which has a higher raw material cost. Such increase was partially offset by the decrease in sales volume due to the COVID-19 pandemic.

Manufacturing costs consist primarily of operating costs for our production machines and facilities, including depreciation, utilities, maintenance costs and factory rentals. Our manufacturing costs decreased from 2019 to 2020, mainly due to the decrease in indirect labor costs as a result of reduction in production activities due to the COVID-19 pandemic. Our

manufacturing costs increased from 2020 to 2021, mainly due to an increase in indirect labor costs and utilities expenses. Our manufacturing costs increased from the first six months of 2021 to the same period of 2022, mainly due to an increase in depreciation in connection with our increased leased properties used as staff quarters for our production staff in Shenzhen, repair and maintenance expenses for production efficiency and safety enhancement and utilities expenses due to the increase in production volume.

Direct labor costs consist primarily of employee benefit expenses for production personnel. The increases in our direct labor costs from 2020 to 2021 and from the first six months of 2021 to the same period of 2022, primarily due to increases in the average salaries and the headcount of production personnel due to the production expansion of our Group to meet increased sales demand. Our direct labor costs decreased from 2019 to 2020, mainly due to the decrease in direct labor costs as our production headcount dropped due to the impact of the COVID-19 pandemic.

The following table sets forth our cost of sales by business line, in absolute amount and as a percentage of total cost of sales, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Coronary interventional medical devices										
Balloon	21,777	70.5%	21,028	69.1%	22,618	64.1%	10,178	60.6%	13,286	62.9%
Stent	4,963	16.1%	5,090	16.7%	5,687	16.1%	2,816	16.8%	3,799	18.0%
Subtotal	26,740	86.6%	26,118	85.8%	28,305	80.2%	12,994	77.4%	17,085	80.9%
Peripheral interventional medical devices										
Balloon	692	2.2%	982	3.2%	2,743	7.8%	1,567	9.3%	1,360	6.4%
Other medical accessories	2,010	6.5%	1,778	5.8%	1,247	3.5%	491	2.9%	747	3.5%
Third party products	1,453	4.7%	1,574	5.2%	2,995	8.5%	1,738	10.4%	1,945	9.2%
Total	30,895	100.0%	30,452	100.0%	35,290	100.0%	16,790	100.0%	21,137	100.0%

Gross Profit and Gross Profit Margin

The following table sets forth our gross profit and gross profit margin by business line and sales channels for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
By business line										
Coronary interventional medical devices										
Balloon	48,592	69.1%	39,869	65.5%	60,140	72.7%	28,955	74.0%	38,583	74.4%
Stent	6,885	58.1%	7,860	60.7%	7,951	58.3%	4,447	61.2%	2,462	39.3%
Subtotal	55,477	67.5%	47,729	64.6%	68,091	70.6%	33,402	72.0%	41,045	70.6%
Peripheral interventional medical devices										
Balloon	6,271	90.1%	6,494	86.9%	8,940	76.5%	5,136	76.6%	4,221	75.6%
Other medical accessories	3,055	60.3%	3,032	63.0%	2,442	66.2%	978	66.6%	1,739	70.0%
Third party products	644	30.7%	765	32.7%	1,699	36.2%	1,033	37.3%	709	26.7%
Total gross profit/ overall gross profit margin	65,447	67.9%	58,020	65.6%	81,172	69.7%	40,549	70.7%	47,714	69.3%
By sales channels										
Direct sales	41,845	82.9%	39,442	80.4%	50,250	78.6%	23,930	77.2%	26,312	78.2%
Sales to distributors	23,602	51.4%	18,578	47.2%	30,922	58.9%	16,619	63.1%	21,402	60.8%
Total gross profit/overall gross profit margin	65,447	67.9%	58,020	65.6%	81,172	69.7%	40,549	70.7%	47,714	69.3%

Our gross profit margin for coronary balloon products slightly decreased from 2019 to 2020, primarily due to a decrease in the average selling prices of our products in Japan. In 2021, our gross profit margin increased mainly due to our introduction of new generation of major products such as Sapphire 3 and Sapphire NC 24 balloons, which have higher average selling prices. Besides, increase in sales volume of scoring balloons, which have higher gross profit margin, in connection with the expansion of our sales network in the PRC also contributed to the increase in gross profit margin for coronary balloon products. Our gross profit margin for coronary balloon products was relatively stable in the first six months of 2021 and the same period of 2022.

Our gross profit margin for coronary stent products continued to increase from 2019 to 2020. The increase in 2020 was mainly due to our introduction of COMBO Plus dual therapy stent products in Japan, which had a higher average selling price. Our gross profit margin for coronary stent products remained stable in 2021. Our gross profit margin for coronary stent products decreased from the first six months of 2021 to the same period of 2022, primarily due to (i) the decrease in selling price in the Japan market as a result of the reduction in the government reimbursement price, (ii) the substantial depreciation of Japanese Yen against USD and (iii) provision for impairment increased as our stent products consigned in the hospitals increased as a result of our expanding hospital coverage in Japan since the launch of our COMBO Plus dual therapy stent products in 2020.

Our gross profit margin for peripheral balloon products remained stable in 2019 and 2020, and the decrease in 2021 was primarily due to the introduction of our new Jade OTW series in the U.S. market which led to lower average selling prices of our products after taking into the discount to local distributors. Gross profit margin for peripheral balloon products were higher than that of coronary balloon products, primarily because majority of our peripheral balloon products were sold in countries under the direct sales, such as Japan, where the average selling prices were higher. Our gross profit margin for peripheral balloon products remained relatively stable in the first six months of 2021 and the same period of 2022.

Our gross profit margin of medical device accessories increased during the Track Record Period, primarily due to the increase in the sales volume of our Teleport products and other accessories in direct sales countries or regions which had higher average selling price and thus higher gross profit margin.

Our gross profit margin for third party products remained relatively stable in 2019 and 2020. The increase from 2020 to 2021 was primarily due to the increase in sales volume of our coronary artery and peripheral orbital atherectomy products in certain countries under the direct sales model with higher average selling prices and thus gross margin. Our gross profit margin for third party products decreased from the first six months of 2021 to the same period of 2022, primarily because the gross profit margin for the distribution of drug eluting balloons launched in the Malaysia and Spain markets in 2022 was relatively low as a result of our commercial negotiations with a new supplier.

Our gross profit margin for direct sales channel decreased slightly from 82.9% in 2019 to 80.4% in 2020, which was primarily due to the decrease in average selling price of our balloon products in Spain and Germany markets and the decrease in average selling price of our stent products in Singapore market as a result of competition in the local markets. Such decrease was in line with the overall decreasing price trend of interventional medical devices.

Our gross profit margin for direct sales channel decreased slightly from 80.4% in 2020 to 78.6% in 2021, which was primarily due to certain of our products were sold under the centralized procurement policy in the PRC market which had a lower average selling price.

Our gross profit margin for direct sales channel remained stable in the first six months of 2021 and the same period of 2022.

Our gross profit margin for sales to distributors decreased from 51.4% in 2019 to 47.2% in 2020, which was primarily due to the decrease in average selling prices of our US and EMEA markets, which was in line with the decreasing price trend of interventional medical devices.

Our gross profit margin for sales to distributors increased from 47.2% in 2020 to 58.9% in 2021, which was primarily due to the expansion of sales network in the PRC by selling to the regional distributors directly. The average selling price of balloon products increased due to the elimination of the intermediate layer of the previous exclusive distributor and therefore increased the gross profit margin.

Our gross profit margin for sales to distributors slightly decreased from 63.1% in the first six months of 2021 to 60.8% in the same period in 2022, primarily due to the increase in sales volume of our balloon products in certain APAC countries with lower average selling price.

Other Income

Other income consists primarily of government grants. Other income accounted for 1.2%, 2.7%, 1.2%, 1.2% and 0.6% of our total revenue in 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, respectively. The following table sets forth the components of our other income, in absolute amount and as a percentage of total other income, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Government grants	1,066	91.7%	2,333	97.0%	1,166	84.2%	670	99.4%	320	81.4%
Others	96	8.3%	73	3.0%	219	15.8%	4	0.6%	73	18.6%
	1,162	100.0%	2,406	100.0%	1,385	100.0%	674	100.0%	393	100.0%

The majority of the government grants are subsidies from the PRC government for encouragement of our PRC operating subsidiary's research and development projects and as incentive for our investing in medical device production lines.

Other Gains/(Losses) – Net

Other gains/(losses) – net consists primarily of net gains/(losses) on foreign exchange, losses on disposals of property, plant and equipment and realized losses on disposals of financial assets. Other gains/(losses) accounted for 0.4%, 1.0%, (0.9)%, (0.9)% and (4.1)% of our total revenue in 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, respectively. The following table sets forth the components of our other gains/(losses) for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net foreign exchange gains/(losses)	365	1,016	(903)	(453)	(1,197)
Losses on disposals of property, plant and equipment	(48)	(3)	(83)	(24)	–
Written off of property, plant and equipment	–	–	–	–	(311)
Realized losses on disposals of financial assets at fair value through profit or loss	(41)	(37)	(22)	(9)	(5)
Unrealized gains/(losses) of fair value change in financial assets at fair value through profit or loss	60	(76)	(29)	(33)	(1,347)
Gain on early termination of a lease contract	2	–	–	–	2
Gain on disposals of subsidiaries	–	10	–	–	–
Others	–	(6)	17	6	4
	338	904	(1,020)	(513)	(2,854)

Selling and Distribution Expenses

Our selling and distribution expenses consist primarily of employee benefit expenses, royalty expense, marketing and advertising expenses and commission expenses paid to local procurement agents designated by hospitals in certain countries. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, selling and distribution expenses accounted for 33.5%, 30.2%, 25.8%, 25.6% and 23.9% of our total revenue, respectively.

The following table sets forth the components of our selling and distribution expenses, in absolute amount and as a percentage of total selling and distribution expenses, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Employee benefit expenses	14,714	45.6%	14,750	55.3%	17,278	57.4%	8,732	59.6%	9,144	55.5%
Royalty expense	2,652	8.2%	2,384	8.9%	2,633	8.7%	1,507	10.3%	1,589	9.6%
Marketing and advertising	4,715	14.6%	2,633	9.9%	2,891	9.6%	989	6.7%	1,960	11.9%
Commission expenses	1,569	4.9%	1,251	4.7%	1,352	4.5%	686	4.7%	669	4.1%
Travel and entertainment	3,961	12.3%	1,606	6.0%	1,474	4.9%	602	4.1%	879	5.3%
Delivery and warehouse charges	681	2.1%	669	2.5%	871	2.9%	427	2.9%	437	2.7%
Depreciation and amortization	665	2.1%	686	2.6%	644	2.1%	318	2.2%	326	2.0%
Transportation costs	656	2.0%	483	1.8%	510	1.7%	239	1.6%	232	1.4%
Others*	2,638	8.2%	2,232	8.3%	2,447	8.2%	1,154	7.9%	1,239	7.5%
Total	32,251	100.0%	26,694	100.0%	30,100	100.0%	14,654	100.0%	16,475	100.0%

* Others primarily include staff recruitment, office and telecommunication expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of employee benefit expenses, depreciation and amortization and legal and professional fees, as well as other miscellaneous expenses, such as insurance expense, [**REDACTED**] and auditors' remuneration. In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, general and administrative expenses accounted for 16.3%, 16.2%, 17.1%, 14.3% and 15.6% of our total revenue, respectively.

The following table sets forth the components of our general and administrative expenses, in absolute amount and as a percentage of total general and administrative expenses, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Employee benefit expenses	7,507	47.8%	6,216	43.5%	9,014	45.2%	4,246	51.9%	4,728	44.0%
Depreciation and amortization	1,744	11.2%	1,698	11.9%	1,525	7.6%	788	9.6%	700	6.5%
Legal and professional fees	1,497	9.5%	2,294	16.0%	1,291	6.5%	643	7.9%	1,003	9.3%
[REDACTED]	–	–	–	–	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Insurance expense	523	3.3%	600	4.2%	565	2.8%	337	4.1%	328	3.1%
Auditors' remuneration	457	2.9%	460	3.2%	352	1.8%	291	3.6%	82	0.8%
IT and telecommunication expenses	988	6.3%	899	6.3%	555	2.8%	239	2.9%	173	1.6%
Travel and entertainment	993	6.3%	411	2.8%	314	1.6%	165	2.0%	177	1.6%
Operating lease charges in respect of office premises	302	1.9%	313	2.2%	288	1.4%	155	1.9%	143	1.3%
Other taxes	104	0.7%	136	1.0%	150	0.8%	172	2.1%	58	0.5%
Others*	1,592	10.1%	1,268	8.9%	1,256	6.2%	659	8.0%	747	7.1%
Total	15,707	100.0%	14,295	100.0%	19,958	100.0%	8,187	100.0%	10,738	100.0%

* Others primarily include utilities, staff training & recruitment expenses and miscellaneous office expenses.

Research and Development Expenses

Our research and development expenses primarily consist of employee benefit expenses, legal and professional fees, materials used in our R&D activities, depreciation and amortization, clinical trial expenses and product registration fees. 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 for the same year/period, respectively. In each year/period during the Track Record Period, we capitalized US$0.3 million, US$2.6 million, US$0.9 million, US$0.7 million and US$0.3 million of our research and development expenses, respectively, while the remaining were recorded as expenses. The following table sets forth the components of our research and development expenses, in absolute amount and as a percentage of total research and development expenses, for the periods indicated:

	For the year ended December 31,						For the six months ended June 30,			
	2019		2020		2021		2021		2022	
							(Unaudited)			
	(US$'000, except percentages)									
Employee benefit expenses	6,687	69.7%	5,634	44.8%	6,206	51.1%	3,079	52.8%	3,547	52.8%
Legal and professional fees	948	9.9%	876	7.0%	701	5.8%	664	11.4%	668	9.9%
Materials	1,391	14.5%	1,251	9.9%	1,153	9.5%	502	8.6%	771	11.5%
Depreciation and amortization	620	6.5%	657	5.3%	828	6.8%	413	7.1%	393	5.8%
(Reversal of clinical trials accruals)/clinical trials expenses	(2,599)	(27.1)%	1,174	9.3%	643	5.3%	306	5.3%	49	0.7%
Product registration fees	441	4.6%	829	6.6%	552	4.5%	279	4.8%	284	4.2%
Outsourced R&D service fees	1,013	10.6%	1,342	10.7%	1,060	8.7%	179	3.1%	594	8.8%
Operating lease charges in respect of office premises	118	1.2%	118	0.9%	157	1.3%	96	1.6%	57	0.8%
Travel and entertainment	333	3.5%	127	1.0%	69	0.6%	22	0.4%	31	0.5%
Others*	641	6.6%	570	4.5%	779	6.4%	287	4.9%	326	5.0%
Total	9,593	100.0%	12,578	100.0%	12,148	100.0%	5,827	100.0%	6,720	100.0%

* Others primarily include utilities and miscellaneous office expenses.

Net (Impairment Losses)/Reversal of Impairment Losses on Financial Assets

Impairment losses on financial assets primarily consist of expected loss allowance for trade receivables. In 2019, we recorded impairment losses on financial assets of US$1.4 million, representing 1.5% of our total revenue for the same period as compared to a net reversal of impairment losses on financial assets of US$0.9 million and US$0.1 million in 2020 and 2021, respectively, representing 1.1% and 0.1% of our total revenue for the same periods. In the first six months of 2021, we recorded a net reversal of impairment losses on financial assets of US$0.2 million, as compared to impairment losses on financial assets of US$0.4 million in the same period of 2022, representing 0.3% and 0.6% of our total revenue for the same periods.

Finance Costs – Net

Our finance costs primarily consist of (i) interest expense on bank loans (ii) interest on lease liabilities, (iii) interest expense to related companies, and (iv) unwinding of interest on convertible redeemable preferred shares partially offset by interest income from our bank deposit. The following table sets forth the components of our finance costs for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Finance income					
Interest income from bank deposit	20	11	12	6	249
Interest income from a loan to an employee	1	1	–	–	–
Finance costs					
Interest expenses on bank loans	(381)	(1,258)	(525)	(403)	(11)
Interest expense to related companies	–	(67)	(151)	(128)	–
Interest expenses on lease liabilities	(120)	(77)	(76)	(40)	(57)
Unwinding of interest on convertible redeemable preferred shares	–	–	(4,853)	(476)	(1,336)
Others	(2)	(3)	(2)	(1)	(3)
Total	(482)	(1,393)	(5,595)	(1,042)	(1,158)

Fair value changes of convertible redeemable preferred shares and loss on derecognition of financial liabilities in relation to convertible redeemable preferred shares

Our fair value losses on convertible redeemable preferred shares was US$14.4 million in 2021. The convertible redeemable preferred shares are hybrid instruments which contain an embedded derivative for the conversion feature. The embedded derivative has been bifurcated from the debt host contract and accounted for at fair value with changes in fair value recognized in the consolidated statements of profit or loss.

Loss on derecognition of financial liabilities in relation to convertible redeemable preferred shares was US$0.6 million in 2021. Upon the completion of the Reorganization on September 28, 2021, the financial liabilities portion of embedded derivative portion of series A preferred shares was derecognized; whereas of series A-2 preferred shares was reclassified to equity, and the difference between the carrying amounts and the fair values of the financial liabilities was recorded in profit or loss.

The fair value changes of these preferred shares are non-cash items that will not recur after the Reorganization on September 28, 2021.

Share of Losses of Investment in a Joint Venture

In 2020, 2021 and the first six months of 2021 and 2022, we recorded share of losses of a joint venture of approximately US$46,000, US$207,000, US$149,000 and US$71,000, respectively, which reflected our investments in ON P&F which engages in the manufacturing and distribution of heart valve products and our share of such joint venture's results of operations under equity method of accounting.

Income Tax

Our Group is primarily subject to the Hong Kong profits tax, PRC corporate income tax, Japan corporate income tax and the Netherlands corporate income tax.

The applicable profits tax rate in Hong Kong is 16.5%, 16.5%, 16.5%, 16.5% and 16.5% for the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, respectively.

The statutory corporate income tax rate in the PRC is 25%. However, our PRC operating subsidiary ONM Shenzhen is qualified as the National High and New Technology Enterprise ("**HNTE**"), which was valid for three years from January 1, 2017 to December 31, 2019 and was further renewed on December 11, 2020 with the validity of three years therefrom. As a result, ONM Shenzhen is entitled to a 15% reduced corporate income tax subject to a record-filing to the in-charge tax bureau. ONM Shenzhen had completed the record-filing with Shenzhen local tax bureau, and its applicable corporate income tax rate was 15% throughout the Track Record Period. Moreover, ONM Shenzhen was qualified to apply an extra 75%, 75%, 100%, 100% and 100% of pre-tax deduction for its eligible research and development expenses for the purpose of corporate income tax for the years ended December 31, 2019, 2020, 2021, and for the six months ended June 30, 2021 and 2022, respectively.

The applicable corporate income tax in Japan is 33.58%, 33.58%, 33.58%, 30.62% and 33.58% for the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, respectively.

For the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, the Netherlands corporate income tax has been provided for at the rate of 25%, 25%, 25%, 25% and 25.8%, respectively, based on the estimated assessable profits of our Netherlands subsidiaries.

For the years ended December 31, 2019 and 2020, our effective income tax rate was 7.3% and 2.5% respectively. The low effective tax rates in 2019 and 2020 was primarily as a result of our utilization of previously unrecognized tax losses and the extra tax deduction for our research and development expenses in the PRC. Loss before income tax in 2021 was mainly due to the fair value loss of convertible redeemable preferred shares, unwinding of interest on convertible redeemable preferred shares and [**REDACTED**]. In the first six months of 2021 and 2022, our effective income tax rate was 33.3% and 17.1%, respectively. The higher effective tax rate in the first six months of 2021 was primarily due to the fair value loss of convertible redeemable preferred shares recognized in the first six months of 2021 was not tax deductible. There was no such fair value loss in the first six months of 2022.

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Current income tax:					
Current income tax on profits for the year/period	562	688	2,556	1,333	1,106
(Over)/under-provision in prior year/period	(30)	61	(98)	(391)	(190)
Current income tax subtotal	532	749	2,458	942	916
Deferred income tax:					
Relating to the origination and reversal of temporary differences	790	(565)	668	716	736
Recognition of previously unrecognized deferred income tax assets	(773)	–	–	–	–
Deferred income tax subtotal	17	(565)	668	716	736
Income tax expense	549	184	3,126	1,658	1,652

For the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, the Group recorded tax effects attributable to expenses not deductible for tax purposes of US$1.1 million, US$0.7 million, US$1.2 million, US$1.1 million and US$0.9 million, respectively. Such effects primarily arose from items including exchange losses for non-trade balances, research and development expenses paid to research institutes that not qualified for tax deduction under applicable tax law, [**REDACTED**], as well as certain expenses which are considered capital nature and therefore non-deductible.

For the years ended December 31, 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, the Group recorded tax effects attributable to income not subject to tax of US$1.2 million, US$1.7 million, US$1.3 million, US$0.6 million and US$0.5 million, respectively. Such effects primarily arose from items including exchange gains for non-trade balances, effect of super deduction of research and development expenditure, non-taxable government grants, as well as certain income which are considered capital nature and therefore non-taxable.

RESULTS OF OPERATIONS

Six Months ended June 30, 2022 Compared to Six Months ended June 30, 2021

Revenue

Our revenue increased by 20.2% from US$57.3 million in the first six months of 2021 to US$68.9 million in the first six months of 2022, primarily attributable to the increase in sales volume of both direct sales and distributor sales. Revenue in our U.S. market increased by US$2.9 million in the first six months of 2022 due to the increase in sales volume of our coronary balloons as a result of the introduction of our Scoreflex NC series in the U.S. market upon product approval by the FDA in late 2021. In addition, the increase in sales volume of our Scoreflex Trio series in the Japan market, which has the higher average selling price among our scoring balloons, brought in an increase in revenue of US$2.4 million in the first six months of 2022. Moreover, revenue in the PRC market increased by US$6.4 million in the first six months of 2022, primarily due to the increase in volume and average selling price for our Scoreflex series as a result of the expansion of our sales networks and change in sales model in the PRC as well as our additional marketing efforts for certain products not subject to the centralized procurement policy.

In terms of product categories sold in relevant periods, our revenue increase in the first six months of 2022 was primarily due to a US$12.7 million increase in revenue generated from our coronary balloon products, particularly our scoring balloon products, in most markets, including the U.S., Japan, APAC and the PRC.

Cost of Sales

Our cost of sales increased by 25.6% from US$16.8 million in the first six months of 2021 to US$21.1 million in the first six months of 2022, primarily due to (i) an increase in raw material costs from US$6.9 million in the first six months of 2021 to US$9.3 million in the first six months of 2022, (ii) an increase in manufacturing costs from US$3.7 million in the first six months of 2021 to US$4.4 million in the first six months of 2022, reflecting our higher production and sales volume during the period, and (iii) an increase in direct labor costs from US$3.6 million in the first six months of 2021 to US$4.7 million in the first six months of 2022, primarily reflecting increases in number and average salaries of our production staff.

Gross profit and Gross Profit Margin

As a result of the foregoing, gross profit increased by 17.8% from US$40.5 million in the first six months of 2021 to US$47.7 million in the first six months of 2022. Gross profit margin was relatively stable in the first six months of 2021 and 2022.

Other Income

Other income decreased by 42.9% from US$0.7 million in the first six months of 2021 to US$0.4 million in the first six months of 2022, primarily due to the decrease in government grants that support our R&D activities in the PRC.

Other Gains/(Losses) – net

Other gains/(losses) – net increased from losses of US$0.5 million in the first six months of 2021 to losses of US$2.9 million in the first six months of 2022, primarily due to the increase in fair value loss of the Commodity Linked Fixed Rate Note of US$1.3 million and the increase in net foreign exchange losses of US$0.7 million, primarily arising from the depreciation of the Japanese Yen against the USD.

Selling and Distribution Expenses

Selling and distribution expenses increased by 12.2% from US$14.7 million in the first six months of 2021 to US$16.5 million in the first six months of 2022, primarily due to the increase in marketing expenses as a result of the resumption of marketing activities such as medical congresses and trade shows.

General and Administrative Expenses

General and administrative expenses increased by 30.5% from US$8.2 million in the first six months of 2021 to US$10.7 million in the first six months of 2022, primarily due to the increase in [**REDACTED**] in the first six months of 2022.

Research and Development Expenses

Research and development expenses increased by 15.5% from US$5.8 million in the first six months of 2021 to US$6.7 million in the first six months of 2022, primarily due to the increase in employee benefit expenses as a result of the overall salary increment and the increase in our outsourced R&D service fees in relation to the consultation services for our pipeline products, which were provided to us by individual experts in universities and hospitals as well as professional medical research institutes and consulting companies. Such consultation services included advising on our clinical study design and trial protocol, performing tests and trials of our pipeline products, providing feedback and clinical evaluation of our pipeline products and assisting with respect to our regulatory strategies and/or submissions.

Net (Impairment Losses)/Reversal of Impairment Losses on Financial Assets

Impairment losses on financial assets increased by 354.4% from a net reversal of approximately US$158,000 in the first six months of 2021 to approximately US$402,000 in the first six months of 2022, primarily due to the increase in trade receivables in 2022.

Finance Cost – Net

Finance costs – net increased by 20.0% from US$1.0 million in the first six months of 2021 to US$1.2 million in the first six months of 2022, primarily due to the increase in unwinding of interest on our convertible redeemable preferred shares from US$0.5 million in the first six months of 2021 to US$1.3 million in the first six months of 2022, partially offset by the decrease in bank loan interests from US$0.4 million in the first six months of 2021 to approximately US$11,000 in the first six months of 2022 and the increase in interest income from the bank deposit from approximately US$6,000 in the first six months of 2021 to US$0.2 million in the first six months of 2022.

Fair Value Changes of Convertible Redeemable Preferred Shares

Our fair value losses on convertible redeemable preferred shares decreased from US$6.0 million in the first six months of 2021 to nil in the first six months of 2022, due to all convertible redeemable preferred shares have been reclassified to equity upon the fulfilment of conditions attached in the relevant agreement in 2022.

Share of Losses of Investment in a Joint Venture

Share of losses of investment in a joint venture in connection with our investment in ON P&F decreased 52.3% from approximately US$149,000 in the first six months of 2021 to approximately US$71,000 the first six months of 2022, primarily due to decrease in net loss of ON P&F as a result of its increase in sales and decrease in research and development expenses in the first six months of 2022 as compared to the same period of 2021.

Income Tax

We recorded income tax expense of US$1.7 million and US$1.7 million with an effective income tax rate of 33.3% and 17.1%, in the first six months of 2021 and 2022, respectively. The higher effective income tax rate in the first six months of 2021 was primarily due to the fair value loss of convertible redeemable preferred shares recognized in the first six months of 2021 was not tax deductible. There was no such fair value loss in the first six months of 2022.

Profit for the Period

As a result of the foregoing, our profit increased by 142.4% from US$3.3 million in the first six months of 2021 to US$8.0 million in the first six months of 2022, and our net profit margin was 5.8% in the first six months of 2021 and 11.7% in the first six months of 2022, mainly attributable to the increase in gross profit of US$7.2 million as a result of the increase in revenue, and we did not incur fair value losses of convertible redeemable preferred shares upon the reclassification to equity in 2022, as compared to US$6.0 million of such losses in the first six months of 2021, partially offset by the fair value loss of the Commodity Linked Fixed Rate Note of US$1.3 million, increase in selling and distribution expenses of US$1.8 million, increase in general and administrative expenses of US$2.6 million and increase in research and development expenses of US$0.9 million.

Under non-HKFRS measures, our adjusted profit for the period (non-HKFRS measure) increased by 23.6% from US$11.0 million in the first six months of 2021 to US$13.6 million in the first six months of 2022, and our adjusted net profit margin (non-HKFRS measure) increased from 19.2% in the first six months of 2021 to 19.8% in the first six months of 2022, primarily due to the increase in gross profit of US$7.2 million as a result of the increase in revenue, partially offset by the increase in selling and distribution expenses of US$1.8 million, the increase in general and administrative expenses of US$2.6 million and the increase in research and development expenses of US$0.9 million.

Year ended December 31, 2021 Compared to Year ended December 31, 2020

Revenue

Our revenue increased by 31.6% from US$88.5 million in 2020 to US$116.5 million in 2021, primarily attributable to increases in sales volume of both direct sales and distributor sales as a result of the resumption of business activities as the COVID-19 pandemic became stabilized. Revenue in our EMEA market increased by US$9.7 million in 2021 due to the increases in average selling price and sales volume of our coronary balloon products and atherectomy devices following the increase in number of PCI cases when COVID-19 was stabilized. Moreover, the acquisition of ON AG, our previous distributor in Switzerland in late 2020 also contributed to the increase in revenue as we enjoyed a higher average selling price under the direct sales model in 2021. In addition, the introduction of our new Jade OTW series in the U.S. market in 2021 brought in an increase in revenue of US$4.2 million. Moreover, the increase in revenue of US$12.0 million in the PRC market was primarily due to the increase

in volume and average selling price for scoring coronary balloon due to (i) the expansion of our sales networks in the PRC as a result of the change in sales model from exclusive distributorship to a combination of direct sales and regional distributors in the PRC, (ii) our additional marketing efforts for the scoring coronary balloon which is not subject to the centralized procurement policy, and (iii) the elimination of the intermediate layer of the previous exclusive distributor.

In terms of product categories sold in relevant periods, our revenue increase in 2021 was primarily due to a US$21.9 million increase in revenue generated from coronary balloon products as demand for our products in most markets, including the PRC, APAC and EMEA recovered when the COVID-19 pandemic became more stable, and to a lesser extent, due to a US$4.2 million increase in revenue generated from peripheral balloon products in connection with the introduction of our new Jade OTW series in the U.S. market. In terms of contribution by different markets, our revenue increase in 2021 was primarily due to a US$9.7 million increase in revenue generated from the EMEA market for coronary balloons, microcatheters and atherectomy devices as well as a US$12.0 million increase in revenue from the PRC in connection with the expansion of our sales network in the PRC.

Cost of Sales

Our cost of sales increased by 15.9% from US$30.5 million in 2020 to US$35.3 million in 2021, primarily due to (i) an increase in raw material costs from US$15.0 million in 2020 to US$15.5 million in 2021, reflecting our higher production and sales volume during the period; (ii) an increase in direct labor costs from US$5.7 million in 2020 to US$7.4 million in 2021, primarily reflecting increases in headcount and average salaries of our production staff; and (iii) an increase in purchase costs of third party products from US$1.6 million in 2020 to US$3.0 million in 2021, primarily resulting from increase in sales volume of third party products.

Gross Profit and Gross Profit Margin

As a result of the foregoing, gross profit increased by 40.0% from US$58.0 million in 2020 to US$81.2 million in 2021. Gross profit margin increased from 65.6% in 2020 to 69.7% in 2021, primarily attributable to improvement in the average selling prices of our balloon products due to the introduction of our new Sapphire 3 and Sapphire NC 24 balloon products, as well as the improvement in the average selling prices of our COMBO Plus dual therapy stent products due to our entering into the Japan market which enjoys a higher average selling price and gross profit margin. Besides, sales volume of our scoring balloons, which have higher average selling price and gross profit margin, increased in connection with the expansion of our sales network in the PRC.

Other Income

Other income decreased by 41.7% from US$2.4 million in 2020 to US$1.4 million in 2021, primarily due to the decrease in government grants that support our R&D activities in the PRC.

Selling and Distribution Expenses

Selling and distribution expenses increased by 12.7% from US$26.7 million in 2020 to US$30.1 million in 2021, primarily due to the setup of our own PRC sales and marketing team.

General and Administrative Expenses

General and administrative expenses increased by 39.9% from US$14.3 million in 2020 to US$20.0 million in 2021, primarily due to the increase in employee benefit expenses as a result of our increased headcount and the overall salary increment. Due to COVID-19, the PRC government granted a one-off waiver of social security expenses of our Shenzhen subsidiary in year 2020 and resulted in lower employee benefit expenses. [**REDACTED**] incurred in 2021 but not 2020 also contributed to the increase in general and administrative expenses.

Research and Development Expenses

Research and development expenses remained relatively stable in 2020 and 2021, and we recorded research and development expenses of US$12.6 million and US$12.1 million in 2020 and 2021, respectively.

Net (Impairment Losses)/ Reversal of Impairment Losses on Financial Assets

We recorded net reversal of impairment losses on financial assets of US$0.9 million in 2020 and net reversal of impairment losses on financial assets of US$0.1 million in 2021, primarily due to the reversal of trade receivable provisions as a result of our improvement in expected credit loss in 2021.

Finance Costs – Net

Finance costs – net increased by 300.0% from US$1.4 million in 2020 to US$5.6 million in 2021, primarily due to unwinding of interest on our convertible redeemable preferred shares of US$4.9 million in 2021.

Fair Value Changes of Convertible Redeemable Preferred Shares

Our fair value losses on convertible redeemable preferred shares was US$14.4 million in 2021, primarily due to the increased fair value of the convertible redeemable preferred shares.

Share of Losses of Investment in a Joint Venture

We recorded share of losses of investment in a joint venture of US$0.2 million in 2021 in connection with our investment in ON P&F, as ON P&F recorded a loss of US$0.4 million primarily attributable to employee benefits expenses and product testing fees.

Income Tax

Income tax expense increased from US$0.2 million in 2020 to US$3.1 million in 2021, primarily due to an increase in profit before tax of our subsidiaries.

Our effective income tax rate in 2020 was 2.5%. Loss before tax in 2021 was mainly due to the fair value loss of convertible redeemable preferred shares, unwinding of interest on convertible redeemable preferred shares and [**REDACTED**].

Profit for the Year

As a result of the foregoing, our profit decreased from US$7.1 million in 2020 to a net loss of US$4.4 million in 2021, and our net profit/(loss) margin was 8.0% in 2020 and (3.8)% in 2021.

Under non-HKFRS measures, our adjusted profit (non-HKFRS measure) increased by 201.4% from US$7.1 million in 2020 to US$21.4 million in 2021, and our adjusted net profit margin (non-HKFRS measure) increased from 8.0% in 2020 to 18.3% in 2021, primarily due to increase in gross profit as a result of increase in revenue, and our relatively stable expenses (excluding reconciling items under non-HKRFS measure) in 2021 as compared to 2020.

Year ended December 31, 2020 Compared to Year ended December 31, 2019

Revenue

Our revenue decreased by 8.1% from US$96.3 million in 2019 to US$88.5 million in 2020, primarily attributable to decreases in sales volume in most of our products as affected by the COVID-19 pandemic which slowed down business activities comprehensively. Other than the U.S. market, our sales volume decreased in all other regions in 2020. On the other hand, the average selling price for our balloon products also decreased slightly in 2020, which was partially offset by the launch of new COMBO Plus dual therapy stent products in Japan as such products enjoyed a relatively higher average selling price.

In terms of product categories sold in relevant periods, our revenue decrease in 2020 was primarily due to a US$9.5 million decrease in revenue generated from coronary balloon products which was mainly the impact of the COVID-19 pandemic that led to a lower number of PCI surgeries performed and reduced the consumption of our products, as well as a decrease in the average selling prices of our products reflecting the product mix sold and the contribution by different markets in relevant periods, partially offset by a US$1.1 million increase in revenue generated from coronary stent products in connection with the introduction

of COMBO Plus products in Japan which had a higher average selling price. In terms of contribution by different markets, our revenue decrease in 2020 was primarily due to an overall decrease in revenue generated from the PRC, Japan, EMEA and APAC which was mainly affected by the COVID-19 pandemic, partially offset by a US$3.0 million increase in revenue generated from the U.S. in connection with the increased sales volume of coronary balloons and microcatheters along with our increased hospital coverage in the U.S.

Cost of Sales

Our cost of sales decreased slightly from US$30.9 million in 2019 to US$30.5 million in 2020, primarily due to a decrease in direct labor costs from US$5.9 million in 2019 to US$5.7 million in 2020 and a decrease in manufacturing costs from US$7.8 million in 2019 to US$7.1 million in 2020 reflecting the decrease of production due to the lower market demand in 2020, partially offset by an increase in raw material costs from US$14.7 million in 2019 to US$15.0 million in 2020 due to the general increase in raw material prices in 2020 as the raw material cost for our COMBO Plus dual therapy stent products was higher.

Gross Profit and Gross Profit Margin

As a result of the foregoing, gross profit decreased by 11.3% from US$65.4 million in 2019 to US$58.0 million in 2020. Gross profit margin also decreased from 67.9% in 2019 to 65.6% in 2020, primarily attributable to an overall decrease in average selling price of our Sapphire series and Scoreflex series balloons in 2020.

Other Income

Other income increased by 100.0% from US$1.2 million in 2019 to US$2.4 million in 2020, primarily due to an increase in government grants received by ONM Shenzhen from local government to support our R&D activities.

Selling and Distribution Expenses

Selling and distribution expenses decreased by 17.3% from US$32.3 million in 2019 to US$26.7 million in 2020, primarily due to the slowdown of business activities and decreased sales volume in 2020 as affected by the COVID-19 pandemic, which led to less marketing activities, lower royalty and travel and entertainment expenses in 2020.

General and Administrative Expenses

General and administrative expenses decreased by 8.9% from US$15.7 million in 2019 to US$14.3 million in 2020, primarily due to a decrease in employee benefit expenses due to the departure of certain former senior management, a decrease in headcount of our U.S. office which has a higher average salary and reduction of bonuses paid to our employees as a result of decreased revenue due to the COVID-19 pandemic, partially offset by an increase in legal and professional fees in connection with our acquisition of ON AG.

Research and Development Expenses

Research and development expenses increased by 31.3% from US$9.6 million in 2019 to US$12.6 million in 2020, primarily due to the increase in clinical trial expenses from a net reversal of US$2.6 million in 2019 to an expense of US$1.2 million in 2020. Upon the approval of COMBO Plus dual therapy stent by PMDA in Japan in 2019, our management reassessed the related clinical trial expenses accrued with suppliers, which resulted in a net credit of US$2.6 million in 2019.

Net (Impairment Losses)/Reversal of Impairment Losses on Financial Assets

We recorded net impairment losses on financial assets of US$1.4 million in 2019 and net reversal of impairment losses on financial assets of US$0.9 million in 2020, primarily due to the reversal of trade receivable provisions as a result of our improvement in expected credit loss in 2020.

Finance Costs – Net

Finance costs – net increased by 180% from US$0.5 million in 2019 to US$1.4 million in 2020, primarily due to increase in average bank loan balance in 2020.

Share of Losses of Investment in a Joint Venture

We recorded share of losses of investment in a joint venture of US$46,000 in 2020 in connection with our investment in ON P&F, as ON P&F recorded a loss of US$92,000 primarily attributable to employee benefits expenses and legal and professional fees.

Income Tax

Income tax expense decreased by 60.0% from US$0.5 million in 2019 to US$0.2 million in 2020, and effective income tax rate decreased from 7.3% to 2.5% in 2019 and 2020, primarily due to extra tax deduction for research and development expenses granted by the PRC government to support R&D activities.

Profit for the Year

As a result of the foregoing, our profit was US$7.0 million in 2019 as compared to US$7.1 million in 2020, and our net profit margin increased from 7.2% in 2019 to 8.0% in 2020.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Our principal sources of liquidity have been cash from operations and financing. Our principal uses of cash have been, and are expected to be, capital expenditures for the expansion of our business and working capital. We expect to fund our future operations and expansion plans principally with cash generated from our operations and equity financing, net [**REDACTED**] from the [**REDACTED**] and other funds raised from capital markets from time to time, when necessary. While our current inventory and trade receivables turnover days are relatively long and our trade payables turnover days is relatively short, which may result in a higher working capital requirement on our Group, we recorded operating profits and positive cash flow during the Track Record Period and do not expect such requirement to have material adverse impact on our operations. To better manage such working capital requirement, we will continue to carefully manage our account receivables and inventory level to gradually reduce the turnover days.

Cash Flow

The following table sets forth a summary of our net cash flow for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net cash generated from operating activities	1,590	12,666	20,498	14,287	13,924
Net cash used in investing activities	(3,053)	(11,245)	(5,219)	(1,516)	(56,177)
Net cash generated from/(used in) financing activities	1,205	(473)	146,308	24,650	(852)
Net (decrease)/increase in cash and cash equivalents	(258)	948	161,587	37,421	(43,105)
Cash and cash equivalents at beginning of year/period	13,812	13,631	15,112	15,112	175,886
Effects of exchange rate changes on cash and cash equivalents	77	533	(813)	(873)	(1,162)
Cash and cash equivalents at end of year/period	13,631	15,112	175,886	51,660	131,619

Net Cash generated from Operating Activities

Cash inflows from our operating activities consist primarily of cash received for sales of our products. Cash outflows from our operating activities consist primarily of employee benefit expenses, procurement of raw materials, research and development expenses, administrative expenses and other operating expenses. Our net cash flows from operating activities reflect our profit before income tax as adjusted for (i) non-cash or non-operating income and expenses, (ii) changes in certain working capital items such as trade receivables, inventories, trade payables, accruals and other payables and (iii) income tax expenses paid.

Net cash generated from operating activities in the first six months of 2022 was US$13.9 million, mainly representing profit before income tax of US$9.7 million, adjusted by depreciation of property, plant and equipment of US$1.0 million, share options granted to directors and employees of US$0.4 million, interest expense of US$1.4 million, fair value losses of the Commodity Linked Fixed Rate Note of US$1.3 million, increase in trade payable of US$1.7 million, increase in accruals and other payables of US$2.6 million, partially offset by an increase in trade receivables of US$5.7 million, an increase in inventories of US$1.2 million and an increase in deposits, prepayments and other receivables of US$1.1 million.

Net cash generated from operating activities in 2021 was US$20.5 million, mainly representing loss before income tax of US$1.3 million, adjusted by depreciation of property, plant and equipment of US$2.3 million, share options granted to directors and employees of US$1.3 million, interest expense of US$5.6 million, fair value losses of convertible redeemable preferred shares of US$14.4 million, loss on derecognition of financial liability in relation to convertible redeemable preferred shares of US$0.6 million, partially offset by an increase in trade receivables of US$1.7 million, an increase in inventories of US$1.6 million and an increase in deposits, prepayments and other receivables of US$0.8 million.

Net cash generated from operating activities in 2020 was US$12.7 million, mainly representing profit before income tax of US$7.3 million, adjusted by depreciation of property, plant and equipment of US$2.5 million, net unrealized foreign exchange gains of US$1.7 million and interest expense of US$1.4 million, as well as a decrease in trade receivables of US$8.6 million, partially offset by a decrease in trade payables of US$2.2 million.

Net cash generated from operating activities in 2019 was US$1.6 million, mainly representing profit before income tax of US$7.5 million, adjusted by depreciation of property, plant and equipment of US$2.4 million, depreciation of right-of-use assets of US$1.6 million and the net impairment losses on financial assets of US$1.4 million, as well as a decrease in accruals and other payables of US$6.5 million and a decrease in trade receivables of US$3.2 million, partially offset by a decrease in deposits, prepayments and other receivables of US$2.5 million.

Net Cash used in Investing Activities

Net cash used in investing activities in the first six months of 2022 was US$56.2 million, primarily due to a US$20.0 million purchase of the Commodity Linked Fixed Rate Note, an increase in the short-term and pledged bank deposit of US$20.0 million and US$15.0 million respectively, a US$0.9 million purchase of property, plant and equipment and a US$0.3 million purchase of intangible assets.

Net cash used in investing activities in 2021 was US$5.2 million, primarily due to a US$3.0 million advance to a joint venture, a US$1.2 million purchase of property, plant and equipment and a US$0.9 million purchase of intangible assets.

Net cash used in investing activities in 2020 was US$11.2 million, primarily due to a US$5.1 million capital contribution to a joint venture, a US$2.8 million purchase of intangible assets and a US$2.2 million payment for acquisition of a subsidiary.

Net cash used in investing activities in 2019 was US$3.1 million, primarily due to a US$2.7 million purchase of property, plant and equipment.

Net Cash generated from Financing Activities

Net cash used in financing activities in the first six months of 2022 was US$0.9 million, primarily due to the repayment of finance lease liabilities.

Net cash generated from financing activities in 2021 was US$146.3 million, primarily due to a net proceeds of US$199.0 million from issuance of convertible redeemable preferred shares of a subsidiary, partially offset by a US$39.9 million net repayment of bank borrowings and a US$10.4 million repayment of loans from related companies.

Net cash used in financing activities in 2020 was US$0.5 million, primarily due to a US$4.0 million repayment to a related company and a US$3.4 million repayment of bank borrowings, partially offset by a US$5.1 million proceeds from loans from related companies.

Net cash generated from financing activities in 2019 was US$1.2 million, primarily due to a US$38.5 million proceeds from bank borrowings, partially offset by a US$35.3 million repayment to a related company.

Capital Expenditures

Capital expenditures principally consist of expenditures for the purchases of property, plant and equipment, intangible assets and right-of-use assets. During the Track Record Period, we financed our capital expenditures primarily through cash flow from operations.

In 2019, 2020, 2021 and for the six months ended June 30, 2021 and 2022, we made the following capital expenditures:

	For the year ended December 31,			For the six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Additions to intangible assets	338	3,785	894	668	271
Additions to property, plant and equipment	2,230	1,003	1,051	604	815
Additions to right-of-use assets	378	278	2,119	1,175	141
Total	2,946	5,066	4,064	2,447	1,227

Current Assets and Current Liabilities

The following table sets forth our current assets and current liabilities as of the dates indicated.

	As of December 31,			As of June 30,	As of September 30,
	2019	2020	2021	2022	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
					(unaudited)
Current assets					
Inventories	26,036	30,038	29,570	27,900	28,064
Trade receivables	32,609	26,316	26,804	29,700	28,283
Deposits, prepayments and other receivables	1,332	2,077	2,796	3,925	4,866
Amounts due from joint ventures	–	90	11	22	645
Amounts due from related companies	177	326	–	–	–
Tax recoverable	392	508	288	202	74
Pledged bank deposit	–	–	–	15,000	15,000
Short-term bank deposit	–	–	–	20,000	94,000
Cash and cash equivalents	13,631	15,112	175,886	131,619	62,019
Total current assets	74,177	74,467	235,355	228,368	232,951
Current liabilities					
Trade payables	3,506	1,364	2,174	3,875	3,577
Accruals and other payables	13,023	12,761	11,866	14,217	13,709
Amount due to a joint venture	–	–	–	129	233
Amount due to a related company	88,193	–	–	–	–
Current income tax liabilities	27	521	927	1,572	1,244
Bank borrowings	38,462	39,898	–	–	–
Lease liabilities	1,470	922	1,483	1,396	1,410
Total current liabilities	144,681	55,466	16,450	21,189	20,173
Net current (liabilities)/assets	(70,504)	19,001	218,905	207,179	212,778

We had net current assets of US$212.8 million as of September 30, 2022 as compared with net current assets of US$207.2 million as of June 30, 2022. The increase in net current assets was primarily attributable to the increase in bank deposits as a result of cash generated from operations.

We had net current assets of US$207.2 million as of June 30, 2022 as compared with net current assets of US$218.9 million as of December 31, 2021. The slight decrease in net current assets was primarily attributable to the purchase of the Commodity Linked Fixed Rate Note of US$20.0 million, which was classified as a non-current asset, partially offset by the net cash generated from operations.

We had net current assets of US$218.9 million as of December 31, 2021 as compared with net current assets of US$19.0 million as of December 31, 2020. The increase in net current assets was primarily attributable to the receipt of US$202.5 million from our Series A and Series A-2 financing in 2021.

We had net current assets of US$19.0 million as of December 31, 2020 as compared with net current liabilities of US$70.5 million as of December 31, 2019. The change from net current liabilities to net current assets was primarily attributable to the waiver of an amount due to a related company as deemed contribution of US$88.2 million in the current liabilities and the recognition of such amount as other reserves in equity in 2020.

Our net current liabilities as of December 31, 2019 were primarily attributable to amount due to a related company and certain bank borrowings to support our research and development and other operating activities.

We do not expect a net current liability position in the foreseeable future, taking into account (i) the proceeds from our Series A financing and Series A-2 financing, (ii) the net [**REDACTED**] from the [**REDACTED**], and (iii) our operating cash inflow.

We had accumulated losses of US$145.1 million, US$137.9 million, US$142.7 million and US$134.4 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. The significant amount of accumulated losses during the Track Record Period primarily contributed by our significant investment in R&D activities prior to the Track Record Period. Specifically, a substantial portion of such R&D expenses were used in the development of our COMBO and COMBO Plus dual therapy stents, which commenced in 2006. The relevant products obtained approval of CE Mark in 2016, approval by PMDA in Japan in 2019 and approval by NMPA in the PRC in 2020, respectively, and prior to these approvals we conducted a total of ten clinical trials as well as various studies in Europe, Japan, the PRC, the U.S. and certain Asia Pacific countries and regions with over 9,500 subjects enrolled under relevant trials and studies since 2006. A substantial majority of the related R&D and clinical trial expenses were paid and the total R&D and clinical trial expenses of COMBO and COMBO Plus and its older product versions accumulated to over US$100.0 million by the end of 2018. As a result, we recorded accumulated losses of US$152.2 million as of January 1, 2019 (being the beginning of the Track Record Period).

DISCUSSION OF CERTAIN KEY ITEMS OF CONSOLIDATED BALANCE SHEETS

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Non-current assets				
Property, plant and equipment	11,994	10,485	8,874	8,219
Right-of-use assets	3,414	2,066	4,567	4,583
Deferred income tax assets	2,967	3,539	2,859	2,123
Financial assets at fair value through profit or loss	1,829	2,048	2,041	20,527
Intangible assets	335	3,966	4,267	4,138
Goodwill	–	1,749	1,749	1,749
Investment in a joint venture	–	5,051	7,888	7,817
Deposits, prepayments and other receivables	976	275	927	1,256
Total non-current assets	21,515	29,179	33,172	50,412
Current assets				
Inventories	26,036	30,038	29,570	27,900
Trade receivables	32,609	26,316	26,804	29,700
Deposits, prepayments and other receivables	1,332	2,077	2,796	3,925
Amounts due from joint ventures	–	90	11	22
Amounts due from related companies	177	326	–	–
Tax recoverable	392	508	288	202
Pledged bank deposit	–	–	–	15,000
Short-term bank deposit	–	–	–	20,000
Cash and cash equivalents	13,631	15,112	175,886	131,619
Total current assets	74,177	74,467	235,355	228,368
Total assets	95,692	103,646	268,527	278,780
Non-current liabilities				
Lease liabilities	1,285	557	2,499	2,657
Convertible redeemable preferred shares	–	–	63,711	–
Retirement benefit obligations	2,227	2,541	2,755	2,208
Loan from related companies	–	10,186	–	–
Amount due to a related company	99,790	–	–	–
Total non-current liabilities	103,302	13,284	68,965	4,865

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Current liabilities				
Trade payables	3,506	1,364	2,174	3,875
Accruals and other payables	13,023	12,761	11,866	14,217
Amount due to a joint venture	–	–	–	129
Amount due to a related company	88,193	–	–	–
Current income tax liabilities	27	521	927	1,572
Bank borrowings	38,462	39,898	–	–
Lease liabilities	1,470	922	1,483	1,396
Total current liabilities	144,681	55,466	16,450	21,189
Total liabilities	247,983	68,750	85,415	26,054

Property, Plant and Equipment

Our property, plant and equipment decreased by US$0.7 million from US$8.9 million as of December 31, 2021 to US$8.2 million as of June 30, 2022 primarily due to the depreciation of our property, plant and equipment during the relevant period.

Our property, plant and equipment decreased by US$1.6 million from US$10.5 million as of December 31, 2020 to US$8.9 million as of December 31, 2021, primarily due to the depreciation of our property, plant and equipment during the relevant period.

Our property, plant and equipment decreased by US$1.5 million from US$12.0 million as of December 31, 2019 to US$10.5 million as of December 31, 2020, primarily due to the depreciation of our property, plant and equipment during the relevant year.

Right-of-use Assets

We had right-of-use assets of US$4.6 million as of June 30, 2022. Balances of right-of-use assets as of June 30, 2022 and December 31, 2021 remained relatively stable.

We had right-of-use assets of US$4.6 million as of December 31, 2021. The increase from December 31, 2020 was mainly because new leases signed and lease renewal during the year.

We had right-of-use assets of US$2.1 million as of December 31, 2020. The decrease from December 31, 2019 was mainly because of depreciation in accordance with the lease terms.

For details of our right-of-use assets, please refer to Note 15 in Appendix I to this document.

Financial Assets at Fair Value through Profit or Loss

During the Track Record Period, our financial assets at fair value through profit or loss primarily consisted of life insurance policies and the Commodity Linked Fixed Rate Note. The Commodity Linked Fixed Rate Note, with an underlying commodity of EU Emissions Allowances, was issued by a reputable international investment bank with a fixed coupon rate of 2.8% upon maturity in December 2023. We recorded financial assets at fair value through profit or loss of US$1.8 million, US$2.0 million, US$2.0 million and US$20.5 million as of December 31, 2019, 2020, 2021 and June 30, 2022. The significant increase from December 31, 2021 to June 30, 2022 was primarily due to the purchase of the Commodity Linked Fixed Rate Note of US$20.0 million for the purpose of generating interest income with minimal credit and liquidity risk, partially offset by the fair value loss thereof.

In order to minimize the risks in relation to our investments in financial assets while generating a reasonable return, we primarily target to invest in low-risk wealth management products. Specifically, our investment policies/strategies and internal control mechanism includes: (i) the wealth management products in which we invest should be issued by reputable financial institutions with principal guaranteed and an overall low-risk profile, and should be no more than two years to ensure liquidity safety; (ii) each investment decision should be made by taking into account the working capital requirement; (iii) when considering each investment, we prudently benchmark against other similar wealth management products issued by multiple financial institutions in order to reduce the risks arising from the fluctuation of loss and gain of such wealth management products; (iv) the Board reviews each investment proposal by taking into account multiple factors, including total investment amount, duration, expected rate of return, background of the issuers and other terms on a case-by-case basis, and the Board's prior approval is required for making each investment; and (v) subsequent to making the investments, we designate personnel to regularly track the performance of the wealth management products and such designated personnel should timely report to the Board if any anomaly is detected in order to avoid or reduce investment losses.

Our Group's investment in financial assets at fair value through profit or loss will be subject to compliance with Chapter 14 of the Rules after the [**REDACTED**].

Goodwill

We recorded goodwill of US$1.7 million, US$1.7 million and US$1.7 million as of December 31, 2020, December 31, 2021 and June 30, 2022, respectively. Goodwill arising on the acquisition of subsidiary represents the excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition-date fair value of any previous equity interest in the acquiree over the fair value of the identified net assets acquired.

Our goodwill is not amortized but it is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Goodwill is allocated to cash-generating units ("**CGUs**") for the purpose of impairment testing. The allocation is made to those CGUs or groups of CGUs that are expected to benefit from the business combination in which the goodwill arose. The units or groups of units are identified at the lowest level at which goodwill is monitored for internal management purposes.

In addition, an impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). The recoverable amount of the CGU is determined based on a value-in-use calculation. The calculation uses cash flow projections prepared based on financial budgets approved by the management covering a period of three years. Cash flows beyond the budget period is extrapolated using an estimated growth rate that does not exceed the long-term average growth rate in which the CGU operates.

The key parameters used for impairment testing are as follows:

	As of December 31,		As of June 30,
	2020	2021	2022
Revenue growth rate	-5.1% to 28.9%	20.2%	20.7% to 27.5%
Gross margin	56.0%	35.9%	35.9%
Profit margin	12.5% to 17.2%	9.8% to 10.9%	6.8% to 10.8%
Terminal growth rate	0.0%	0.0%	0.0%
Pre-tax-discount rate	30.6%	32.9%	32.9%

When performing impairment testing, due to the outbreak of COVID-19, our Directors considered the revenue growth rate for the acquired subsidiary would be negative in the initial years of acquisition, and will only turn around at a later time. As such, the forecasted revenue growth rate ranges from -5.1% to 28.9% during the forecast period for the purpose of goodwill impairment testing performed at December 31, 2020.

As at December 31, 2020, 2021 and June 30, 2022, the recoverable amount calculated based on the value-in-use calculation exceeded the carrying amount of the CGU by approximately US$184,000, US$178,000 and US$165,000, respectively. Our Directors performed sensitivity analysis based on the key assumptions and considered that a reasonable possible changes on the key assumptions would not cause the carrying amount of the CGU to exceed its recoverable amount. For details on the impairment assessment methods for our intangible assets (including goodwill), please see Notes 2.7 and 2.8 to Appendix I to this document.

With all other variable held constant, our management estimates that the headroom would drop to zero as of December 31, 2020 and 2021, respectively.

	As of December 31, 2020	2021	As of June 30, 2022
Revenue growth rate	Decrease to -8.6% to 25.4%	Decrease to 19.2%	Decrease to 19.6% to 26.0%
Gross margin	Decrease to 53.0%	Decrease to 35.2%	Decrease to 35.4%
Profit margin	Decrease to 11.3% to 15.3%	Decrease to 9.3% to 10.3%	Decrease to 6.5% to 10.3%
Pre-tax discount rate	Increase to 35.7%	Increase to 37.6%	Increase to 36.4%

Inventories

The following table sets forth the components of our inventories as of the dates indicated:

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Raw materials	14,251	14,659	14,130	14,210
Work in progress	3,005	3,205	2,597	3,293
Finished goods	8,828	12,238	13,118	11,426
Inventories – gross	26,084	30,102	29,845	28,929
Less: Provision for inventories	(48)	(64)	(275)	(1,029)
	26,036	30,038	29,570	27,900

Our inventories remained stable at US$30.0 million, US$29.6 million and US$27.9 million as of December 31, 2020 and 2021 and June 30, 2022, respectively. Our provision for inventories increased from approximately US$64,000 as of December 31, 2020 to approximately US$275,000 as of December 31, 2021 and further increased to US$1.0 million as of June 30, 2022, primarily due to the increase in provision for our COMBO Plus products. We strategically increased our inventory level of raw materials, work in progress and finished goods in 2021 in preparation of a rising demand when the COVID-19 pandemic become stabilized.

Our inventories increased from US$26.0 million as of December 31, 2019 to US$30.0 million as of December 31, 2020, primarily due to the increase in inventories for our COMBO Plus dual therapy stent products as of result of its product launch in Japan, as well as an increase in stock of our balloon products and an increase in raw material of our Shenzhen subsidiary in preparation of a rising demand when the COVID-19 pandemic became stabilized.

The following table sets forth an aging analysis of our inventory as of June 30, 2022:

Inventory aging analysis as at June 30, 2022	**0-12 months** *US$'000*	**13-24 months** *US$'000*	**over 24 months** *US$'000*	**Total amount** *US$'000*
Raw materials	10,731	1,474	2,005	14,210
Work-in-progress	3,290	3	–	3,293
Finished goods	9,505	1,802	119	11,426
	23,526	3,279	2,124	28,929
Less: Provision for impairment	(252)	(684)	(93)	(1,029)
Inventories, net	23,274	2,595	2,031	27,900

As of June 30, 2022, US$10.7 million, or 75.5% of raw materials aged below 1 year. The useful lives of these raw materials are relatively long with no definite expiry dates. In order to avoid shortage of raw material and reduce unit costs, we order certain raw materials in large quantities which can support our production for up to 2 years. Besides, long aged raw materials also included raw materials for R&D projects, which may last for 3 to 5 years.

The following table sets forth the subsequent sales of our finished goods as of June 30, 2022:

	0-12 months *US$'000*	**13-24 months** *US$'000*	**over 24 months** *US$'000*	**Total amount** *US$'000*
Finished goods	9,505	1,802	119	11,426
Less: Provision for impairment	(252)	(679)	(93)	(1,024)
Finished goods, net	9,253	1,123	26	10,402
Subsequent sales of finished goods up to November 16, 2022	5,062	276	32	5,370

As of June 30, 2022, US$9.3 million, or 89.0% of finished goods, net aged below 1 year. Our coronary and peripheral interventional products generally have shelf lives ranging from approximately 1.5 to 2 years. Finished goods aged over 2 years primarily represented atherectomy devices with 5 years of useful lives.

The following table sets forth our inventory turnover days for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Average balance of inventories	25,534	28,093	29,974	29,387
Cost of sales	30,895	30,452	35,290	21,137
Turnover days*	302	337	310	250

* Calculated by dividing the average balance of gross inventories by cost of sales for the relevant period multiplied by 365 days or 180 days, where applicable. Average balance equals the sum of the beginning balance and ending balance for the year divided by two.

During the Track Record Period, our inventories were mainly accounted for our raw materials and finished goods.

For raw materials, we strategically maintained a higher level of raw materials to ensure our production activities are not disrupted due to shortage of key raw materials. 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.

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. To ensure there is no excessive write off due to expiry, we regularly perform stock take and review the condition of our products.

The combine effect of the above thereby leads to a higher overall inventory turnover days.

Our inventory turnover days increased from 302 days in 2019 to 337 days in 2020 primarily attributable to (i) the high level of inventories maintained by us in anticipation for the launch of COMBO Plus products in Japan, and (ii) an increase in inventories of the balloon and stent products and an increase in raw materials in preparation of a rising customer demand. Our inventory turnover days decreased slightly to 310 days in 2021 and further decreased to 250 days in the first six months of 2022, primarily attributable to the increasing sales volume

and cost of sales during the period from December 31, 2020 to June 30, 2022. The relatively high number of inventory turnover days during the Track Record Period was primarily attributable to the sale of products manufactured by our PRC and Netherlands facilities in both EMEA and APAC markets, which took longer delivery time as compared to companies that produce and deliver their products within the same territories, and the increase in finished goods and raw materials of the balloon and stent products in preparation of a rising customer demand.

67.0% or US$18.7 million of our total inventories as of June 30, 2022 had been subsequently used or sold as of November 16, 2022. We believe that our inventories were recoverable and sufficient impairment provision for such inventories were made as of June 30, 2022, based on the following:

(i) the useful lives of the raw materials used by the Group are relatively long with no definite expiry dates and the shelf lives of the finished goods range from approximately 1.5 to 2 years;

(ii) the revenue of the Company has been increasing steadily since 2020 and its inventory turnover days have been improving from 337 days in 2020 to 310 days in 2021 and further improved to 250 days in the first six months of 2022, which indicates a continued increase in market demand for the Company's products and improving inventory management by the Company;

(iii) approximately 89.0%, or US$9.3 million, of the Company's finished goods as of June 30, 2022 were aged less than 1 year; and

(iv) up to November 16, 2022, US$0.8 million of the Company's finished goods as of June 30, 2022 aged over 1 year remained unsold, and it only accounted for 3.0% of the Company's inventories as of June 30, 2022.

Trade Receivables

The following table sets forth our trade receivables as of the dates indicated:

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Trade receivables	35,475	28,406	28,391	31,558
Loss allowance	(2,866)	(2,090)	(1,587)	(1,858)
Trade receivables – net	32,609	26,316	26,804	29,700

Our trade receivables increased by 10.8% from US$26.8 million as of December 31, 2021 to US$29.7 million as of June 30, 2022, primarily due to the increase in our revenue in the first six months of 2022. Our trade receivables were relatively stable in 2020 and 2021.

Our trade receivables decreased by 19.3% from US$32.6 million as of December 31, 2019 to US$26.3 million as of December 31, 2020, primarily due to the decrease in our revenue in 2020 and the settlement of long aged trade receivables from certain of our customers in Europe and the PRC.

We make provisions for impairment of trade receivables based on our assessment of risk of default and expected losses. For the first six months of 2022, we made provisions for impairment of trade receivables of US$0.4 million. In the year ended December 31, 2020 and 2021, we reversed impairment of trade receivables which amounted to US$0.9 million and US$0.1 million, respectively, while we made provisions for impairment of trade receivables of US$1.4 million in the year ended December 31, 2019. Subsequent to the Track Record Period, we have received settlement of trade receivables of US$24.9 million as of November 16, 2022, representing 83.9% of our trade receivables as of June 30, 2022.

The following table sets forth an aging analysis of our trade receivables based on invoice date as of the dates indicated:

	As of December 31,			As of June 30,
	2019	**2020**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*
0 to 30 days	10,221	7,935	11,493	10,790
31 to 60 days	6,483	6,409	6,770	8,180
61 to 90 days	7,189	5,435	4,704	4,592
Over 90 days	11,582	8,627	5,424	7,996
	35,475	28,406	28,391	31,558

We generally grant customers credit periods ranging from 30 to 180 days. We determine the credit terms for our customers on a case-by-case basis, taking into account a customer's credit history, ability to pay and operating environment.

The following table sets forth the turnover days for trade receivables from customers for the periods indicated:

	For the year ended December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Average balance of trade receivables	33,960	31,941	28,399	29,975
Revenue	96,342	88,472	116,462	68,851
Turnover days*	129	132	89	78

* Calculated by dividing the average balance of gross trade receivables from customers by the corresponding revenue for the relevant period multiplied by 365 days or 180 days, where applicable. Average balance equals the sum of the beginning balance and ending balance for the year divided by two.

Our turnover days remained relatively stable at 129 days in 2019 and 132 days in 2020. In 2021, we ceased the cooperation with Customer A, our former sole distributor in the PRC, and changed our distribution model in the PRC from sole distributorship to a combination of regional distributors and direct sales. For sales to most of these regional distributors in the PRC, we do not grant credit terms to them and generally request for payments upon delivery, which led to a decrease in our trade receivables turnover days to 89 days in 2021. Our turnover days further decreased to 78 days for the first six months of 2022 as a result of increase in sales to distributors in the PRC in such period, which generally paid upon delivery. Our trade receivables turnover days were long primarily due to our diversified sales and distribution network in the PRC, Japan, Europe, U.S. and other Asia Pacific regions, as distributors in the PRC are typically required to pay cash on delivery while the local market practices of distributors in other markets generally require a 30 to 180-day credit term.

Trade Payables

The following table sets forth our trade payables as of the dates indicated:

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Trade payables	3,506	1,364	2,174	3,875

Our trade payables increased by 77.3% from US$2.2 million as of December 31, 2021 to 3.9 million as of June 30, 2022, primarily due to the increase in payable for certain third party products.

Our trade payables increased by 57.1% from US$1.4 million as of December 31, 2020 to US$2.2 million as of December 31, 2021, primarily due to the increase in payable for certain third party products and also the increase in payable for raw material due to the increase in stock.

Our trade payables decreased by 60.0% from US$3.5 million as of December 31, 2019 to US$1.4 million as of December 31, 2020, primarily due to the advance/earlier payment to the suppliers with an aim to secure the supply of certain raw materials since shipment may be affected by the COVID-19 pandemic.

The following table sets forth an aging analysis of our trade payables as of the dates indicated:

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
0 to 30 days	2,176	1,131	1,797	3,172
31 to 60 days	554	226	299	446
61 to 90 days	305	5	46	184
Over 90 days	471	2	32	73
	3,506	1,364	2,174	3,875

Most of our suppliers grant us a credit period of 30 to 90 days. The following table sets forth the turnover days for our trade payables for the periods indicated:

	For the year ended December 31,			For the six months ended June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Average balance of trade payables	3,974	2,435	1,769	3,025
Cost of sales	30,895	30,452	35,290	21,137
Turnover days*	47	29	18	26

* Calculated by dividing the average balance of trade payable by cost of sales for the relevant period multiplied by 365 days or 180 days, where applicable. Average balance equals the sum of the beginning balance and ending balance for the year divided by two.

Our trade payables turnover days increased from 18 days in 2021 to 26 days in the first six months of 2022, primarily due to the increase in purchase of certain third party products in June 2022.

Our trade payables turnover days decreased from 47 days in 2019 to 29 days in 2020, and further decreased to 18 days in 2021. This was a result of our advance/earlier payment to the suppliers with an aim to secure the supply of raw material as global shipment has been affected by the COVID-19 pandemic. 98.2% or US$3.8 million of our trade payables as of June 30, 2022 had been subsequently settled as of November 16, 2022.

Accruals and Other Payables

The following table sets forth our accruals and other payables as of the dates indicated:

	As of December 31,			As of June 30,
	2019	**2020**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*
Accrued expenses	9,996	9,804	8,961	10,153
Accrued [**REDACTED**]	–	–	[**REDACTED**]	[**REDACTED**]
Other payables	3,027	2,957	1,576	1,595
	13,023	12,761	11,866	14,217

Our accruals and other payables primarily include accruals and payables for clinical trials, employee benefit expenses, legal and professional fees and other miscellaneous expenses. The balances of our accruals and other payables maintained at a stable level from December 31, 2019 to 2021. The balance of our accruals and other payables increased from US$11.9 million as of December 31, 2021 to US$14.2 million as of June 30, 2022, primarily due to the increase in accrued [**REDACTED**].

INDEBTEDNESS

As of December 31, 2019, 2020, 2021 and June 30, 2022, except as disclosed in the table below, we did not have any outstanding mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, any guarantees or other material contingent liabilities. Since September 30, 2022, the latest practicable date for the purpose of this indebtedness statement, and up to the date of this document, there had been no material adverse change to our indebtedness. The following table sets forth the components of our indebtedness as of the dates indicated.

	As of December 31,			As of June 30,	As of September 30,
	2019	*2020*	*2021*	*2022*	*2022*
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
					(unaudited)
Bank loans					
– Secured	38,462	38,462	–	–	–
– Unsecured	–	1,436	–	–	–
Lease liabilities – Current	1,470	922	1,483	1,396	1,410
Lease liabilities – Non-current	1,285	557	2,499	2,657	2,274
Loans from related companies	–	10,186	–	–	–
Amount due to a related company	187,983	–	–	–	–
Convertible redeemable preferred shares – financial liability at amortized cost	–	–	63,711	–	–

Our Directors confirm that we had no material defaults in payment of trade and non-trade payables and borrowings, and had not breached any financial covenants during the Track Record Period and up to the Latest Practicable Date.

As of December 31, 2019, 2020, 2021, June 30, 2022 and September 30, 2022, the outstanding amount of our interest-bearing bank borrowings was US$38.5 million, US$39.9 million, nil, nil and nil, respectively. The weighted average effective interest rate of these short-term bank borrowings were 3.77%, 3.30%, 1.98% and 2.75% per annum for 2019, 2020, 2021 and for the six months ended June 30, 2022, respectively. As of December 31, 2019 and 2020, the secured bank borrowings were secured by (1) certain properties held by our Directors, (2) corporate guarantee given by a related company of our Group and (3) personal guarantee given by a Controlling Shareholder and a related party of our Group.

As of June 30, 2022 and September 30, 2022, our Group had two unutilized banking facilities amounting to US$15.0 million and US$30.0 million respectively. Both facilities were secured by (1) the corporate guarantee given by our Company and (2) the personal guarantee given by the Controlling Shareholders. The US$30.0 million facility was additionally secured by the corporate guarantee given by ONM Group Ltd. Further, such banking facility requires us to maintain a US$15.0 million deposit as comfort cash with the relevant bank. The comfort cash requirement was subsequently released on November 7, 2022. The corporate guarantee given by ONM Group Ltd. and the personal guarantee given by the Controlling Shareholders will be released upon completion of the [**REDACTED**].

As of December 31, 2021, the outstanding amount of convertible redeemable preferred shares was US$63.7 million. Upon fulfillment of the conditions attached in the relevant agreement in April 2022, we reclassified such financial liability to equity.

Our Directors confirm that we had not experienced any difficulty in obtaining bank loans, default in payment of bank borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date.

Lease Liabilities

The following table below sets forth our lease liabilities as of December 31, 2019, 2020 and 2021, and June 30, 2022:

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Current	1,470	922	1,483	1,396
Non-current	1,285	557	2,499	2,657
	2,755	1,479	3,982	4,053

We lease office premises, warehouses, office equipment and motor vehicles. Rental contracts are typically made for fixed periods of two to five years but may have extension options. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. We also obtained the land use right through lease contract with local government in the PRC with 50 years term.

Convertible Redeemable Preferred Shares

Our convertible redeemable preferred shares outstanding as of June 30, 2022 was nil, as the conditions attached to relevant agreement have been fulfilled and all outstanding convertible redeemable preferred shares have been reclassified to equity.

The series A preferred shares are hybrid instruments which contain financial liability hosts and embedded derivatives. The financial liability hosts have been accounted for as financial liability carried at amortized cost. The embedded derivatives of series A preferred shares have been bifurcated from the financial liability hosts and measured at fair value at inception date with changes in fair value recognized in the consolidated statements of profit or loss. The series A-2 preferred shares are also hybrid instruments which contain financial liability hosts and embedded derivatives. The financial liability hosts have been accounted for as financial liability carried at amortized cost. The embedded derivatives of series A-2 preferred shares have been bifurcated from the liability hosts and measured at fair value at inception date with changes in fair value recognized in the consolidated statements of profit or loss. Upon the completion of the Reorganization on September 28, 2021, the financial liability portion and embedded derivative portion of series A preferred shares was derecognised; whereas of series A-2 preferred shares was reclassified to equity, and the difference between the carrying amounts and the fair values of the financial liabilities amounting to US$0.6 million was recorded in profit or loss. For Series A Preferred Shares, a new liability at amortized cost amounting to US$62.4 million was recognized upon the completion of the Reorganization on September 28, 2021; whereas for Series A-2 Preferred Shares, amounting to US$167.2 million was reclassified to equity upon the completion of the Reorganization on September 28, 2021.

Upon completion of the [**REDACTED**], all Preferred Shares will be converted into our Ordinary Shares.

The movements of the financial liability hosts and the bifurcated embedded derivatives of the Series A and Series A-2 Preferred Shares are set out as below:

	Financial liability at amortized cost	**Bifurcated embedded derivatives**	**Total**
	US$'000	*US$'000*	*US$'000*
At January 1, 2021	–	–	–
Issuance of Series A Preferred Shares	34,482	518	35,000
Issuance of Series A-2 Preferred Shares	165,895	1,605	167,500
Transaction costs incurred	(3,535)	–	(3,535)
Accrued interest	4,853	–	4,853
Fair value losses	–	14,397	14,397
Loss on derecognition of financial liability charged to profit or loss	559	–	559
Derecognition of Series A Preferred Shares upon completion of the Reorganization	(35,238)	(15,006)	(50,244)
Derecognition of Series A-2 Preferred Shares upon completion of the Reorganization	(165,679)	(1,514)	(167,193)
Recognition of Series A Preferred Shares upon completion of the Reorganization	62,374	–	62,374
At December 31, 2021	63,711	–	63,711
At January 1, 2022	63,711	–	63,711
Accrued Interest	1,336	–	1,336
Reclassification of Series A Preferred Shares to equity	(65,047)	–	(65,047)
At June 30, 2022	–	–	–

CAPITAL COMMITMENTS

As of December 31, 2019, 2020, 2021 and June 30, 2022, we had capital commitment of nil, nil, US$74,000 and US$210,000, respectively.

CONTINGENT LIABILITIES

We did not have outstanding mortgages, charges, debentures, loan capital, bank overdrafts, loans, or other similar indebtedness, or hire purchase commitments, liabilities under acceptances or acceptance credits, any guarantees or other material contingent liabilities.

We are not currently involved in any material legal, arbitration or administrative proceedings that if adversely determined, would materially and adversely affect our financial position or results of operations, although there can be no assurance that this will be the case in the future.

Our Directors have confirmed that except as disclosed in the paragraph headed "– Indebtedness" in this section, there has not been any material changes in our indebtedness or contingent liabilities as of the Latest Practicable Date.

KEY FINANCIAL RATIOS

The following table sets forth our key financial ratios for the periods and as of the dates indicated.

	For the year ended/as of December 31,			For the six months ended/as of June 30	
	2019	2020	2021	2021	2022
Gross profit margin[(1)]	67.9%	65.6%	69.7%	70.7%	69.3%
Net profit margin[(2)]	7.2%	8.0%	N/A[(7)]	5.8%	11.7%
Adjusted net profit margin (non-HKFRS measure)[(3)]	7.2%	8.0%	18.3%	19.2%	19.8%
Return on total assets[(4)]	7.3%	7.1%	N/A[(7)]	5.4%	5.9%
Current ratio[(5)]	0.5 times	1.3 times	14.3 times	2.1 times	10.8 times
Interest coverage ratio[(6)]	15.9 times	6.2 times	0.8 times	5.8 times	7.9 times

(1) Calculated by dividing gross profit for the year/period by total revenue.

(2) Calculated by dividing profit for the year/period by total revenue.

(3) Calculated by dividing the adjusted profit for the year/period (non-HKFRS measure) by total revenue.

(4) Calculated by dividing profit for the year by the average of total assets at the beginning and the end of each year/period. For return on total assets for the six months ended June 30, 2021 and 2022, the numbers are annualized by dividing the profit for these periods by 180 and multiplying it by 360, and then dividing it by the average of total assets at the beginning and end of the period.

(5) Calculated by dividing total current assets by total current liabilities.

(6) Calculated by dividing profit before income tax and interest expenses by interest expense.

(7) We recorded net loss during the year.

Gross Profit Margin

Please refer to the section headed "Financial Information – Description of Consolidated Statements of Profit or Loss" in this document.

Net Profit Margin

Please refer to the section headed "Financial Information – Results of Operations" in this document.

Return on Total Assets

Our return on total assets increased from nil in 2021 to 5.9% in the first six months of 2022, primarily reflecting the increases in our net profit in such period. Our return on total assets in 2021 was nil, primarily attributable to the impact of fair losses in connection with our convertible redeemable preferred shares. Our return on total assets was 7.3% in 2019, 7.1% in 2020, primarily reflecting the increases in our net profit in relevant periods.

Current Ratio

Our current ratio decreased from 14.3 times as of December 31, 2021 to 10.8 times as of June 30, 2022, primarily attributable to the purchase of the Commodity Linked Fixed Rate Note of US$20.0 million, which was classified as a non-current asset.

Our current ratio increased significantly from 1.3 times as of December 31, 2020 to 14.3 times as of December 31, 2021, primarily attributable to increased cash and cash equivalents in connection with our Series A and Series A-2 financing.

Our current ratio increased from 0.5 time as of December 31, 2019 to 1.3 times as of December 31, 2020, primarily attributable to the capitalization of an amount due to a related company.

Interest Coverage Ratio

Our interest coverage ratio increased from 0.8 times as of December 31, 2021 to 7.9 times as of June 30, 2022, primarily attributable to our increased profit before income tax, as well as the decreased interest expenses arising from the unwinding of interests on convertible redeemable preferred shares.

Our interest coverage ratio decreased from 6.2 times as of December 31, 2020 to 0.8 times as of December 31, 2021, primarily attributable to our decreased profit before income tax due to fair value loss of convertible redeemable preferred shares, as well as the higher interest expenses due to unwinding of interests on convertible redeemable preferred shares.

Our interest coverage ratio decreased from 15.9 times as of December 31, 2019 to 6.2 times as of December 31, 2020, primarily attributable to the increased interest expenses due to an increase in the average bank loan balances.

[REDACTED]

[**REDACTED**]

WORKING CAPITAL

We have positive operating cash flows in 2019, 2020, 2021 and for the six months ended June 30, 2022.

Taking into account the financial resources available to us including our cash and cash equivalents on hand, our operating cash flows, and the estimated net [**REDACTED**] from the [**REDACTED**], our Directors, after due and careful inquiry, confirm that the working capital available to us is sufficient at present and for at least the next 12 months from the date of this document. Based on the discussion with our Directors and the written confirmation from the Company in relation to the working capital sufficiency, and taking into account the working capital statement and memorandum on working capital forecast as well as the Company's cash and cash equivalents, operating cash inflow and net [**REDACTED**] from the [**REDACTED**], the Joint Sponsors concur with the view of our Directors regarding the working capital sufficiency of our Group.

RELATED PARTY TRANSACTIONS

During the Track Record Period, our transactions with related parties primarily include (i) payment of remuneration to key management personnel, (ii) transactions with certain of our related parties in connection with our operations, (iii) year-end balances with related parties, and (iv) security interest and guarantees provided by our directors and controlling shareholders relating to our short-term bank borrowings, as described in Note 39 to the Accountant's Report attached as Appendix I to this document.

We have settled the bank loans relating to the security interest and guarantees provided by our directors and controlling shareholders. In addition, we intend to settle our balances with related parties prior to the [**REDACTED**].

Our Directors believe that our related party transactions during the Track Record Period were conducted on an arm's length basis and entered into in the ordinary course of business, and would not distort our track record results or make our historical results not reflective of our future performance.

QUALITATIVE AND QUANTITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to credit, liquidity and foreign currency risks in the ordinary course of business. We describe below our exposure to these risks, and the financial risk management policies and practices we use to manage these risks.

Credit Risk

Our credit risk is primarily attributable to trade and other receivables. We typically do not require collateral from customers. For external receivables, we have policies in place to assess the credit worthiness of our customers to ensure that sales of products are made to customers with an appropriate credit history. Besides, our management monitors the credit risk of our Group on an ongoing basis by reviewing the debtors' aging to minimize our exposure to credit risk. As at December 31, 2019, 2020 and 2021 and June 30, 2022, we had concentration of credit risk given that our largest customer accounted for 12%, 7%, 2% and 11% respectively, of our total trade receivables.

Liquidity and Interest Rate Risk

Our interest rate risk arises from bank borrowings, loan from related companies and lease liabilities. Our bank borrowings obtained at variable rates expose us to cash flow and interest rate risks.

Loan from related companies and lease liabilities were obtained at fixed rates, and therefore our Directors are of the opinion that our interest rate risk exposure is low.

As at December 31, 2019 and 2020, if interest rates on bank borrowings had been 100 basis points higher or lower with all other variables held constant, the impact on our profit for the year would have been approximately US$0.3 million and US$0.3 million lower or higher, respectively.

Bank deposits at variable rates expose us to cash flow interest rate risk. We manage our interest rate risk by performing regular reviews and continually monitoring its interest rate exposures. We have not used any interest rate swaps to hedge our exposure to interest rate risk.

Our Directors are of the opinion that as at December 31, 2019, 2020, 2021 and June 30, 2022, any reasonable changes in interest rates on bank deposits would not result in a significant change in our results of operations. Accordingly, no sensitivity analysis is presented for interest rate risk arising from bank deposits.

Foreign Currency Risk

We operate internationally and are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the Hong Kong dollar ("**HK$**"), Renminbi ("**RMB**"), Japanese Yen ("**JPY**") and Euro ("**EUR**"). Foreign exchange risk arises when future commercial transactions or recognized assets or liabilities are denominated in a currency that is not the entity's functional currency.

Our management manages the foreign exchange risks by performing regular review and monitoring our foreign exchange exposure. Our management has also set up a policy to require our Group Companies to manage their foreign exchange risk against their functional currency.

The table below summaries the changes in our profit or loss in response to reasonably possible changes in the foreign exchange rates to which we have significant exposure at the balance sheet date. The analysis has been determined assuming that the general depreciation trend in foreign exchange rates against functional currency in respective countries had occurred at the balance sheet date and that all other variables remain constant.

		As at December 31, 2019		As at December 31, 2020		As at December 31, 2021		As at June 30, 2022	
Functional currency	Foreign currency	Hypothetical Appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*	Hypothetical Appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*	Hypothetical Appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*	Hypothetical Appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*
US$	RMB	+/- 5%	(117)/117	+/- 5%	(136)/136	+/- 5%	(67)/67	+/- 5%	(6)/6
JPY	US$	+/- 5%	(703)/703	+/- 5%	(919)/919	+/- 5%	(375)/375	+/- 5%	(1,024)/1,024
EUR	US$	+/- 5%	(34)/34	+/- 5%	(118)/118	+/- 5%	41/(41)	+/- 5%	87/(87)

OFF-BALANCE SHEET ARRANGEMENTS

We did not have any off-balance sheet arrangements as of June 30, 2022.

DIVIDENDS AND DIVIDEND POLICY

We retain distributable profits not distributed in a given year and make them available for distribution in subsequent years. We generally do not distribute dividends in a year in which we do not have any distributable profits. Shareholders must also approve the payment of any dividends at a shareholders' general meeting.

The Board of Directors is responsible for submitting proposals for dividend payments to the shareholders' general meeting for approval. The determination of whether to pay a dividend and in which amount is based on our results of operations, cash flow, financial condition, future business prospects, statutory and regulatory restrictions and other factors that the Board of Directors deems relevant. We have not declared or paid any dividend during the Track Record Period. Any future declarations and payments of dividends will be at the absolute discretion of our Directors. There can be no assurance that we will be able to declare or distribute any dividend in the amount set out in any plan of the Board or at all. Currently, we do not have any dividend policy or intention to declare or pay any dividends in the near future.

DISTRIBUTABLE RESERVES

As of June 30, 2022, our Company did not have any distributable reserves.

NO MATERIAL ADVERSE CHANGE

Our Directors have confirmed that, up to the date of this document, there has been no material adverse change in our financial or trading position or prospects since June 30, 2022, the date of our latest audited consolidated financial statements, and there has been no event since June 30, 2022 which materially affects the information in the Accountant's Report in Appendix I to this document.

NO ADDITIONAL DISCLOSURE REQUIRED UNDER THE LISTING RULES

Our Directors have confirmed that as at the Latest Practicable Date, there are no circumstances which, had we been required to comply with Rules 13.13 to 13.19 of the Listing Rules, would have given rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

UNAUDITED PRO FORMA ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

For details or our unaudited pro forma adjusted consolidated net tangible assets, please refer to Appendix II to this document.

OUR CONTROLLING SHAREHOLDERS

As of the date of this document, the equity interest of our Company was controlled as to 67.46% by HART, which is owned as to 55% and 45% by Mr. David CHIEN and Ms. Kwai Ching Denise LAU, respectively. HART is an investment holding vehicle jointly held by Mr. David CHIEN and Ms. Kwai Ching Denise LAU. For background and experience of Mr. David CHIEN and Ms. Kwai Ching Denise LAU, please refer to the section headed "Directors and Senior Management" in this document.

Immediately following the completion of the [**REDACTED**], HART will be interested in approximately [**REDACTED**]% of our issued share capital, without taking into account any Shares which may be allotted and issued under the Share Incentive Schemes. Therefore, HART, Mr. David CHIEN and Ms. Kwai Ching Denise LAU are a group of Controlling Shareholders as defined under the Listing Rules upon [**REDACTED**].

NO COMPETITION AND CLEAR DELINEATION OF BUSINESS

Each of our Controlling Shareholders has confirmed that, as of the Latest Practicable Date, none of them had any interest in any business, other than our business, which compete, or is likely to compete, either directly or indirectly, with our business and would require disclosure under Rule 8.10 of the Listing Rules.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independently from our Controlling Shareholders after the [**REDACTED**].

Management Independence

Our Directors are of the view that our Board and senior management team are able to manage our business independently from the Controlling Shareholders and their respective close associates for the following reasons:

(a) our Board of Directors consists of eight Directors, six of whom do not hold any interest or management positions in our Controlling Shareholders. As of the Latest Practicable Date, other than Mr. David CHIEN and Ms. Kwai Ching Denise LAU who are our Controlling Shareholders, none of our Directors or senior management hold any position or own any interest in our Controlling Shareholders;

(b) each Director is aware of his or her fiduciary duties as a director which require, among other things, that he or she acts for the benefit and in the interest of our Company and does not allow any conflict between his duties as a Director and his or her personal interests;

(c) our daily management and operations are carried out by a senior management team, five of whom do not hold any interest or management positions in our Controlling Shareholders. Our senior management team has substantial experience in the industry in which our Company is engaged, and will therefore be able to make business decisions that are in the best interests of our Group;

(d) we have three independent non-executive Directors and certain matters of our Company must always be referred to the independent non-executive Directors for review;

(e) according to the Articles of Association, in respect of any contract or arrangement or any other proposal whatsoever in which a Director or any of his or her close associates (or, if required by the Listing Rules, his or her other associates) has any material interest, such Director shall abstain from voting on the resolutions and shall not be counted towards the quorum for the voting;

(f) where a Shareholders' meeting is held to consider a proposed transaction in which any Controlling Shareholder has a material interest, the Controlling Shareholders shall abstain from voting on the resolutions and shall not be counted towards the quorum for the voting; and

(g) our Company has appointed Rainbow Capital (HK) Limited as our compliance advisor, which will provide advice and guidance to our Group in respect of compliance with the applicable laws and Listing Rules including various requirements relating to Directors' duties and corporate governance.

Based on the above, our Directors are satisfied that our Board as a whole together with our senior management team is able to perform the managerial role in our Group independently.

Operational Independence

We have full rights to make business decisions and to carry out our business independent of our Controlling Shareholders and their respective close associates. On the basis of the following reasons, our Directors consider that our Company will continue to be operationally independent of our Controlling Shareholders and their respective close associates after [**REDACTED**]:

(a) we are not reliant on trademarks owned by our Controlling Shareholders;

(b) we are the holder of all relevant licenses material to the operation of our business and have sufficient capital, equipment and employees to operate our business independently;

(c) we have our own administrative and corporate governance infrastructure, including our own accounting, legal and human resources departments;

(d) our Directors do not expect that there will be any connected transactions between our Group and our Controlling Shareholders or their respective associates upon or shortly after [**REDACTED**]; and

(e) none of our Controlling Shareholders and their respective close associates has any interest which competes or is likely to compete with the business of our Group.

Financial Independence

We have independent internal control and accounting systems. We also have an independent finance department responsible for discharging the treasury function. We are capable of obtaining financing from third parties, if necessary, without reliance on our Controlling Shareholders.

No loans or guarantees provided by, or granted to, our Controlling Shareholders or their respective close associates will be outstanding as of the Latest Practicable Date.

Based on the above, our Directors are of the view that they and our senior management are capable of carrying on our business independently of, and do not place undue reliance on our Controlling Shareholders and their close associates after the [**REDACTED**].

CORPORATE GOVERNANCE

Other than deviation from Code Provision C.2.1 as disclosed in "Directors and Senior Management – Corporate Governance," our Company will comply with the provisions of the Code, which sets out principles of good corporate governance in relation to, among other matters, directors, the chairman and chief executive officer, board composition, the appointment, re-election and removal of Directors, their responsibilities and remuneration and communications with Shareholders.

Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. We would adopt the following corporate governance measures to manage potential conflict of interests between our Group and the Controlling Shareholders:

(a) where a Shareholders meeting is to be held for considering proposed transactions in which the Controlling Shareholders or their associates has a material interest, the Controlling Shareholders shall not vote on the resolutions and shall not be counted in the quorum for the voting;

(b) the Company has established internal control mechanisms to identify connected transactions. Upon [**REDACTED**], if the Company enters into connected transactions with the Controlling Shareholders or their associates, the Company will comply with the applicable Listing Rules;

(c) our Board will consist of a balanced composition of executive and non-executive Directors, including not less than one-third of independent non-executive Directors to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors, details of whom are set out in "Directors and Senior Management" individually and together possess the requisite knowledge and experience. All of our independent non-executive Directors are experienced. They will review whether there is any conflict of interests between the Group and the Controlling Shareholders annually and provide impartial and professional advice to protect the interest of our minority Shareholders;

(d) in the event that the independent non-executive Directors are requested to review any conflicts of interests circumstances between the Group and the Controlling Shareholders, the Controlling Shareholders and/or the Company shall provide the independent non-executive Directors with all necessary information and the Company shall disclose the decisions of the independent non-executive Directors (including why business opportunities referred to it by the Controlling Shareholders were not taken up) either in its annual report or by way of announcements;

(e) where the advice from independent professional, such as that from financial advisor, is reasonably requested by our Directors (including the independent non-executive Directors), the appointment of such independent professional will be made at our Company's expenses; and

(f) we have appointed Rainbow Capital (HK) Limited as our compliance advisor, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules including various requirements relating to corporate governance.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and our Controlling Shareholders, and to protect minority Shareholders' rights after the [**REDACTED**].

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company in issue and to be issued as fully paid prior to and immediately following the completion of the [**REDACTED**]:

Before Share Consolidation

Authorized share capital		**Aggregate par value** *(US$)*
6,000,000,000	Shares of par value of US$0.0001 each as of the date of this document	600,000
Issued and to be issued, fully paid or credited as fully paid as of the date of this document		
3,865,684,688	Shares of par value of US$0.0001 each in issue as at the date of this document (assuming all preferred shares are converted into ordinary Shares on a 1:1 basis)	386,568.469

After Share Consolidation

Authorized share capital		**Aggregate par value** *(US$)*
1,200,000,000	Shares of par value of US$0.0005 each immediately upon completion of the Share Consolidation	600,000
To be issued, fully paid or credited as fully paid immediately upon Share Consolidation and immediately prior to completion of the [**REDACTED**]		
[773,136,937]	Shares of par value of US$0.0005 each in issue immediately upon completion of the Share Consolidation and immediately prior to completion of the [**REDACTED**] (assuming all Preferred Shares are converted into Ordinary Shares on a 1:1 basis)	[386,568.469]
To be issued, fully paid or credited as fully paid immediately upon completion of the [**REDACTED**]		
[**REDACTED**]	Shares of par value of US$0.0005 each to be [**REDACTED**] under the [**REDACTED**]	[**REDACTED**]
[**REDACTED**]	Total Shares of par value of US$0.0005 each in issue immediately upon completion of the [**REDACTED**]	[**REDACTED**]

ASSUMPTION

The above table assumes that the [**REDACTED**] becomes unconditional and the Shares are issued pursuant to the [**REDACTED**]. The above table does not take into account any Shares which may be allotted and issued pursuant to the exercise of options which may be granted under the Share Incentive Schemes or any Shares which may be issued or repurchased by our Company pursuant to the general mandates granted to our Directors to issue or repurchase Shares as described below.

RANKING

The [**REDACTED**] are ordinary shares in the share capital of our Company and will rank equally in all respects with all Shares in issue or to be issued as set forth in the above table, and will qualify and rank in full for all dividends or other distributions declared, made or paid after the date of this document.

SHARE INCENTIVE SCHEMES

We have adopted the Pre-[**REDACTED**] Share Option Scheme and conditionally adopted the Post-[**REDACTED**] Share Option Scheme. The principal terms of the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme are summarized in the section headed "Statutory and General Information – D. Share Incentive Scheme" in Appendix IV to this document.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Our Company will have only one class of Shares upon completion of the [**REDACTED**], namely ordinary shares, and each ranks pari passu with the other Shares. Pursuant to the Cayman Companies Act and the terms of the Memorandum and Articles of Association, our Company may from time to time by ordinary resolution of shareholders (i) increase its capital; (ii) consolidate and divide its capital into shares of larger amount; (iii) divide its shares into several classes; (iv) subdivide its shares into shares of smaller amount; and (v) cancel any shares which have not been taken. In addition, our Company may subject to the provisions of the Cayman Companies Act reduce its share capital or capital redemption reserve by its shareholders passing a special resolution. For details, please refer to the section headed "Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law" in this document.

GENERAL MANDATE TO ISSUE SHARES

Subject to the [**REDACTED**] becoming unconditional, our Directors have been granted a general unconditional mandate to allot, issue and deal with Shares and to make or grant offers, agreements or options which might require such Shares to be allotted and issued or dealt with at any time subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, shall not exceed the sum of:

(a) 20% of the aggregate nominal value of the share capital of the Company in issue immediately following completion of the [**REDACTED**]; and

(b) the nominal amount of our share capital repurchased by the Company (if any) pursuant to the repurchase mandate (as mentioned below).

This mandate does not cover Shares to be allotted, issued, or dealt with under a rights issue or scrip dividend scheme or similar arrangements or a specific authority granted by our Shareholders or upon the exercise of options which were granted under the Pre-[**REDACTED**] Share Option Scheme or may be granted under the Post-[**REDACTED**] Share Option Scheme.

This mandate to issue Shares will remain in effect until:

(i) at the conclusion of our next annual general meeting; or

(ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or

(iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting,

whichever is the earliest.

For further details of this general mandate, please see the section headed "Statutory and General Information – A. Further Information about Our Group – 4. Resolutions of the Shareholders of the Company Passed on [●]" in Appendix IV to this document.

GENERAL MANDATE TO REPURCHASE SHARES

Subject to the [**REDACTED**] becoming unconditional, our Directors have been granted a general unconditional mandate to exercise all the powers of our Company to repurchase Shares with an aggregate nominal value of not more than 10% of the aggregate nominal value of our share capital in issue immediately following the [**REDACTED**] (excluding any Shares which may be allotted and issued pursuant to the exercise of options which were granted under the Pre-[**REDACTED**] Share Option Scheme or may be granted under the Post-[**REDACTED**] Share Option Scheme).

This mandate relates to repurchases made on the Stock Exchange, or on any other stock exchange which the Shares may be listed (and which is recognized by the SFC and the Stock Exchange for this purpose), and made in accordance with all applicable laws and regulations and the requirements of the Listing Rules. A summary of the relevant Listing Rules is set out in the section headed "Statutory and General Information – A. Further Information About Our Group – 5. Restrictions on Repurchase".

This general mandate to repurchase Shares will remain in effect until:

(a) at the conclusion of our next annual general meeting; or

(b) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or

(c) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting, whichever is the earliest.

For further details of this general mandate, please see the paragraph headed "Statutory and General Information – A. Further Information about Our Group – 4. Resolutions of the Shareholders of the Company Passed on [●]" in Appendix IV to this document.

So far as our Directors are aware, immediately following the completion of the [**REDACTED**] and without taking into account any Shares to be issued upon the exercise of options which were granted under the Share Incentive Schemes, the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company:

Name	Capacity/ nature of interest[1]	Number of Shares held as of the date of this document	Approximate percentage of shareholding in the total issued share capital of our Company as of the date of this document	Number of Shares held immediately following completion of the [REDACTED]	Approximate percentage of shareholding in the total issued share capital of our Company immediately following completion of the [REDACTED]
HART[2]	Interest of controlled corporation	2,607,619,221	67.46%	[**REDACTED**]	[**REDACTED**]%
Mr. David CHIEN[2]	Interest of controlled corporation	2,607,619,221	67.46%	[**REDACTED**]	[**REDACTED**]%
Ms. Kwai Ching Denise LAU[2]	Interest of controlled corporation	2,607,619,221	67.46%	[**REDACTED**]	[**REDACTED**]%
Suzhou Red Earth Yeju Investment Ltd. ("**SZYJ**")[3]	Beneficial owner	349,805,473	9.05%	[**REDACTED**]	[**REDACTED**]%
Shenzhen Capital Group Co., Ltd. ("**SCGC**")[3]	Interest of controlled corporation	490,173,274	12.68%	[**REDACTED**]	[**REDACTED**]%

Notes:

1. All interests stated are long positions.

2. Mr. David CHIEN and Ms. Kwai Ching Denise LAU holds 55% and 45% of shareholdings of HART, respectively. As such, under the SFO, each of Mr. David CHIEN and Ms. Kwai Ching Denise LAU is deemed to be interested in the Shares held by HART.

3. Upon completion of the [**REDACTED**], SCGC Capital Holding Company Limited ("**SCGC Capital**"), Suzhou Red Earth Yeju Investment Ltd. ("**SZYJ**") and HTYL Investment Holdings Limited ("**HTYL**") hold [**REDACTED**], [**REDACTED**] and [**REDACTED**] Shares, respectively. Each of SCGC Capital, SZYJ and HTYL is controlled by Shenzhen Capital Group Co., Ltd. (深圳市創投資集團有限公司). As such, under the SFO, SCGC is deemed to be interested in the Shares collectively held by SCGC Capital, SZYJ and HTYL.

SUBSTANTIAL SHAREHOLDERS

Except as disclosed above, our Directors are not aware of any other person who will, immediately following the completion of the [**REDACTED**] (assuming the share options granted under the Share Incentive Schemes are not exercised and each Preferred Share will be automatically converted to one Share upon the [**REDACTED**] becoming unconditional), have any interest and/or short positions in the Shares or underlying Shares of our Company which would fall to be disclosed to us pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or, who are, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

BOARD OF DIRECTORS

Our Board consists of eight Directors, with four executive Directors, one non-executive Director and three independent non-executive Directors. Our Board is responsible for, and has general powers for, the management and conduct of our business.

The table below sets out certain information in respect of the members of the Board.

Name	Position	Age	Date of appointment as Director	Date of joining the Group	Role and responsibility	Relationship with other Directors and senior management
David CHIEN (錢永勛)	Chairman of our Board, executive Director and chief executive officer	57	July 22, 2021	February 16, 2000	Overall strategic planning and policy execution of the Group	Spouse of Kwai Ching Denise LAU
Kwai Ching Denise LAU (劉桂禎)	Executive Director and chief operating officer	48	July 22, 2021	April 3, 2018	Leading, overseeing and supervising the operation of the Group	Spouse of David CHIEN
Wing Shing CHEN (陳泳成)	Executive Director, chief financial officer and company secretary	41	July 22, 2021	April 24, 2017	Overseeing financial and accounting operations, human resources, IT and internal controls, and provides financial and business advice to the Board and senior management of the Group	N/A
Ching Chung John CHOW (周靜忠)	Executive Director and head of business development	64	July 22, 2021	August 1, 2000	Overseeing overall business development activities of our Group	N/A
Yi ZHOU (周伊)	Non-executive Director	41	September 28, 2021	July 20, 2021	Providing advice on business management of the Group	N/A
Yip Keung CHAN (陳業強)	Independent non-executive Director	39	September 29, 2021 (effective from the [**REDACTED**])	September 29, 2021	Supervising and providing independent judgment to our Board	N/A
Lai Fan Gloria TAM (譚麗芬)	Independent non-executive Director	65	September 29, 2021 (effective from the [**REDACTED**])	September 29, 2021	Supervising and providing independent judgment to our Board	N/A
Ka Keung LAU *BBS, MH, JP* (樓家強)	Independent non-executive Director	47	September 29, 2021 (effective from the [**REDACTED**])	September 29, 2021	Supervising and providing independent judgment to our Board	N/A

The following sets forth the biographies of our Directors:

Executive Directors

David CHIEN (錢永勛), aged 57, is the chairman and chief executive officer of our Company. Mr. Chien joined the Group in February 2000, has been a Director since July 22, 2021 and was redesignated as an executive Director on September 29, 2021. Mr. Chien has been the chief executive officer of our Group since November 11, 2016 and is primarily responsible for overseeing the overall strategic planning and policy execution of the Group. Mr. Chien also holds the following positions in the subsidiaries of our Group:

Name of the subsidiary	Position	Period
OrbusNeich Medical Group Limited ("**ONM Group Ltd.**")	Director	June 2017 to present
OrbusNeich Medical Company Limited (業聚醫療有限公司) ("**ONM HK**")	Director	February 2000 to present
OrbusNeich Medical Sdn. Bhd. ("**ONM Malaysia**")	Director	November 2011 to present
OrbusNeich Medical Pte. Ltd. ("**ONM Singapore**")	Director	January 2005 to present
OrbusNeich Medical K.K. ("**ONM Japan**")	Director	September 2001 to present
OrbusNeich Medical B.V. ("**ONM BV**")	Director	July 2006 to present
Orbus International B.V. ("**OIBV**")	Director	March 2017 to present
OrbusNeich (Switzerland) AG ("**ON AG**")	Director	September 2020 to present
OrbusNeich Medical (Shenzhen) Company Limited (業聚醫療器械(深圳)有限公司) ("**ONM Shenzhen**")	Chairman of the board	August 20, 2010 to June 3, 2013
	Director	October 16, 2020 to present

Mr. Chien has around 28 years of experience in the medical devices industry, and was the director of Cordis-Neich Limited from January 1994 to October 1997. He was a director of Tysan Holdings Limited, a company listed on the Main Board of the Stock Exchange (stock code: 0687), from November 1997 to January 2014. Mr. Chien has been the trustee of the Chien Foundation since January 1997 and the governor of KFoundation since July 2019. Mr. Chien was elected as a member of the Board of Trustees of Chung Chi College, the Chinese University of Hong Kong, in 2020.

Mr. Chien studied at York University in Canada. Mr. Chien is the spouse of Ms. Kwai Ching Denise LAU, an executive Director and chief operating officer of our Group.

Mr. Chien was a director of the following subsidiary of ONM Group Ltd. prior to its deregistration, which had been dissolved at the Latest Practicable Date:

Name of subsidiary	Place of incorporation	Date of dissolution	Means of dissolution	Reasons of dissolution
OrbusNeich Medical Technology Development (Shenzhen) Company Limited (業聚醫療技術開發(深圳)有限公司)	PRC	July 31, 2019	Deregistration	Cessation of business

Mr. Chien confirmed that (i) the above company was solvent immediately prior to their dissolutions; (ii) there was no wrongful act on his part leading to dissolutions of the above company and was not aware of any actual or potential claim that had been or would be made against him as a result of dissolutions; and (iii) no misconduct or misfeasance had been involved in the dissolution of the above company.

Kwai Ching Denise LAU (劉桂禎), aged 48, has been a Director since July 22, 2021 and was redesignated as an executive Director on September 29, 2021. She has been the chief operating officer of the Group since September 14, 2020, and is primarily responsible for leading, overseeing and supervising the operation of the Group. Ms. Lau has been the director of ONM HK, ONM Japan, ONM Shenzhen and ONM Group Ltd. since May 2019, November 2019, November 2019 and April 2021, respectively.

Ms. Lau has more than 22 years of legal, business operation and management experience. Ms. Lau was trained and admitted as a solicitor in Hong Kong in 1999, and was subsequently admitted to practice law in England and Wales and the state of New York in 2000 and 2001, respectively. She worked as an attorney in Paul, Weiss, Rifkind, Wharton & Garrison from 2000 to 2006 and joined Morgan Stanley in February 2006, and left as managing director in April 2015. She joined the Group as the general counsel on April 3, 2018, and has been the senior vice president since April 3, 2018.

Ms. Lau obtained her bachelor of law degree from The University of Hong Kong in 1996 and obtained her postgraduate certificate in laws from the same university in 1997. Ms. Lau also obtained her master's degree in international economic law from the University of Warwick in the United Kingdom in January 2001. Ms. Lau is the spouse of Mr. David CHIEN, the chairman, executive Director and chief executive officer of our Group.

Wing Shing CHEN (陳泳成), aged 41, has been the Director of our Company since July 22, 2021 and was redesignated as an executive Director on September 29, 2021. Mr. Chen has been the company secretary of our Company since September 29, 2021, and the chief financial officer of our Group since January 8, 2018. Mr. Chen also holds the following positions in the subsidiaries of our Group:

Name of the subsidiary	Position	Period
ONM Group Ltd.	Director	April 2021 to present
ONM HK	Director	January 2018 to present
ONM Malaysia	Director	January 2018 to present
ONM Singapore	Director	January 2018 to present
ONM BV	Director	November 2018 to present
OIBV	Director	November 2018 to present
ON AG	Director	September 2020 to present
ONM Shenzhen	Director	March 2018 to present
	Supervisor	November 2017 to March 2018

Mr. Chen has around 18 years of experience in auditing, accounting and corporate finance. He joined PricewaterhouseCoopers in December 2003 in the assurance practice and left as senior manager in February 2017. Before joining our Group, Mr. Chen worked in corporate finance in property development and investment sector in the PRC. Mr. Chen joined our Group in April 2017 as the financial controller, and was later promoted as the chief financial officer of our Group in January 2018.

Mr. Chen obtained his bachelor's degree in business administration, concentrating in financial engineering from The Chinese University of Hong Kong with first class honors in December 2003. He is a certified public accountant in Hong Kong, the State of Washington and the State of Delaware of the United States. He is also a charter holder of the Chartered Financial Analyst Institute.

Ching Chung John CHOW (周靜忠), aged 64, has been the Director of our Company since July 22, 2021 and was redesignated as an executive Director on September 29, 2021. Mr. Chow is currently the head of business development of our Group, and is primarily responsible for overseeing overall business development activities of our Group.

Mr. Chow has around 37 years of experience in interventional cardiology. He worked in Cordis-Neich Limited in May 1984 and was promoted as the general manager in January 1991. Prior to joining our Group, he was appointed as the Asia Pacific regional marketing director of the Cordis franchise in Johnson & Johnson in June 1999. After his employment at Johnson & Johnson, Mr. Chow joined the Group in August 2000 and served as the head of sales and marketing for the Asia Pacific region from 2010 to 2015. Mr. Chow was appointed as the director of business development of the Group on May 17, 2006 and was appointed as the head of business development on September 29, 2021.

Mr. Chow obtained his bachelor of arts degree from York University in Canada in June 1980.

Mr. Chow was a director of the following group companies, which had been dissolved at the Latest Practicable Date:

Name of subsidiary	Place of incorporation	Date of dissolution	Means of dissolution	Reasons of dissolution
OrbusNeich Medical Technology Development (Shenzhen) Company Limited (業聚醫療技術開發(深圳)有限公司)	PRC	July 31, 2019	Deregistration	Cessation of business
OrbusNeich Medical Trading Pte. Limited	Singapore	March 12, 2019	Strike-off	Cessation of business

Mr. Chow confirmed that (i) the above companies were solvent immediately prior to their dissolutions; (ii) there was no wrongful act on his part leading to dissolutions of the above companies and was not aware of any actual or potential claim that had been or would be made against him as a result of dissolutions; and (iii) no misconduct or misfeasance had been involved in the dissolution of the above companies.

Non-executive Director

Yi ZHOU (周伊), aged 41, has been the Director of our Company since September 28, 2021. Dr. Zhou was redesignated as a non-executive Director on September 29, 2021. Dr. Zhou is primarily responsible for providing advice on the business development of the Group. Dr. Zhou has been a director of ONM Group Ltd. from July 2021 to September 28, 2021.

Dr. Zhou has around 15 years of research and working experience in the chemistry, pharmaceutical and biotechnology industries. He was an analyst in pharmaceutical industry at Shenzhen Capital Group Co., Ltd. from May 2012 to September 2017. Since October 2017, Dr. Zhou has served as the head of department of the health industry fund in Shenzhen Capital Group Co., Ltd. Dr. Zhou has been a non-executive director of Akeso, Inc., a company listed on the Main Board of the Stock Exchange (stock code: 9926), since November 2019, and a director of Shenzhen YHLO Biotech Co., Ltd. (深圳市亞輝龍生物科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688575), since December 2016.

Dr. Zhou obtained his bachelor's degree in chemistry from Hengyang Normal University in Hunan, the PRC in June 2003, his master's degree in organic chemistry from Hunan Normal University in Hunan, the PRC in July 2007, and his Ph.D. degree in medicinal chemistry from Peking University in the PRC in June 2011.

Independent non-executive Directors

Yip Keung CHAN (陳業強), aged 39, was appointed as an independent non-executive Director on September 29, 2021 and is primarily responsible for supervising and providing independent judgment to our Board.

Mr. Chan has around 17 years of experience in auditing, accounting and corporate finance. He started working in PricewaterhouseCoopers in September 2005 and was promoted as manager in October 2010. Mr. Chan was the finance manager of Mapletree Hong Kong Management Limited under Temasek of Singapore from November 2011 to April 2015, specialized in real estate investment trusts sector. He was the chief financial officer of the Pine Care Group Limited, a listed company on the Stock Exchange (stock code: 1989), from April 2015 to October 2020 and is currently the chief executive officer and executive director of the aforementioned group.

Mr. Chan obtained his bachelor of business administration degree from the Chinese University of Hong Kong in 2005 and masters' degree in corporate governance from Hong Kong Polytechnic University in 2017. He is a certified public accountant in Hong Kong, a fellow of the Hong Kong Institute of Certified Public Accountant, and an associate member of the Hong Kong Institute of Chartered Secretaries and the Chartered Governance Institute.

Lai Fan Gloria TAM (譚麗芬), aged 65, was appointed as an independent non-executive Director on September 29, 2021 and is primarily responsible for supervising and providing independent judgment to our Board.

Dr. Tam has around 38 years of experience in healthcare industry. She started working as a medical and health officer in the then Medical and Health Department, Hong Kong Government in January 1984 and was promoted as deputy director of health in July 2008. She was also the Controller of Centre for Food Safety in Hong Kong from June 2012 to June 2017. She is the founder of 3 Srs Company (仨仁一人有限公司), a public health consultancy cum investment firm, since June 2020. Dr. Tam served as an independent non-executive director of Zhaoke Ophthalmology Limited, a company listed on the Main Board of the Stock Exchange (stock code: 6622), from April 2021 to April 2022. Dr. Tam has been an independent non-executive director of Arta TechFin Corporation Limited (formerly known as Freeman FinTech Corporation Limited), a company listed on the Main Board of the Stock Exchange (stock code: 279), since October 2021.

Dr. Tam obtained her bachelor of medicine and bachelor of surgery from The University of Hong Kong in 1983 and master degree of medicine from the National University of Singapore in May 1993. She was elected as a Fellow of the Faculty of Public Health of the Royal Colleges of Physicians, United Kingdom in February 2007.

Ka Keung LAU (樓家強), *BBS, MH, JP*, aged 47, was appointed as an independent non-executive Director on September 29, 2021 and is primarily responsible for supervising and providing independent judgment to our Board.

Mr. Lau has around 24 years of experience in business management. Mr. Lau held several positions in the Nameson Group from August 1999 to March 2013, including information technology manager, vice president, and executive director. From August 2015 to April 2018, Mr. Lau served as a non-executive director in Nameson. Mr. Lau has served as an executive director and chief executive officer of Million Cities Holdings Limited (萬城控股有限公司) ("**Million Cities**"), a company listed on the Main Board of the Stock Exchange (stock code: 2892) since 2016, and has assumed various directorships in subsidiaries of Million Cities.

Mr. Lau received his bachelor's degree from Manchester Metropolitan University, the United Kingdom in July 1997 and obtained his master's degree in business administration from University of Leicester, the United Kingdom in July 2008. Mr. Lau has served as national committee member of the 13th Chinese People Political Consultative Conference in the PRC (中國人民政治協商會議第十三屆全國委員會), executive committee member of the 14th Tianjin Committee of Chinese People' Political Consultative Conference (中國人民政治協商會議天津市第十四屆常務委員會) and Vice Chairman of Tianjin Federation of Industry and Commerce (天津市工商業聯合會). Mr. Lau is also the chairman of the 28th Hong Kong United Youth Association (香港青年聯會).

General

Our Directors have confirmed that:

(1) save as disclosed in the section headed "Statutory and General Information – C. Further Information about Directors and Substantial Shareholders – 2. Particulars of Directors' Service Contracts and Letters of Appointment" in Appendix IV to this document, none of our Directors has any existing or proposed service contract with our Company or any of its subsidiaries other than contracts expiring or determinable by the relevant member of our Group within one year without payment of compensation (other than statutory compensation);

(2) save as disclosed in the section headed "Statutory and General Information – C. Further Information about Directors and Substantial Shareholders – 1. Disclosure of Interests" in Appendix IV to this document and above, each of our Directors has no interests in the Shares within the meaning of Part XV of the SFO;

(3) save as disclosed above, each of our Directors has not been a director of any other publicly listed company during the three years prior to the Latest Practicable Date and as at the Latest Practicable Date;

(4) save as disclosed herein, other than being a Director of our Company, none of our Directors has any relationship with any other Directors, senior management of our Company or substantial shareholders of our Company or Controlling Shareholders; and

(5) none of our Directors completed their respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Except as disclosed in this document, to the best of the knowledge, information and belief of our Directors after having made all reasonable enquiries:

(1) there is no other matter with respect to the appointment of our Directors that need to be brought to the attention to the Shareholders as at the Latest Practicable Date; and

(2) there is no other information relating to our Directors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as at the Latest Practicable Date.

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management and operation of our business. The table below sets out certain information in respect of the senior management of the Group.

Name	Position	Age	Date of appointment as Senior Management of the Group	Date of joining the Group	Role and responsibility	Relationship with other Directors and senior management
David CHIEN (錢永勛)	Chief executive officer	57	November 16, 2016	February 16, 2000	Overall strategic planning and policy execution of the Group	Spouse of Kwai Ching Denise LAU
Kwai Ching Denise LAU (劉桂禎)	Chief operating officer	48	September 14, 2020	April 3, 2018	Leading, overseeing and supervising the operation of the Group	Spouse of David CHIEN
Wing Shing CHEN (陳泳成)	Chief financial officer	41	January 8, 2018	April 24, 2017	Overseeing financial and accounting operations, human resources, IT and internal controls, and provides financial and business advice to the Board and senior management of the Group	N/A

Name	Position	Age	Date of appointment as Senior Management of the Group	Date of joining the Group	Role and responsibility	Relationship with other Directors and senior management
Ching Chung John CHOW (周靜忠)	Executive Director and head of business development	64	May 17, 2006	August 1, 2000	Overseeing overall business development activities of our Group	N/A
Alain Djamel KHAIR	Chief commercial officer	52	January 1, 2020	January 21, 2008	Overseeing global commercial activities, steering the directions of market penetration of the Group's products, and managing the development and the implementation of all commercial strategies of the Group's product portfolio	N/A
Robert John COTTONE JR	Chief technical officer	59	May 13, 2019	November 2005	Overseeing the overall design, technology and product research and development and the global intellectual property strategies and protection of the Group	N/A

David CHIEN (錢永勛), see "– Board of Directors – Executive Directors" for details.

Kwai Ching Denise LAU (劉桂禎), see "– Board of Directors – Executive Directors" for details.

Wing Shing CHEN (陳泳成), see "– Board of Directors – Executive Directors" for details.

Ching Chung John CHOW (周靜忠), see "– Board of Directors – Executive Directors" for details.

Alain Djamel KHAIR, aged 52, has been the chief commercial officer of our Group since January 1, 2020. He is responsible for overseeing global commercial activities, steering the directions of market penetration of the Group's products, and managing the development and the implementation of all commercial strategies of the Group's product portfolio. He also directs and oversees our Group's growth matrix, distribution channels and the deployment of the company sales and marketing resources. Mr. Khair also holds directorship in OIBV, ON GmbH, OrbusNeich Medical, Sociedad Limitada and ON AG since May 2020, December 2017, April 2017 and September 2020, respectively.

Mr. Khair has around 19 years of sales and marketing experience in the medical device industry. He held several management roles including products advisor, territory sales manager, clinical specialist for Eastern Europe and Middle East at Abbott Laboratories Limited from 2003 to 2008. He joined the Group as regional product manager in January 2008 and was the vice president in sales of EMEA from May 1, 2017 to December 31, 2019.

Mr. Khair received his registered nurse qualification from the Nursing & Midwifery Council in the United Kingdom in May 2002 and obtained his master of business administration degree in marketing from University of Leicester in the United Kingdom in 2013.

Robert John COTTONE JR, aged 59, has been the chief technical officer of our Group since May 13, 2019. He is responsible for overseeing the overall design, technology and product research and development and the global intellectual property strategies and protection of the Group.

Mr. Cottone has more than 32 years of experience in the medical device field. Before joining our group, Mr. Cottone worked at the Cordis Corporation from 1989 to 1996. In 1997, Mr. Cottone co-founded Orbus Medical Technologies Inc., which was a longstanding partner of our Group and was subsequently acquired by ONM BVI (under its former name, Neich Medical Limited) in 2005, and continued to work in our Group since our acquisition of Orbus Medical Technologies Inc.

Mr. Cottone obtained his bachelor of science degree from Florida International University in the United States in 1988.

General

Save as disclosed above, each of our senior management members has confirmed that:

(1) he/she does not hold and has not held any other positions in our Company and any other members of our Group as at the Latest Practicable Date;

(2) save as being a member of the Company's senior management, he/she does not have any other relationship with any Directors, substantial shareholders of our Company, our Controlling Shareholders or other members of senior management of our Group as at the Latest Practicable Date;

(3) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to the Latest Practicable Date and as at the Latest Practicable Date; and

(4) save as disclosed above, he/she has not completed their respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

COMPANY SECRETARY

Wing Shing CHEN (陳泳成) was appointed as our company secretary on September 29, 2021, see "– Board of Directors – Executive Directors" for details.

COMPLIANCE ADVISOR

We have appointed Rainbow Capital (HK) Limited as our compliance advisor pursuant to Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance advisor will advise us on the following circumstances:

- before the publication of any announcements, circulars or financial reports required by regulatory authorities or applicable laws;
- where a transaction, which might be a notifiable or connected transaction under Chapters 14 and 14A of the Listing Rules is contemplated, including share issues and share repurchases;
- where we propose to use the [**REDACTED**] of the [**REDACTED**] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of us regarding unusual price movement and trading volume or other issues under Rule 13.10 of the Listing Rules.

The terms of the appointment shall commence on the [**REDACTED**] and end on the date which we distribute our annual report of our financial results for the first full financial year commencing after the [**REDACTED**].

BOARD COMMITTEES

We have established the following committees on our Board: an audit committee, a remuneration committee and a nomination committee. The committees operate in accordance with the terms of reference established by our Board.

Audit Committee

The Company has established an audit committee (effective from the [**REDACTED**]) with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of the Corporate Governance Code as set out in Appendix 14 to the Listing Rules (the "**Corporate Governance Code**"). The audit committee consists of Mr. Yip Keung CHAN, Dr. Lai Fan Gloria TAM and Mr. Ka Keung LAU, with Mr. Yip Keung CHAN serving as the chairman. Mr. Chan holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the audit committee are to assist our Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group, overseeing the audit process, and performing other duties and responsibilities as assigned by our Board.

Remuneration Committee

The Company has established a remuneration committee (effective from the [**REDACTED**]) with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of the Corporate Governance Code. The remuneration committee consists of Mr. Ka Keung LAU, Mr. David CHIEN and Mr. Yip Keung CHAN, with Mr. Ka Keung LAU serving as the chairman. The primary duties of the remuneration committee include, but are not limited to, the following: (i) making recommendations to our Board on our policy and structure for all remuneration of Directors and senior management and on the establishment of a formal and transparent procedure for developing policy on such remuneration; (ii) determining the specific remuneration packages of all Directors and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Board from time to time.

Nomination Committee

The Company has established a nomination committee (effective from the [**REDACTED**]) with written terms of reference in compliance with paragraph B.3 of the Corporate Governance Code. The nomination committee consists of Mr. David CHIEN, Dr. Lai Fan Gloria TAM and Mr. Ka Keung LAU, with Mr. David CHIEN serving as the chairman. The primary functions of the nomination committee include, without limitation, reviewing the structure, size and composition of our Board, assessing the independence of independent non-executive Directors and making recommendations to our Board on matters relating to the appointment of Directors.

CORPORATE GOVERNANCE

Code Provision C.2.1 of the Corporate Governance Code

Mr. David CHIEN is the chief executive officer of our Company. With extensive experience in the medical devices industry and having served in our Company since its establishment, Mr. David CHIEN is in charge of overall strategic planning and policy execution of our Group. Our Board considers that vesting the roles of chairman and chief executive officer in the same person is beneficial to the management of our Group. The balance of power and authority is ensured by the operation of our Board and our senior management, which comprises experienced and diverse individuals. Our Board currently comprises four executive Directors, one non-executive Director and three independent non-executive Directors, and therefore has a strong independence element in its composition.

Save as disclosed above, our Company intends to comply with all code provisions under the Corporate Governance Code after the [**REDACTED**].

Board Diversity

We have adopted a board diversity policy (the "**Board Diversity Policy**") to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Pursuant to the Board Diversity Policy, in reviewing and assessing suitable candidates to serve as a Director of the Company, the nomination committee will consider a range of diversity perspectives with reference to the Company's business model and specific needs, including but not limited to gender, age, language, cultural and educational background, professional qualifications, skills, knowledge, industry and regional experience and/or length of service.

Our Board consists of eight Directors, six of whom are male and two of whom are female. Our Directors have a balanced mix of knowledge and skills, including but not limited to overall business management, finance and accounting, research and development, and investment. They obtained degrees in various majors including business administration, law and corporate governance, chemistry and medicine. Furthermore, our Board has a relatively wide range of ages, ranging from 39 years old to 65 years old. The Board of Directors is of the view that our Board satisfies the Board Diversity Policy.

Given that two out of eight of our Directors are female upon [**REDACTED**], we will continue to take steps to promote gender diversity at the Board of our Company. After the [**REDACTED**], we will strive to achieve gender balance of the Board through certain measures to be implemented by our nomination committee in accordance with our Board Diversity Policy. In particular, we will actively identify female individuals suitably qualified to become our Board members and we aim to achieve a target of approximately 30% female representation in our Board. To further ensure gender diversity of our Board in the long run, our Group will also identify and select several female individuals with a diverse range of skills, experience and knowledge in different fields from time to time, and maintain a list of such female individuals who possess qualities to become our Board members, which will be reviewed by our nomination committee periodically in order to develop a pipeline of potential successors to our Board to promote gender diversity of our Board.

Our nomination committee is responsible for reviewing the diversity of our Board. After [**REDACTED**], our nomination committee will continue to monitor and evaluate the implementation of the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives on an annual basis. We will also continue to take steps to promote gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels.

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules.

SHARE INCENTIVE SCHEMES

We have adopted the Pre-[**REDACTED**] Share Option Scheme and the Post-[**REDACTED**] Share Option Scheme (collectively the "**Share Incentive Schemes**"). The principal terms of the Share Incentive Schemes are summarized in the paragraph headed "Statutory and General Information – D. Share Incentive Schemes" in Appendix IV to this document.

COMPENSATION OF DIRECTORS

Our Directors receive compensation in the form of fees, salaries, bonuses, other allowances and benefits in kind, including the Company's contribution to the pension scheme on their behalf. We determine the salaries of our Directors based on each Director's responsibilities, qualification, position and seniority.

The aggregate amount of remuneration which was paid to our Directors for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 were US$1.2 million, US$1.2 million, US$1.4 million and US$1.0 million, respectively.

It is estimated that remuneration and benefits in kind (excluding any possible payment of discretionary bonus) equivalent to approximately US$1.9 million (equivalent to HK$15.1 million) in aggregate will be paid and granted to our Directors by us in respect of the year ending December 31, 2022 under arrangements in force at the date of this document.

The aggregate amount of remuneration which were paid by the Group to our five highest paid individuals (including both employees and Directors) for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 were US$2.5 million, US$1.9 million, US$2.3 million and US$1.5 million, respectively.

During the Track Record Period, (i) no remuneration was paid to our Directors or the five highest paid individuals as an inducement to join, or upon joining our Group, (ii) no compensation was paid to, or receivable by, our Directors or past Directors or the five highest paid individuals for the loss of office as director of any member of our Group or any other office in connection with the management of the affairs of any member of our Group, and (iii) none of our Directors waived any emoluments.

Our Directors' remuneration is determined with reference to the relevant Director's experience and qualifications, level of responsibility, performance and the time devoted to our business, and the prevailing market conditions.

For additional information on Directors' remuneration during the Track Record Period as well as information on the highest paid individuals, please see Note 9 of the Accountant's Report set out in Appendix I to this document.

Save as disclosed herein, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries, there was no other matter with respect to the appointment of our Directors that needs to be brought to the attention of the Shareholders and there was no information relating to our Directors that is required to be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

FUTURE PLANS

For a detailed description of our future plans, see "Business – Our Strategies."

[REDACTED]

We estimate that we will receive net [**REDACTED**] of approximately HK$[**REDACTED**] million after deducting the [**REDACTED**] fees and expenses payable by us in the [**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] per [**REDACTED**], being the mid-point of the indicative [**REDACTED**] of HK$[**REDACTED**] to HK$[**REDACTED**] per [**REDACTED**] in this document. We intend to use the net [**REDACTED**] we will receive from the [**REDACTED**] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- [**REDACTED**]%, or approximately HK$[**REDACTED**] allocated to the development and commercialization of our pipeline products as follows, and the allocation and expected timeline for using such [**REDACTED**] will depend on the timing, progress and size of our respective R&D projects, as well as our projected R&D and clinical trial related expenses taking into account the continued expansion of our product portfolio:

  (i) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], will be used for the ongoing R&D activities, clinical trial and product registration of drug eluting balloon products. We expect to commence animal studies in respect of our drug eluting balloon products in 2022, conduct clinical trials and product registration for such products in 2023 and 2024, and commercialize them in the PRC, Japan, Europe and the U.S. markets in 2025 and 2026, respectively;

  (ii) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], will be used for the product registration and commercialization of new generation of COMBO dual therapy stent products primarily in the PRC, Japan and Europe markets. We plan to commence animal studies in respect of the new generation of COMBO dual therapy stent products in 2022 and 2023, conduct clinical trial and product registration for such products in 2024 and 2025, and commercialize them in 2026 in the PRC, Japan, Europe and Asia Pacific markets, respectively;

  (iii) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], will be used for the ongoing R&D activities, clinical trial and product registration of our new coronary and peripheral balloon and catheter-based products. We plan to conduct clinical trials and product registration in respect of such products in the next six years for various coronary and peripheral balloon and catheter-based products and commercialize such products primarily in the PRC, Japan, the U.S., Europe and Asia Pacific markets;

(iv) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], will be used for the ongoing R&D activities for new generation of neuro interventional products. We plan to conduct animal studies and prototyping in respect of such products in 2022 and 2023, respectively, with a primary focus on the PRC market; and

(v) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], to support the expansion of our R&D team in our Shenzhen facility. We plan to gradually expand the team to approximately 90 employees by the end of 2026;

- [**REDACTED**]%, or approximately HK$[**REDACTED**] allocated to the expansion of our production capacities. The amount required for the planned expansion is estimated based on the preliminary design of our new manufacturing site and our internal estimates, which take into consideration the size of our Netherlands and PRC production sites, materials to be used and estimated construction time, as well as types and quantities of equipment to be purchased. We intend to complete the acquisition of a new land parcel with a land area of approximately 20,000 sq.m by June 2023 and it will require approximately 3.5 years to construct, renovate and obtain the required licenses to commence operations in early 2027.

  Our expected production capacity expansion are based on the following factors:

  - First, both the coronary and peripheral interventional instrument markets are expected to continue growing rapidly across the globe. 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, according to the Industry Consultant. For more details, please refer to the paragraphs headed "Industry Overview – Overview of Percutaneous Coronary Intervention Procedural Instrument Market – PCI market overview" and "Industry Overview – Overview of Percutaneous Transluminal Angioplasty Procedural Instrument Market – Market overview" in this document.

  - Second, our Group has been growing rapidly. Our revenue increased by 31.6% from US$88.5 million in 2020 to US$116.5 million in 2021, and increased by 20.2% from US$57.3 million in the first six months of 2021 to US$68.9 million in the first six months of 2022.

- Third, we have been actively developing and expanding our pipeline products. For example, we intend to expand our product offerings to cover structural heart disease intervention products and neuro intervention products. For more details, please refer to the paragraphs headed "Business – Our Strategies – Further enrich product offerings both vertically and horizontally" and "Business – Our Products and Product Pipeline" in this document.

- Fourth, we expect to extend our sales network and hospital coverage and deepen our market penetration. For example, we are looking to have immediate or better access to new geographic markets such as Latin America or certain provinces in the PRC in which we have relatively less presence.

We project that we will maintain a strong growth due to growing market demand, primarily based on (i) the overall increase in the size of the PCI/PTA interventional instrument market as set forth in the CIC Report, (ii) the estimated increase in sales volume of our existing products in connection with our expansion into new markets or further penetration in existing markets and (iii) the estimated increase in sales volume in connection with our pipeline products upon their respective approval and commercial launch. We expect the newly increased capacity will be used to manufacture our pipeline products currently under development, such as Sapphire X NC Balloon Catheter, Sapphire X Balloon Catheter and Neuro Balloon Catheter as well as coronary and peripheral products that are sold in China. The expected allocation for using such [**REDACTED**] is as follows:

(i) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**] on acquiring a new land parcel with a land area of approximately 20,000 sq.m. The land premium is estimated with reference to the average price of industrial land of certain second-tier cities in the Pearl River Delta and Yangtze River Delta areas. We are in contact with several local governments in the Pearl River Delta and Yangtze River Delta areas to explore the opportunities to acquire the land parcel but has yet to confirm the location. To the best knowledge of our Directors, as of the date of this document, we are not aware of any material legal or regulatory obstacles to acquire the land and/or to obtain the relevant licenses/permits to commence construction of the production facilities;

(ii) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**] on constructing and renovating new facilities to be built on the above-mentioned newly acquired land with a gross floor area of 50,000 sq.m., applying an estimated plot ratio of 2.5. A floor area of 40,000 sq.m. is expected to be constructed for manufacturing and R&D purposes, and a floor area of 10,000 sq.m. is expected to be constructed for staff accommodation and recreational purposes;

(iii) [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**] on purchasing new machinery and equipment for the new manufacturing site. The new machinery and equipment mainly include but not limited to balloon forming machine, balloon pleating and folding machine, extrusion machine, welding and soldering systems, coating machine, swaging machine, heat treatment systems, body fusing machine, crimping machine which can be generally used across different coronary, peripheral and neuro balloon products. Upon completion of our planned expansion, it is expected that our production capacity for balloons will increase from 1,352,000 units per year to approximately 3,700,000 units per year by the end of 2027, production capacity for stents will increase from 56,400 units per year to approximately 85,000 units per year by the end of 2027. For details, see "Business – Our Strategies – Expand production capacity and continuously improve operational efficiencies";

- [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], to fund potential strategic acquisitions, entering into strategic partnerships, and other business development, with an aim to expand our product portfolio, strengthen our R&D capabilities, broaden our hospital coverage and increase our market penetration. We intend to identify opportunities for acquisition of or entering into strategic partnerships with companies, typically medical device manufacturers and/or distributors, that:

  (i) offer innovative and potentially breakthrough products and technology complementary to our current vascular disease treatment product lines, technology offerings and sales network, which may potentially include but not limited to products and/or technology relating to electrophysiology products, diagnostic or mapping products, electrode or laser ablation products, lithotripsy technology, light signal processing and vascular imaging products or technology and technology that will enhance our development of active medical device products used for vascular disease treatment;

  (ii) has reasonable length of operations which is not less than three years, a hospital coverage rate of over 25% in our target markets, sound track record with no material legal or regulatory proceedings or non-compliance and will enable us to consolidate and expand our market share in key geographic markets such as the U.S. and Europe, or provide us with immediate or better access to new geographic markets such as Latin America or certain provinces in the PRC in which we have relatively less presence; and

  The estimated amount of [**REDACTED**] to be used for potential acquisitions is based on our internal assessment and projection in accordance with the criteria set forth above. As of the Latest Practicable Date, we have not identified any specific acquisition targets, formed any specific acquisition plans or entered into any agreements with potential targets. We will seek potential acquisition targets through

internal market research and/or recommendations from industry consultants and our business partners. In evaluating acquisition targets, we will consider various factors including the level of synergy, the degree of innovation of the underlying technology, time and cost required to integrate the target operation or technology into our Group, the target's current customer base, as well as the potential growth and profitability of the business. As advised by the Industry Consultant, there are more than 1,000 medical device manufacturers and/or distributors that meet the above criteria; and

- [**REDACTED**]% of net [**REDACTED**], or approximately HK$[**REDACTED**], for working capital and other general corporate purposes.

If the [**REDACTED**] is determined at the highest point of the stated range, the net [**REDACTED**] to our Company would be increased by approximately HK$[**REDACTED**]. If the [**REDACTED**] is determined at the lowest point of the stated range, the net [**REDACTED**] to our Company would be decreased by approximately HK$[**REDACTED**]. The above allocation of the net [**REDACTED**] will be adjusted on a pro rata basis in the event that the [**REDACTED**] is fixed at a higher or lower level compared to the mid-point of the indicative [**REDACTED**] stated in this document.

To the extent that our net [**REDACTED**] are not sufficient to fund the purposes set out above, we intend to fund the balance through a variety of means, including cash generated from operations and equity financing, bank loans and other borrowings and other funds raised from capital markets from time to time, when necessary. For instance, additional funds available to fund the purposes set out above include (i) existing bank deposit (including cash and cash equivalents, bank deposit and Commodity Linked Fixed Rate Note) amounting to US$185.6 million as of July 31, 2022 and (ii) unused banking facility amounted to US$45.0 million as of July 31, 2022. For more information about our capital resources, please refer to the paragraph headed "Financial Information – Liquidity and Capital Resources – Overview" in this document.

To the extent that the net [**REDACTED**] of the [**REDACTED**] are not immediately required for the above purposes or if we are unable to put into effect any part of our development plan as intended, we will only hold such funds in short-term deposits at licensed commercial banks and/or other authorized financial institutions (as defined under the [Securities and Futures Ordinance]) so long as it is deemed to be in the best interests of the Company. In such event, we will comply with the appropriate disclosure requirements under the Listing Rules. We will issue an appropriate announcement if there is any material change to the above proposed [**REDACTED**].

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[REDACTED]

The following is the text of a report set out on pages I-1 to [I-3], received from the Company's reporting accountant, [PricewaterhouseCoopers], Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document. It is prepared and addressed to the directors of the Company and to the Joint Sponsors pursuant to the requirements of HKSIR 200 Accountants' Reports on Historical Financial Information in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants.

[Letterhead of PricewaterhouseCoopers] ***[Draft]***

ACCOUNTANT'S REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF ORBUSNEICH MEDICAL GROUP HOLDINGS LIMITED AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED AND CCB INTERNATIONAL CAPITAL LIMITED

Introduction

We report on the historical financial information of OrbusNeich Medical Group Holdings Limited (the "Company") and its subsidiaries (together, the "Group") set out on pages [I-4] to [I-103], which comprises the consolidated balance sheets as at December 31, 2019, 2020 and 2021 and June 30, 2022, the Company's balance sheets as at December 31, 2021 and June 30, 2022, and the consolidated statements of profit or loss, the consolidated statements of comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows for each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2022 (the "Track Record Period") and a summary of significant accounting policies and other explanatory information (together, the "Historical Financial Information"). The Historical Financial Information set out on pages [I-4] to [I-103] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [**REDACTED**] (the "Document") in connection with the [**REDACTED**] of shares of the Company on the [**REDACTED**] of [**REDACTED**].

Directors' responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountant's responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200, *Accountants' Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountant's judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountant considers internal control relevant to the entity's preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountant's report, a true and fair view of the financial position of the Company as at December 31, 2021 and June 30, 2022 and the consolidated financial position of the Group as at December 31, 2019, 2020 and 2021 and June 30, 2022 and of its consolidated financial performance and its consolidated cash flows for the Track Record Period in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information.

Review of stub period comparative financial information

We have reviewed the stub period comparative financial information of the Group which comprises the consolidated statement of profit or loss, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the six months ended June 30, 2021 and other explanatory information (the "Stub Period Comparative Financial Information"). The directors of the Company are responsible for the presentation and preparation of the Stub Period Comparative Financial Information in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that

causes us to believe that the Stub Period Comparative Financial Information, for the purposes of the accountant's report, is not prepared, in all material respects, in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to Note 12 to the Historical Financial Information which states that no dividends have been paid by OrbusNeich Medical Group Holdings Limited in respect of the Track Record Period.

No statutory financial statements for the Company

No statutory financial statements have been prepared for the Company since its date of incorporation.

[PricewaterhouseCoopers]
Certified Public Accountants
Hong Kong, [Date]

I HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountant's report.

The financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, were audited by PricewaterhouseCoopers in accordance with Hong Kong Standards on Auditing issued by the HKICPA ("Underlying Financial Statements").

The Historical Financial Information is presented in United States Dollars ("US$") and all values are rounded to the nearest thousand (US$'000) except when otherwise indicated.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Note	Year ended December 31, 2019 US$'000	2020 US$'000	2021 US$'000	Six months ended June 30, 2021 US$'000 (Unaudited)	2022 US$'000
Revenue	5	96,342	88,472	116,462	57,339	68,851
Cost of sales	8	(30,895)	(30,452)	(35,290)	(16,790)	(21,137)
Gross profit		65,447	58,020	81,172	40,549	47,714
Other income – net	6	1,162	2,406	1,385	674	393
Other gains/(losses) – net	7	338	904	(1,020)	(513)	(2,854)
Selling and distribution expenses	8	(32,251)	(26,694)	(30,100)	(14,654)	(16,475)
General and administrative expenses	8	(15,707)	(14,295)	(19,958)	(8,187)	(10,738)
Research and development expenses	8	(9,593)	(12,578)	(12,148)	(5,827)	(6,720)
Net (impairment losses)/reversal of impairment losses on financial assets	24	(1,407)	931	109	158	(402)
Operating profit		7,989	8,694	19,440	12,200	10,918
Finance income	10	21	12	12	6	249
Finance costs	10	(503)	(1,405)	(5,607)	(1,048)	(1,407)
Finance costs – net		(482)	(1,393)	(5,595)	(1,042)	(1,158)
Fair value losses of convertible redeemable preferred shares	29	–	–	(14,397)	(6,030)	–
Loss on derecognition of financial liability in relation to convertible redeemable preferred shares	29	–	–	(559)	–	–
Share of loss of investment in a joint venture	21	–	(46)	(207)	(149)	(71)
Profit/(loss) before income tax		7,507	7,255	(1,318)	4,979	9,689
Income tax expense	11	(549)	(184)	(3,126)	(1,658)	(1,652)
Profit/(loss) for the year/period attributable to owners of the Company		6,958	7,071	(4,444)	3,321	8,037
Earnings/(loss) per share	13					
Basic		0.24	0.25	(0.15)	0.12	0.28
Diluted		0.24	0.25	(0.15)	[0.12]	0.24

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

		Year ended December 31,			Six months ended June 30,	
		2019	2020	2021	2021	2022
	Note	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
					(Unaudited)	
Profit/(loss) for the year/period		6,958	7,071	(4,444)	3,321	8,037
Other comprehensive (loss)/income:						
Item that will not be subsequently reclassified to profit or loss						
Remeasurements of post-employment benefit obligations	*30*	40	(134)	(340)	(38)	246
Items that may be subsequently reclassified to profit or loss						
Currency translation differences		(256)	1,246	(3,394)	(2,056)	(4,084)
Realization of accumulated exchange difference upon dissolution of subsidiaries		–	17	(8)	(8)	–
Other comprehensive (loss)/income for the year/period, net of tax		(216)	1,129	(3,742)	(2,102)	(3,838)
Total comprehensive income/(loss) for the year/period		6,742	8,200	(8,186)	1,219	4,199

CONSOLIDATED BALANCE SHEETS

	Note	As at December 31, 2019	2020	2021	As at June 30, 2022
		US$'000	*US$'000*	*US$'000*	*US$'000*
ASSETS					
Non-current assets					
Property, plant and equipment	*14*	11,994	10,485	8,874	8,219
Right-of-use assets	*15*	3,414	2,066	4,567	4,583
Deferred income tax assets	*17*	2,967	3,539	2,859	2,123
Financial assets at fair value through profit or loss	*18*	1,829	2,048	2,041	20,527
Intangible assets	*19*	335	3,966	4,267	4,138
Goodwill	*20*	–	1,749	1,749	1,749
Interest in a joint venture	*21*	–	5,051	7,888	7,817
Deposits, prepayments and other receivables	*22*	976	275	927	1,256
Total non-current assets		21,515	29,179	33,172	50,412
Current assets					
Inventories	*23*	26,036	30,038	29,570	27,900
Trade receivables	*24*	32,609	26,316	26,804	29,700
Deposits, prepayments and other receivables	*22*	1,332	2,077	2,796	3,925
Amounts due from joint ventures	*39*	–	90	11	22
Amounts due from related companies	*39*	177	326	–	–
Tax recoverable		392	508	288	202
Pledged bank deposit	*25*	–	–	–	15,000
Short-term bank deposit	*25*	–	–	–	20,000
Cash and cash equivalents	*25*	13,631	15,112	175,886	131,619
Total current assets		74,177	74,467	235,355	228,368
Total assets		95,692	103,646	268,527	278,780
EQUITY					
Capital and reserves attributable to owners of the Company					
Share capital	*26*	–	–	288	288
Other reserves	*28*	(7,163)	172,797	325,509	386,840
Accumulated losses	*28*	(145,128)	(137,901)	(142,685)	(134,402)
Total (deficit)/equity		(152,291)	34,896	183,112	252,726

	Note	As at December 31, 2019	2020	2021	As at June 30, 2022
		US$'000	*US$'000*	*US$'000*	*US$'000*
LIABILITIES					
Non-current liabilities					
Lease liabilities	*15*	1,285	557	2,499	2,657
Convertible redeemable preferred shares	*29*	–	–	63,711	–
Retirement benefit obligations	*30*	2,227	2,541	2,755	2,208
Loans from related companies	*31,39*	–	10,186	–	–
Amount due to a related company	*39*	99,790	–	–	–
Total non-current liabilities		103,302	13,284	68,965	4,865
Current liabilities					
Trade payables	*32*	3,506	1,364	2,174	3,875
Accruals and other payables	*33*	13,023	12,761	11,866	14,217
Amount due to a joint venture	*39*	–	–	–	129
Amount due to a related company	*39*	88,193	–	–	–
Current income tax liabilities		27	521	927	1,572
Bank borrowings	*34*	38,462	39,898	–	–
Lease liabilities	*15*	1,470	922	1,483	1,396
Total current liabilities		144,681	55,466	16,450	21,189
Total liabilities		247,983	68,750	85,415	26,054
Total equity and liabilities		95,692	103,646	268,527	278,780

BALANCE SHEET OF THE COMPANY

	Note	As at December 31, 2021 US$'000	As at June 30, 2022 US$'000
ASSETS			
Non-current assets			
Investment in a subsidiary	*16*	30,265	30,633
Financial assets at fair value through profit or loss	*18*	–	18,734
Total non-current assets		30,265	49,367
Current assets			
Prepayments and other receivables	*22*	881	1,293
Amounts due from subsidiaries	*39*	64,544	110,971
Short-term bank deposit	*25*	–	20,000
Cash and cash equivalents	*25*	149,104	60,831
Total current assets		214,529	193,095
Total assets		244,794	242,462
EQUITY			
Capital and reserves attributable to owners of the Company			
Share capital	*26*	288	288
Other reserves	*28*	185,040	250,455
Accumulated losses	*28*	(5,606)	(10,750)
		179,722	239,993
LIABILITIES			
Non-current liability			
Convertible redeemable preferred shares	*29*	63,711	–
Total non-current liability		63,711	–
Current liabilities			
Accruals and other payables	*33*	1,329	2,469
Amount due to a subsidiary	*39*	32	–
Total current liabilities		1,361	2,469
Total liabilities		65,072	2,469
Total equity and liabilities		244,794	242,462

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Share capital	Other reserves	Accumulated losses	Total
	US$'000	*US$'000* (Note 28)	*US$'000* (Note 28)	*US$'000*
At January 1, 2019	–	(6,845)	(152,188)	(159,033)
Profit for the year	–	–	6,958	6,958
Other comprehensive (loss)/income:				
– Remeasurements of post-employment benefit obligations	–	–	40	40
– Currency translation differences	–	(256)	–	(256)
Total other comprehensive (loss)/income, net of tax	–	(256)	40	(216)
Total comprehensive (loss)/income	–	(256)	6,998	6,742
Transaction with owner:				
– Employee share option scheme: lapse of share options	–	(62)	62	–
Total transaction with owner	–	(62)	62	–
At December 31, 2019	–	(7,163)	(145,128)	(152,291)

	Share capital *US$'000*	Other reserves *US$'000* *(Note 28)*	Accumulated losses *US$'000* *(Note 28)*	Total *US$'000*
At January 1, 2020	–	(7,163)	(145,128)	(152,291)
Profit for the year	–	–	7,071	7,071
Other comprehensive income/(loss):				
– Remeasurements of post-employment benefit obligations	–	–	(134)	(134)
– Realization of accumulated exchange difference upon dissolution of a subsidiary	–	17	–	17
– Currency translation differences	–	1,246	–	1,246
Total other comprehensive income/(loss), net of tax	–	1,263	(134)	1,129
Total comprehensive income	–	1,263	6,937	8,200
Transactions with owner:				
– Deemed contribution *(Note 1.2)*	–	187,828	–	187,828
– Deemed distribution to shareholders *(Note 28(a))*	–	(8,841)	–	(8,841)
– Employee share option scheme: lapse of share options	–	(290)	290	–
Total transactions with owner	–	178,697	290	178,987
At December 31, 2020	–	172,797	(137,901)	34,896

	Share capital *US$'000*	Other reserves *US$'000 (Note 28)*	Accumulated losses *US$'000 (Note 28)*	Total *US$'000*
At January 1, 2021	–	172,797	(137,901)	34,896
Loss for the year	–	–	(4,444)	(4,444)
Other comprehensive loss:				
– Remeasurements of post-employment benefit obligations	–	–	(340)	(340)
– Realization of accumulated exchange difference upon dissolution of subsidiaries	–	(8)	–	(8)
– Currency translation differences	–	(3,394)	–	(3,394)
Total other comprehensive loss, net of tax	–	(3,402)	(340)	(3,742)
Total comprehensive loss	–	(3,402)	(4,784)	(8,186)
Transactions with owners:				
– Issuance of share	–*	–	–	–*
– Issuance of shares pursuant to share swap *(Note 26(c))*	288	(288)	–	–
– Reclassification of Series A-2 Preferred Shares upon completion of the Reorganization *(Note 28(b))*	–	167,193	–	167,193
– Changes in value of Series A Preferred Shares upon completion of the Reorganization	–	(12,130)	–	(12,130)
– Employee share option scheme: value of employee services	–	1,339	–	1,339
Total transactions with owners	288	156,114	–	156,402
At December 31, 2021	288	325,509	(142,685)	183,112

* The amount is less than US$1,000.

	Share capital *US$'000*	Other reserves *US$'000* *(Note 28)*	Accumulated losses *US$'000* *(Note 28)*	Total *US$'000*
At January 1, 2022	288	325,509	(142,685)	183,112
Profit for the period	–	–	8,037	8,037
Other comprehensive (loss)/income:				
– Remeasurements of post-employment benefit obligations	–	–	246	246
– Currency translation differences	–	(4,084)	–	(4,084)
Total other comprehensive (loss)/income, net of tax	–	(4,084)	246	(3,838)
Total comprehensive (loss)/income	–	(4,084)	8,283	4,199
Transactions with owners:				
– Reclassification from financial liabilities to equity for Series A Preferred Shares *(Note 28(e))*	–	65,047	–	65,047
– Employee share option scheme: value of employee services	–	368	–	368
Total transactions with owners	–	65,415	–	65,415
At June 30, 2022	288	386,840	(134,402)	252,726

	Share capital *US$'000*	Other reserves *US$'000* *(Note 28)*	Accumulated losses *US$'000* *(Note 28)*	Total *US$'000*
(Unaudited)				
At January 1, 2021	–	172,797	(137,901)	34,896
Profit for the period	–	–	3,321	3,321
Other comprehensive loss:				
– Remeasurements of post-employment benefit obligations	–	–	(38)	(38)
– Realization of accumulated exchange difference upon dissolution of subsidiaries	–	(8)	–	(8)
– Currency translation differences	–	(2,056)	–	(2,056)
Total other comprehensive loss, net of tax	–	(2,064)	(38)	(2,102)
Total comprehensive loss	–	(2,064)	3,283	1,219
Transactions with owners:				
– Employee share option scheme: value of employee services	–	670	–	670
Total transactions with owners	–	670	–	670
At June 30, 2021	–	171,403	(134,618)	36,785

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Note	Year ended December 31, 2019	2020	2021	Six months ended June 30, 2021	2022
		US$'000	*US$'000*	*US$'000*	*US$'000 (Unaudited)*	*US$'000*
Cash flows from operating activities						
Cash generated from operations	*35(a)*	3,949	13,290	22,344	14,829	14,102
Income tax paid		(2,434)	(895)	(2,044)	(740)	(199)
Income tax refunded		75	271	198	198	21
Net cash generated from operating activities		1,590	12,666	20,498	14,287	13,924
Cash flows from investing activities						
Purchase of property, plant and equipment		(2,732)	(943)	(1,247)	(698)	(935)
Proceeds from disposal of property, plant and equipment	*35(b)*	45	113	217	16	99
Purchase of intangible assets		(338)	(2,813)	(894)	(668)	(271)
Capital contribution to a joint venture		–	(5,097)	–	–	–
Advance to a joint venture		–	–	(3,044)	–	–
Increase in short-term bank deposit		–	–	–	–	(20,000)
Increase in pledged bank deposit		–	–	–	–	(15,000)
Purchase of financial assets at fair value through profit or loss		(341)	(390)	(407)	(206)	(20,180)
Proceeds from disposal of financial assets at fair value through profit or loss	*35(c)*	292	157	144	34	11
Payment for acquisition of a subsidiary, net of cash acquired	*38*	–	(2,240)	–	–	–
Disposal of subsidiaries, net of cash disposed		–	(44)	–	–	–
Interest received		21	12	12	6	99
Net cash used in investing activities		(3,053)	(11,245)	(5,219)	(1,516)	(56,177)

		Year ended December 31,			Six months ended June 30,	
		2019	2020	2021	2021	2022
	Note	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
					(Unaudited)	
Cash flows from financing activities						
Interest paid		(501)	(1,335)	(752)	(443)	(70)
Principal elements of lease payments	*35(e)*	(1,497)	(1,363)	(1,297)	(707)	(698)
Proceeds from bank borrowings	*35(e)*	38,462	4,513	3,057	3,057	5,000
Repayment of bank borrowings	*35(e)*	–	(3,411)	(42,955)	(7,077)	(5,000)
Proceeds from loans from related companies	*35(e)*	–	5,128	230	230	–
Repayment to a related company	*35(e)*	(35,259)	(4,005)	(10,416)	(5,022)	–
Net proceeds from issuance of convertible redeemable preferred shares *(Note 29)*	*35(e)*	–	–	198,965	34,681	–
Payment for [REDACTED]		–	–	([REDACTED])	([REDACTED])	([REDACTED])
Net cash generated from/(used in) financing activities		1,205	(473)	146,308	24,650	(852)
Net (decrease)/increase in cash and cash equivalents		(258)	948	161,587	37,421	(43,105)
Cash and cash equivalents at beginning of year/period		13,812	13,631	15,112	15,112	175,886
Effects of exchange rate changes on cash and cash equivalents		77	533	(813)	(873)	(1,162)
Cash and cash equivalents at end of year/period	*25*	13,631	15,112	175,886	51,660	131,619

II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1 General information, reorganization and basis of presentation

1.1 General information

OrbusNeich Medical Group Holdings Limited (the "Company") is a limited liability company incorporated and domiciled in the Cayman Islands. The address of its registered office is Conyers Trust Company (Cayman) Limited, Cricket Square, Hutchins Drive, PO Box 2681, Grand Cayman, KY1-1111, Cayman Islands.

The Company is an investment holding company and its subsidiaries (collectively, the "Group"), are principally engaged in the manufacturing, trading, sales and marketing of medical devices/instruments used for the treatment of coronary and peripheral vascular diseases (the "[**REDACTED**]"). The immediate and ultimate holding company is Harmony Tree Limited, a company incorporated in the British Virgin Islands with limited liability. The ultimate controlling shareholder of the Group is Mr. David Chien and Ms. Lau Kwai Ching Denise, spouse of Mr. David Chien (the "Controlling Shareholders").

1.2 Reorganization

Immediately prior to the Reorganization (as defined below) and during the Track Record Period, the [**REDACTED**] were operated by OrbusNeich Medical Group Limited ("ONM Group Ltd.") and its subsidiaries (the "Operating Companies"). The Operating Companies were collectively controlled by the Controlling Shareholders throughout the Track Record Period.

In preparation for the [**REDACTED**] ("[**REDACTED**]") and [**REDACTED**] (the "[**REDACTED**]") of the Company's shares on the [**REDACTED**] of [**REDACTED**], a group reorganization (the "Reorganization") was undertaken pursuant to which the companies engaged in the [**REDACTED**] were transferred to the Company. The Reorganization involved the following steps:

(i) Cosmic Ascent Limited ("COSMIC") was incorporated in the British Virgin Islands ("BVI") with limited liability on July 7, 2020. COSMIC was held by Harmony Tree Limited and eight individual minority shareholders ("Initial COSMIC Shareholders") as to 98.53% and 1.47% respectively prior to the Reorganization.

(ii) On July 31, 2020, a balance due by ONM Group Ltd., amounting to US$187,828,000, to OrbusNeich Medical Company Limited ("ONM BVI"), a company incorporated in the BVI and controlled by Mr. David Chien through Belinfer Corporation, a company incorporated in Panama with limited liability, was waived and recognised as other reserve of ONM Group Ltd. On the same date, the entire equity interest in ONM Group Ltd. was transferred from ONM BVI to COSMIC at a consideration of approximately US$187,828,000. The consideration was settled by way of issuance of 1,878,278,823 shares in COSMIC to the shareholders of ONM BVI. As a result of the transaction, ONM Group Ltd. became a wholly-owned subsidiary of COSMIC.

(iii) On April 23, 2021, ONM Group Ltd. and three series A pre-[**REDACTED**] independent investors (the "Series A Investors") entered into a share subscription agreement, pursuant to which ONM Group Ltd. issued and allotted 234,784,854 convertible redeemable preferred shares ("series A preferred shares") to the Series A Investors at a consideration of US$35,000,000.

(iv) On June 10, 2021, ONM Group Ltd. and eight series A-2 pre-[**REDACTED**] independent investors (the "Series A-2 Investors") entered into a share subscription agreement, pursuant to which ONM Group Ltd. issued and allotted 746,400,213 convertible redeemable preferred shares ("series A-2 preferred shares") to the Series A-2 Investors in July 2021 and August 2021 at a consideration of US$167,500,000.

(v) On July 7, 2021, COSMIC transferred its entire equity interest in OrbusNeich HeartValve Company Limited to ONM Group Ltd. at a consideration of US$150,000,000. The consideration was satisfied by the allotment and issuance of 1,006,220,798 new shares of ONM Group Ltd. credited as fully paid to COSMIC.

(vi) On July 22, 2021, the Company was incorporated in the Cayman Islands as an exempted company with limited liability and authorized share capital of US$50,000 divided into 500,000,000 shares with par value of US$0.0001. On the same day, the initial subscriber transferred one ordinary share at par to Harmony Tree Limited.

(vii) On August 20, 2021, the Controlling Shareholders transferred 117,210,115 shares and 42,977,042 shares of COSMIC to Mr. Kelvin Kai Hang Lau ("Mr. Lau"), a family member of the Controlling Shareholders, and one of the Initial COSMIC Shareholders respectively.

(viii) On September 28, 2021, Harmony Tree Limited, the Initial COSMIC Shareholders and Mr. Lau transferred the entire equity interest in COSMIC to the Company in return of 90.40%, 3.36% and 6.24% of the equity interest of the Company respectively.

(ix) The Company, the Series A Investors, Series A-2 Investors, COSMIC, ONM Group Ltd. and OrbusNeich Medical Company Limited (業聚醫療有限公司) ("ONM HK") entered into a share agreement on September 28, 2021. Upon the completion of the share exchange, ONM Group Ltd. became wholly owned by COSMIC, a direct wholly-owned subsidiary of the Company.

The Reorganization was completed on September 28, 2021. Upon completion of the Reorganization, substantially all of the equity holders of COSMIC became the shareholders of the Company, and the Company became the holding company of the Operating Companies.

After the completion of the Reorganization and as at the date of this report, the Company has direct or indirect interests in the following subsidiaries:

			Attributable equity interest of the Group						
			December 31,			June 30,	As at the date of this		
Company name	Place and date of incorporation/ establishment and type of legal entity	Registered/ issued and paid-up capital	2019	2020	2021	2022	report	Principal activities and place of operation	*Note*
Directly owned									
Cosmic Ascent Limited	BVI, July 7, 2020, limited liability company	US$187,827,882	N/A	100%	100%	100%	100%	Investment holding, BVI	*(i)*
Indirectly owned									
OrbusNeich Medical Group Limited	Cayman Islands, June 8, 2017, limited liability company	US$386,568	100%	100%	100%	100%	100%	Investment holding, Cayman Islands	*(i)*
OrbusNeich Medical Investment Holdings Limited	BVI, May 15, 2017, limited liability company	US$2	100%	100%	100%	100%	100%	Investment holding, BVI	*(i)*
OrbusNeich Medical Cyprus Holding Company Limited	Cyprus, May 17, 2006, limited liability company	Cyprus Pound 1,000	100%	100%	100%	100%	100%	Investment holding, Cyprus	*(ii)*
OrbusNeich Medical Holding B.V.	The Netherlands, May 30, 2001, limited liability company	EUR18,000	100%	100%	100%	100%	100%	Investment holding, The Netherlands	*(iii)*
OrbusNeich Medical B.V.	The Netherlands, July 13, 2006, limited liability company	EUR18,000	100%	100%	100%	100%	100%	Manufacturing of medical devices/ instruments, The Netherlands	*(iii)*
OrbusNeich Medical Trading Holdings Company Limited	BVI, May 15, 2017, limited liability company	US$1	100%	100%	100%	100%	100%	Investment holding, BVI	*(i)*
OrbusNeich Medical Manufacturing Holdings (BV) Company Limited	BVI, May 15, 2017, limited liability company	US$1	100%	100%	100%	100%	100%	Investment holding, BVI	*(i)*

Company name	Place and date of incorporation/ establishment and type of legal entity	Registered/ issued and paid-up capital	Attributable equity interest of the Group					Principal activities and place of operation	Note
			December 31,			June 30,	As at the date of this report		
			2019	2020	2021	2022			
OrbusNeich Medical Manufacturing Holdings (APAC) Company Limited	BVI, May 15, 2017, limited liability company	US$2	100%	100%	100%	100%	100%	Investment holding, BVI	*(i)*
OrbusNeich Medical Company Limited (業聚醫療有限公司)	Hong Kong, February 23, 1998, limited liability company	HK$2	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, Hong Kong	*(iv)*
OrbusNeich Medical Sdn. Bhd.	Malaysia, December 23, 2004, limited liability company	Malaysian Ringgit 2,500	100%	100%	100%	100%	100%	Trading of medical devices/ instruments, Malaysia	*(viii)*
OrbusNeich Medical K.K.	Japan, September 13, 2001, limited liability company	JPY90,000,000	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, Japan	*(vii)*
OrbusNeich Medical K.K. Foundation	Japan, September 4, 2013, limited liability company	JPY3,000,000	100%	100%	100%	100%	100%	Dormant, Japan	*(vii)*
Advanced Medical Works K.K.	Japan, June 13, 2017, limited liability company	JPY500,000	100%	100%	100%	100%	100%	Research and development of medical devices/ instruments, Japan	*(vii)*
OrbusNeich Medical Pty Limited	Australia, March 29, 2001, limited liability company	Australian Dollar 100	100%	100%	100%	100%	100%	Trading of medical devices/instruments, Australia	*(vii)*
OrbusNeich Medical Investments Limited B.V.	The Netherlands, July 20, 2017, limited liability company	EUR1	100%	100%	100%	100%	100%	Investment holding, The Netherlands	*(iii)*
Orbus International B.V.	The Netherlands, March 10, 1999, limited liability company	EUR45,320,279	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, The Netherlands	*(iii)*
OrbusNeich (Switzerland) AG	Switzerland, January 3, 2018, limited liability company	CHF100,000	N/A	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, Switzerland	*(vii)*
OrbusNeich Medical Pte. Ltd.	Singapore, August 16, 1995, limited liability company	Singaporean Dollar 2	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, Singapore	*(vi)*

Company name	Place and date of incorporation/ establishment and type of legal entity	Registered/ issued and paid-up capital	Attributable equity interest of the Group					Principal activities and place of operation	Note
			December 31,			June 30,	As at the date of this report		
			2019	2020	2021	2022			
OrbusNeich Medical India Private Limited	India, March 9, 2009, limited liability company	Indian Rupee 100,000	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, India	*(ix)*
OrbusNeich Medical Trading, Inc.	The United States of America (the "USA"), September 14, 2017, limited liability company	US$1	100%	100%	100%	100%	100%	Research and development of medical devices/ instruments, USA	*(i)*
OrbusNeich Medical, Sociedad Limitada	Spain, July 2, 2016, limited liability company	EUR3,000	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, Spain	*(vii)*
OrbusNeich Medical GmbH	Germany, December 1, 2007, limited liability company	EUR25,000	100%	100%	100%	100%	100%	Trading, sales and marketing of medical devices/ instruments, Germany	*(vii)*
OrbusNeich Medical (Shenzhen) Company Limited (業聚醫療器械(深圳)有限公司)	People's Republic of China (the "PRC"), May 29, 2000, Wholly foreign owned enterprises	US$5,000,000	100%	100%	100%	100%	100%	Manufacturing of medical devices/ instruments, The PRC	*(v)*
OrbusNeich Medical I.P. Holdings (Stent) Company Limited	BVI, May 15, 2017, limited liability company	US$1	100%	100%	100%	100%	100%	Investment holding, BVI	*(i)*
OrbusNeich Medical, Inc.	USA, July 28, 1999, limited liability company	US$193,090	100%	100%	100%	100%	100%	Research and development of medical devices/ instruments, USA	*(i)*
OrbusNeich HeartValve Company Limited	BVI, May 15, 2017, limited liability company	US$1	100%	100%	100%	100%	100%	Investment holding, BVI	*(i)*
OrbusNeich International B.V.	The Netherlands, April 1, 2021, limited liability company	EUR1	N/A	N/A	100%	100%	100%	Inactive, The Netherlands	*(x)*
OrbusNeich Medical Technology (Beijing) Company Limited ((業聚醫療技術(北京)有限公司)	The PRC, July 8, 2021, limited liability company	RMB1,000,000	N/A	N/A	100%	100%	100%	Research and development of medical devices/ instruments, The PRC	*(xi)*

Notes:

(i) No audited financial statements were issued for these subsidiaries as there is no statutory audit requirement in their place of incorporation.

(ii) The statutory financial statements of the company for the years ended December 31, 2019, 2020 and 2021 were audited by Joannides + Co Limited, Certified Public Accountants.

(iii) The statutory financial statements of these companies for the years ended December 31, 2019 and 2020, were audited by Coney Assurance B.V., Certified Public Accountants. The statutory financial statements for the year ended December 31, 2021 have not yet been issued.

(iv) The statutory financial statements of the company for the years ended December 31, 2019, 2020 and 2021 were audited by PricewaterhouseCoopers, Certified Public Accountants.

(v) The statutory financial statements of the company for the years ended December 31, 2019, 2020 and 2021 were audited by Shenzhen Huaqin Certified Public Accountants' Firm 深圳華勤會計師事務所, Certified Public Accountants.

(vi) The statutory financial statements of the company for the year ended December 31, 2019 were audited by P G Wee Partnership LLP, Certified Public Accountants and for the years ended December 31, 2020 and 2021 were audited by Precursor Assurance PAC, Certified Public Accountants.

(vii) No statutory financial statements have been prepared for these companies during the Track Record Period as they are exempted from statutory audit requirements.

(viii) The statutory financial statements of the company for the years ended December 31, 2019, 2020 and 2021 were audited by Mohamed, Yeng & Co., Certified Public Accountants.

(ix) The statutory financial statements of the company for the years ended December 31, 2019, 2020 and 2021 were audited by D.S.K. & Associates, Chartered Accountants.

(x) No audited financial statements were issued as the company was newly incorporated.

(xi) The statutory financial statements of the company for the period ended December 31, 2021 were audited by Shenzhen Huaqin Certified Public Accountants' Firm 深圳華勤會計師事務所, Certified Public Accountants.

1.3 Basis of presentation

Immediately prior to and after the Reorganization, the [**REDACTED**] is conducted through the Operating Companies. Pursuant to the Reorganization, the [**REDACTED**] was transferred to and held by the Company. The Company has not been involved in any other business prior to the Reorganization and do not meet the definition of a business. The Reorganization is merely a reorganization of the [**REDACTED**] with no change in management of such business and the ultimate owners of the [**REDACTED**] remain the same. Accordingly, the Group resulting from the Reorganization is regarded as a continuation of the [**REDACTED**] conducted through the Operating Companies.

For the purpose of this report, the Historical Financial Information has been prepared and presented as a continuation of the consolidated financial information of the [**REDACTED**], with the results, assets and liabilities recognized and measured at the carrying amounts of the [**REDACTED**] under the consolidated financial statements for all the years/periods presented.

Inter-company transactions, balances and unrealized gains/losses on transactions between group companies in the [**REDACTED**] were eliminated on consolidation.

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of the Historical Financial Information are set out below. These policies have been consistently applied to all the years and periods presented, unless otherwise stated.

2.1 Basis of preparation

The principal accounting policies applied in the preparation of the Historical Financial Information which are in accordance with the Hong Kong Financial Reporting Standards ("HKFRSs") issued by Hong Kong Institute of Certified Public Accountant (the "HKICPA") are set out below. The Historical Financial Information have been prepared under the historical cost basis, except for financial assets at fair value through profit or loss or other comprehensive income, convertible redeemable preferred shares and contingent liabilities, which are carried at fair value.

All effective standards, amendments to standards and interpretations, which are mandatory for the financial year beginning January 1, 2022, have been consistently applied to the Group for the Track Record Period.

The preparation of Historical Financial Information in conformity with HKFRSs requires the use of certain critical accounting estimates. It also requires management of the Group to exercise its judgment in the process of applying the Group's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the Historical Financial Information are disclosed in Note 4.

The followings are new standard, amendments to standards and interpretation which have been issued but are not yet effective during the Track Record Period and have not been early adopted by the Group in preparing the Historical Financial Information:

		Effective for accounting year beginning on or after
HKFRS 17	Insurance Contracts and the Related Amendments	January 1, 2023
Amendments to HKAS 1	Classification of Liabilities as Current or Non-current	January 1, 2023
Amendments to HKAS 1 and HKFRS Practice Statement 2	Disclosure of Accounting Policies	January 1, 2023
Amendments to HKAS 8	Definition of Accounting Estimates	January 1, 2023
Amendments to HKAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
Hong Kong Interpretation 5 (2020)	Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause	January 1, 2023
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	To be determined

The Group will adopt the above new standard, amendments to standards and interpretation as and when they become effective. The directors of the Company have performed preliminary assessment and do not anticipate any significant impact on the Group's financial position and results of operations upon adopting these standard, amendments and interpretation to existing HKFRSs.

2.2 Principles of consolidation

2.2.1 Subsidiaries

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the Group (refer to Note 2.2.4).

Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Non-controlling interests in the results and equity of subsidiaries are shown separately in the consolidated statements of profit or loss, consolidated statements of comprehensive income, consolidated statements of changes in equity and consolidated balance sheets respectively.

2.2.2 Common control business combinations

Merger accounting method stipulated under Hong Kong Accounting Guideline 5, 'Merger accounting for common control combinations' is used to account for acquisitions of businesses under common control before and after the acquisitions. The difference between fair value of acquisition consideration and carrying amount of net assets acquired is adjusted to merger reserve.

The Historical Financial Information incorporate the financial statements of the combining entities or businesses in which the common control combination occurs as if they had been consolidated from the date when the combining entities or businesses first came under the control of the controlling party.

The net assets of the combining entities or businesses are consolidated using the existing book values from the controlling parties' perspective. No amount is recognized in respect of goodwill or excess of acquirer's interest in the net fair value of acquired identifiable assets and liabilities over cost at the time of common control combination, to the extent of the continuation of the controlling party's interest.

The consolidated statements of profit or loss includes the results of each of the combining entities or businesses from the earliest date presented or since the date when the combining entities or businesses first came under common control, where this is a shorter period, regardless of the date of the common control combination.

The comparative amounts in the consolidated financial statements are presented as if those entities or businesses had been consolidated at the previous reporting date or when they first came under common control, whichever is shorter.

Business combination related costs are generally recognized in consolidated statements of profit or loss as incurred.

2.2.3 Changes in ownership interests

The Group treats transactions with non-controlling interests that do not result in a loss of control as transactions with equity owners of the Group. A change in ownership interest results in an adjustment between the carrying amounts of the controlling and non-controlling interests to reflect their relative interests in the subsidiary. Any difference between the amount of the adjustment to non-controlling interests and any consideration paid or received is recognized in a separate reserve within equity attributable to owners of the Company.

When the Group ceases to consolidate or equity account for an investment because of a loss of control, joint control or significant influence, any retained interest in the entity is remeasured to its fair value with the change in carrying amount recognized in profit or loss. This fair value becomes the initial carrying amount for the purposes of subsequently accounting for the retained interest as an associate, joint venture or financial asset. In addition, any amounts previously recognized in other comprehensive income in respect of that entity are accounted for as if the Group had directly disposed of the related assets or liabilities. This may mean that amounts previously recognized in other comprehensive income are reclassified to profit or loss or transferred to another category of equity as specified/permitted by applicable HKFRSs.

2.2.4 Business combinations

The acquisition method of accounting is used to account for all business combinations, regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises the:

- fair values of the assets transferred,
- liabilities incurred to the former owners of the acquired business,
- equity interests issued by the Group,
- fair value of any asset or liability resulting from a contingent consideration arrangement, and
- fair value of any pre-existing equity interest in the subsidiary.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. The group recognizes any non-controlling interest in the acquired entity on an acquisition-by-acquisition basis either at fair value or at the non-controlling interest's proportionate share of the acquired entity's net identifiable assets.

Acquisition-related costs are expensed as incurred.

The excess of the

- consideration transferred,
- amount of any non-controlling interest in the acquired entity, and
- acquisition-date fair value of any previous equity interest in the acquired entity

Over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the business acquired, the difference is recognized directly in profit or loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The discount rate used is the entity's incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions. Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognized in profit or loss.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer's previously held equity interest in the acquiree is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognized in profit or loss.

2.2.5 Joint arrangements

Under HKFRS 11 Joint Arrangements, investments in joint arrangements are classified as either joint operations or joint ventures. The classification depends on the contractual rights and obligations of each investor, rather than the legal structure of the joint arrangement. The Group has assessed the nature of its joint arrangement and determined it to be joint venture. Joint venture is accounted for using the equity method.

Under the equity method of accounting, the investments are initially recognized at cost and adjusted thereafter to recognize the Group's share of the post-acquisition profits or losses of the investee in profit or loss, and the Group's share of movements in other comprehensive income of the investee in other comprehensive income. Dividends received or receivable from a joint venture are recognized as a reduction in the carrying amount of the investment.

Where the Group's share of losses in an equity-accounted investment equals or exceeds its interest in the entity, including any other unsecured long-term receivables, the Group does not recognize further losses, unless it has incurred obligations or made payments on behalf of the other entity.

Unrealized gains on transactions between the Group and its joint venture are eliminated to the extent of the Group's interest in these entities. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of equity-accounted investees have been changed where necessary to ensure consistency with the policies adopted by the Group.

The carrying amount of equity-accounted investments is tested for impairment in accordance with the policy described in Note 2.8.

2.3 Segment reporting

Operating segment is reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ("CODM"). The CODM, who is responsible for allocating resources and assessing performance of the operating segment, has been identified as the Executive Directors of the Company that make strategic decisions.

2.4 Foreign currency translation

(a) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The consolidated financial statements are presented in US$, which is the Company's functional and Group's presentation currency.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the consolidated statements of profit or loss. Foreign exchange gains and losses are presented in the consolidated statements of profit or loss within "other gains/(losses) – net".

(c) Group companies

The results and financial position of all the Group's entities (none of which has the currency of a hyper-inflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

(i) assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;

(ii) income and expenses for each consolidated statement of profit or loss are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions); and

(iii) all resulting currency translation differences are recognized in other comprehensive income.

2.5 Property, plant and equipment

Buildings comprise mainly factories and offices. Property, plant and equipment other than construction in progress are stated at historical cost less accumulated depreciation and accumulated impairment losses. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to the consolidated statements of profit or loss during the financial period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost to their residual values over their estimated useful lives, as follows:

Buildings	20 years
Leasehold improvements	Shorter of 10 years or the lease term
Plant and machinery	5 to 10 years
Furniture, fixtures and equipment	4 to 10 years
Motor vehicles	3 to 5 years
Computer equipment	3 to 5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (Note 2.8).

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized within "other gains/(losses) – net", in the consolidated statements of profit or loss.

Construction-in-progress represents plant and machinery, leasehold improvements, furniture, fixtures and equipment and computer equipment on which construction work has not been completed and which, upon completion, management intend to hold for the use of the Group. They are carried at cost which includes development and construction expenditure incurred and other direct costs attributable to the development less any accumulated impairment losses. On completion, the amounts are transferred to respective categories of property, plant and equipment and depreciated in accordance with the policy as stated above.

2.6 Intangible assets

Intangible assets comprise (i) expenditure on product development activities; and (ii) customer relationship.

Expenditure on research activities is recognized as an expense in the period in which it is incurred. Expenditure on development activities is capitalized if the product or process is technically and commercially feasible and the Group has sufficient resources and the intention to complete development. The expenditure capitalized includes the costs of materials, direct labor, and an appropriate proportion of overheads. Capitalized development costs are stated at cost less accumulated amortization and impairment losses. Other development expenditure is recognized as an expense in the period in which it is incurred.

Customer relationships acquired in a business combination are recognized at fair value at the acquisition date. Customer relationships have finite useful lives and are carried at costs less accumulated amortization and impairment losses.

Amortization of intangible assets with finite useful lives is charged to profit or loss on a straight-line basis over the assets' estimated useful lives. The following intangible assets with finite useful lives are amortized from the date they are available for use and their estimated useful lives are as follows:

Capitalized development costs	10 years
Customer relationships	9 years

2.7 Goodwill

Goodwill arising on the acquisition of subsidiary represents the excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition-date fair value of any previous equity interest in the acquiree over the fair value of the identified net assets acquired. Goodwill is not amortized but it is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or groups of cash-generating units that are expected to benefit from the business combination in which the goodwill arose. The units or groups of units are identified at the lowest level at which goodwill is monitored for internal management purposes.

2.8 Impairment of non-financial assets

Assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment. Assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount.

The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at each reporting date.

Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset in prior years. A reversal of an impairment loss is recognized immediately in the consolidated statements of profit or loss.

2.9 Financial assets

(a) Classification

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income or through profit or loss), and
- those to be measured at amortized cost.

The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or other comprehensive income. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income.

(b) Recognition and derecognition

Regular way purchases and sales of financial assets are recognized on trade-date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

(c) Measurement

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss.

Debt instruments

Subsequent measurement of debt instruments depends on the Group's business model for managing the asset and the cash flow characteristics of the asset. Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognized directly in profit or loss and presented within "other gains/(losses) – net".

Assets that do not meet the criteria for amortised or fair value through other comprehensive income ("FVOCI") are measured at fair value through profit or loss ("FVPL"). A gain or loss on a debt instrument that is subsequently measured at FVPL is recognised in profit or loss and presented within "other gains/(losses) – net" in the period in which it arises.

Equity instruments

The Group subsequently measures all equity investments at fair value. Where the Group's management has elected to present fair value gains and losses on equity investments in other comprehensive income, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when the Group's right to receive payments is established.

Changes in the fair value of financial assets at fair value through profit or loss are recognized as "other gains/(losses) – net" in the consolidated statements of profit or loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at fair value through other comprehensive income are not reported separately from other changes in fair value.

(d) Impairment

The Company assesses on a forward-looking basis the expected credit losses associated with its debt instruments carried at amortized cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For trade receivables, the Company applies the simplified approach permitted by HKFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables. For the other financial assets, expected credit losses are assessed according to change in credit quality since initial recognition.

2.10 Offsetting financial instruments

Financial assets and liabilities are offset and the net amount is reported in the balance sheet where the Group currently has a legally enforceable right to offset the recognized amounts, and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously. The Group has also entered into arrangements that do not meet the criteria for offsetting but still allow for the related amounts to be set off in certain circumstances, such as bankruptcy or the termination of a contract.

2.11 Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out (FIFO) method. The cost of finished goods and work in progress comprises design costs, raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity). It excludes borrowing costs. Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses.

2.12 Trade receivables

Trade receivables are amounts due from customers for goods sold in the ordinary course of business. They are generally due for settlement within 30 to 180 days and therefore are all classified as current.

Trade receivables are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value. The Group holds the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method. See Note 24 for further information about the Group's accounting for trade receivables and Note 3.1(b) for a description of the Group's impairment policies.

2.13 Cash and cash equivalents

In the consolidated statements of cash flows, cash and cash equivalents includes cash in hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

Bank deposits with original maturities more than three months are included within "short-term bank deposit" in the consolidated balance sheets.

Cash that is being pledged as security is reported separately on the face of the consolidated balance sheet, and is not included in total cash and cash equivalents in the consolidated statement of cash flows.

2.14 Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

2.15 Trade and other payables

These amounts represent liabilities for goods and services provided to the group prior to the end of financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method.

2.16 Convertible redeemable preferred shares ("Preferred Shares")

Preferred Shares issued by the Group are redeemable at the option of the holder upon occurrence of certain events. These instruments can also be converted into ordinary shares at any time at the option of the holders, or automatically upon occurrence of an [**REDACTED**]. For details, refer to Note 29.

Derivatives embedded in Preferred Shares are treated as separate derivatives when:

– Their economic characteristics and risks are not closely related to those of the host contract;

– A separate instrument with the same terms would meet the definition of a derivative; and

– The hybrid contract is not measured at fair value through profit or loss.

These embedded derivatives which meet the above separation criteria (such as the conversion option in Preferred Shares) are separately accounted for at fair value, with changes in fair value recognized in the consolidated statements of profit or loss unless the Group chooses to designate the hybrid contracts at fair value through profit or loss.

2.17 Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently carried at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the consolidated statements of profit or loss over the period of the borrowings using the effective interest method.

Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw-down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period.

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognized in profit or loss as finance costs.

2.18 Borrowing costs

General and specific borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, which are assets that necessarily take a substantial period of time to get ready for their intended use or sale, are added to the cost of those assets, until such time as the assets are substantially ready for their intended use or sale.

Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs eligible for capitalization.

All other borrowing costs are recognized in profit or loss in the period in which they are incurred.

2.19 Current and deferred income tax

The income tax expense for the year comprises current and deferred tax. Tax is recognized in the consolidated statements of profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

(a) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet dates in the countries where the Company's subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

(b) Deferred income tax

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in foreign operations where the Company is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

2.20 Employee benefits

The Group operates various post-employment schemes, including both defined benefit and defined contribution pension plans.

(a) Pension obligations

The Group has both defined benefit and defined contribution plans. A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity. The Group has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. A defined benefit plan is a pension plan that is not a defined contribution plan. Defined benefit plans typically define an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and compensation.

The liability recognized in the consolidated balance sheets in respect of defined benefit pension plans is the present value of the defined benefit obligation at the end of each reporting period. The defined benefit obligation is calculated by independent actuaries using the projected unit credit method.

The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms approximating to the terms of the related obligation.

Past-service costs are recognized immediately in consolidated statements of profit or loss. Changes in the present value of the defined benefit obligation resulting from plan amendments or curtailments are recognized immediately in profit or loss as past service costs.

Remeasurement gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized in the period in which they occur, directly in other comprehensive income.

For defined contribution plans, the Group pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expense when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments is available.

(b) Termination benefits

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or whenever an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes termination benefits at the earlier of the following dates: (i) when the Group can no longer withdraw the offer of those benefits; and (ii) when the entity recognizes costs for a restructuring that is within the scope of HKAS 37 and involves the payment of termination benefits. In the case of an offer made to encourage voluntary redundancy, the termination benefits are measured based on the number of employees expected to accept the offer. Benefits falling due more than 12 months after the end of the reporting period are discounted to their present value.

(c) Profit-sharing and bonus plans

The Group recognizes a liability and an expense for bonuses and profit-sharing, based on a formula that takes into consideration the profit attributable to the Company's shareholder after certain adjustments. The Group recognizes a provision where contractually obliged or where there is a past practice that has created a constructive obligation.

(d) Employee leave entitlements

Employee entitlements to annual leave are recognized when they accrue to employees. A provision is made for the estimated liability for annual leave as a result of services rendered by employees up to the end of the reporting period.

Employee entitlements to sick leave and maternity leave are not recognized until the time of leave.

2.21 Share-based payments

(a) Equity-settled share-based payment transactions

The Group operates a number of equity-settled share-based compensation plans under which the entity receives services from employees as consideration for equity instruments (options) of the Group. The fair value of the employee services received in exchange for the grant of the options is recognized general and administrative expenses in the consolidated statements of profit or loss with a corresponding increase in the reserve under equity.

The total amount to be expensed is determined by reference to the fair value of the options granted:

– including any market performance conditions (for example, an entity's share price);

– excluding the impact of any service and non-market performance vesting conditions (for example, profitability, sales growth targets and remaining an employee of the entity over a specified time period); and

– including the impact of any non-vesting conditions (for example, the requirement for employees to save).

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At each balance sheet date, the estimate of the number of these share options that are expected to become vested is revised based on the non-market performance and service conditions. It recognizes the impact of the revision to original estimates, if any, in the consolidated statements of profit or loss, with a corresponding adjustment to equity.

In addition, in some circumstances employees may provide services in advance of the grant date and therefore the grant date fair value is estimated for the purposes of recognizing the expense during the period between service commencement period and grant date.

At the end of each reporting period, the Group revises its estimates of the number of options that are expected to vest based on the non-market performance and service conditions. It recognizes the impact of the revision to original estimates, if any, in the consolidated statements of profit or loss, with a corresponding adjustment to equity.

When the options are exercised, the Company issues new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

(b) Share-based payment transactions among Group entities

The grant of options over its equity instruments to the employees of subsidiary undertakings in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognized over the vesting period as an increase to investment in subsidiary undertakings, with a corresponding credit to equity in the parent entity accounts.

2.22 Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events; it is probable that an outflow of resources will be required to settle the obligation; and the amount has been reliably estimated. Provisions are not recognized for future operating losses.

Where there are a number of similar obligations, the likelihood that an outflow will be required in settlement is determined by considering the class of obligations as a whole. A provision is recognized even if the likelihood of an outflow with respect to any one item included in the same class of obligations may be small.

Provisions are measured at the present value of management's best estimate the expenditures expected to be required to settle the present obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to passage of time is recognized as interest expense.

2.23 Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable, and represents amounts receivable for goods supplied, stated net of discounts, returns and value added taxes. Revenue is recognized when, or as, the control of the goods is transferred to the customer.

The Group bases its estimates of return on historical results, taking into consideration the type of customers, the type of transactions and the specifics of each arrangement. Revenue is recognized as follows:

(a) Sales of goods

The Group manufactures and sells medical instruments in vascular therapies. Revenue from sales are recognized when control of the products has transferred to the customers, and there is no unfulfilled obligation that could affect the customers' acceptance of the products. There are two major channels of sales: (i) Distributor sales and (ii) Direct sales.

(i) Distributor sales

Revenue are recognized at point in time when control has been transferred to the customers, and either the customers has accepted the products in accordance with the sales contract, the acceptance provisions have lapsed, or the Group has objective evidence that all criteria for acceptance have been satisfied. Majority of such revenue are recognized when the products are dispatched from the Group's warehouse. Revenue from these sales is recognized based on the price specified in the contract.

(ii) Direct sales

Direct sales represents consignment sales of goods to private and public hospitals. Revenue are recognized at point in time when control has been transferred to customers, that is, at the time when the customer has actually consumed the goods.

2.24 Interest income

Interest income is presented as finance income where it is earned from financial assets that are held for cash management purposes. Any other interest income is included in other income.

Interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset except for financial assets that subsequently become credit-impaired. For credit-impaired financial assets the effective interest rate is applied to the net carrying amount of the financial asset (after deduction of the loss allowance).

2.25 Government grants

Grants from the government are recognized at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions.

Government grants relating to costs are deferred and recognized within "other income – net" in the consolidated statements of profit or loss over the period necessary to match them with the costs that they are intended to compensate. Government grants relating to property, plant and equipment are recognized as deferred income in consolidated statements of profit or loss on a systematic basis over the useful life of the asset.

2.26 Leases

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group.

Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. However, for leases of real estate for which the Group is a lessee, it has elected not to separate lease and non-lease components and instead accounts for these as a single lease component.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as at the commencement date; and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

To determine the incremental borrowing rate, the Group:

- where possible, uses recent third-party financing received by the individual lessee as a starting point, adjusted to reflect changes in financing conditions since third party financing was received.
- uses a build-up approach that starts with a risk-free interest rate adjusted for credit risk for leases held by the Group, which does not have recent third-party financing, and makes adjustments specific to the lease, e.g. term, country, currency and security.

The Group is exposed to potential future increases in variable lease payments based on an index or rate, which are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability;
- any lease payments made at or before the commencement date less any lease incentives received;
- any initial direct costs; and
- restoration costs.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less.

2.27 Research and development costs

Research costs are expensed as incurred. Costs incurred on development projects relating to the design and testing of new or improved products are recognized as an intangible asset when the technical feasibility and intention of completing the product under development has been demonstrated and the resources are available to do so, costs are identifiable and there is an ability to sell or use the asset that will generate probable future economic benefits. Such development costs are recognized as an asset and amortized on the straight-line basis to reflect the pattern in which the related economic benefits are recognized. Development costs that do not meet the above criteria are expensed as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period.

2.28 Dividend distribution

Dividend distribution to the Company's shareholders is recognized as a liability in the consolidated financial statements in the period in which the dividends are approved by the Company's shareholders or directors, where appropriate.

Dividend proposed or declared after the reporting period but before the financial statements are authorized for issue, are disclosed as a non-adjusting event and are not recognized as liability at the end of the reporting period.

2.29 Financial guarantee contracts

Financial guarantee contracts are recognized as a financial liability at the time the guarantee is issued. The liability is initially measured at fair value and subsequently at the higher of

- the amount determined in accordance with the expected credit loss model under HKFRS 9 "Financial Instruments" and
- the amount initially recognized less, where appropriate, the cumulative amount of income recognized in accordance with the principles of HKFRS 15 "Revenue from Contracts with Customers".

The fair value of financial guarantees is determined based on the present value of the difference in cash flows between the contractual payments required under the debt instrument and the payments that would be required without the guarantee, or the estimated amount that would be payable to a third party for assuming the obligations.

2.30 Contingent liabilities

A contingent liability is a possible obligation that arises from past events and whose existence will only be confirmed by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Group. It can also be a present obligation arising from past events that is not recognized because it is not probable that outflow of economic resources will be required or the amount of obligation cannot be measured reliably.

A contingent liability is not recognized but is disclosed in the notes to the historical financial information, if any. When a change in the probability of an outflow occurs so that outflow is probable, it will then be recognized as a provision.

3 FINANCIAL RISK MANAGEMENT

3.1 Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (including foreign exchange risk and cash flow and fair value interest rate risk), credit risk and liquidity risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

(a) Market risk

(i) Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the Hong Kong dollar ("HK$"), Renminbi ("RMB"), Japanese Yen ("JPY") and Euro ("EUR"). Foreign exchange risk arises when future commercial transactions or recognized assets or liabilities are denominated in a currency that is not the entity's functional currency.

Management manages its foreign exchange risks by performing regular review and monitoring its foreign exchange exposure. Management has also set up a policy to require group companies to manage their foreign exchange risk against their functional currency.

The table below summarizes the changes in the Group's profit or loss in response to reasonably possible changes in the foreign exchange rates to which the Group has significant exposure at the balance sheet date. The analysis has been determined assuming that the general depreciation trend in foreign exchange rates against functional currency in respective countries had occurred at the balance sheet date and that all other variables remain constant.

		As at December 31, 2019		As at December 31, 2020		As at December 31, 2021		As at June 30, 2022	
Functional currency	Foreign currency	Hypothetical appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*	Hypothetical appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*	Hypothetical appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*	Hypothetical appreciation/ (depreciation) in foreign exchange rate	(Negative)/ profit effect on profit or loss *US$'000*
US$	RMB	+/- 5%	(117)/117	+/- 5%	(136)/136	+/- 5%	(67)/67	+/- 5%	(6)/6
JPY	US$	+/- 5%	(703)/703	+/- 5%	(919)/919	+/- 5%	(375)/375	+/- 5%	(1,024)/1,024
EUR	US$	+/- 5%	(34)/34	+/- 5%	(118)/118	+/- 5%	41/(41)	+/- 5%	87/(87)

For HK$, since it is pegged to the US$, the directors consider that the Group does not have any material foreign exchange exposure arising from HK$.

(ii) Cash flow and fair value interest rate risk

The Group's interest rate risk arises from bank borrowings, loans from related companies and lease liabilities. Bank borrowings obtained at variable rates expose the Group to cash flow interest rate risk.

Loans from related companies and lease liabilities were obtained at fixed rates, therefore, the directors are of the opinion that the interest rate risk exposure is low.

As at December 31, 2019 and 2020, if interest rates on bank borrowings had been 100 basis points higher or lower with all other variables held constant, the impact on the Group's profit or loss for the year would have been approximately US$321,000 and US$333,000 lower or higher, respectively.

Bank deposits at variable rates expose the Group to cash flow interest rate risk. The Group manages its interest rate risk by performing regular reviews and continually monitoring its interest rate exposures. The Group has not used any interest rate swaps to hedge its exposure to interest rate risk.

The directors are of the opinion that as at December 31, 2019, 2020 and 2021 and June 30, 2022, any reasonable changes in interest rates on bank deposits would not result in a significant change in the Group's results. Accordingly, no sensitivity analysis is presented for interest rate risk arising from bank deposits.

(b) Credit risk

Credit risk refers to the risk that the counterparty to a financial instrument would fail to discharge its obligation under the terms of the financial instrument and cause a financial loss to the Group. The credit risk of the Group's financial assets, which mainly comprise cash and bank deposits, trade receivables, deposits and other receivables and amounts due from joint ventures and amounts due from related companies with a maximum exposure equal to the carrying amounts of these instruments.

Credit risk is managed on a group basis, except for credit risk relating to trade receivable balances which are managed by each local entity. For each trade receivables, each local entity is responsible for managing and analyzing the credit risk for each of their new clients before standard payment and delivery terms and conditions are offered.

(i) Credit risk of cash and bank deposits

The credit risk arises from cash at banks and deposits with banks are monitored closely by management of the Group. The majority of the Group's bank balances and deposits are placed in banks and financial institutions which are independently rated with high credit ratings assigned by international credit-rating agencies. Management does not expect any losses from non-performance by these banks and financial institutions as they have no recent history of default.

(ii) Credit risk of trade receivables

For external receivables, the Group has policies in place to assess the credit worthiness of customers to ensure that sales of products are made to customers with an appropriate credit history. Besides, management of the Group monitors its credit risk on an ongoing basis by reviewing the debtors' ageing to minimize its exposure to credit risk. As at December 31, 2019, 2020 and 2021 and June 30, 2022, the Group has concentration of credit risk given that the largest customer accounted for 12%, 7%, 2% and 9% respectively, of the total trade receivables. The extent of credit risk relating to the Group's trade receivables is disclosed in Note 24.

The Group applies the simplified approach to providing for expected credit losses prescribed by HKFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. To measure expected credit losses, the Group categorises its trade receivables based on customer accounts and shared credit risk characteristics.

All customers of the Group are assessed collectively using a provision matrix. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables. The Group also considered the forward-looking information on macroeconomic factors including gross domestic product.

For trade receivables relating to accounts in which there are objective evidence that the debtor faces significant financial difficulties or enter liquidation, they are assessed individually for impairment allowance.

The loss allowance provision for trade receivables from third parties as at December 31, 2019, 2020 and 2021 and June 30, 2022 are as follows:

At December 31, 2019	Current	Past due by 1 to 90 days	Past due by 91 to 180 days	Past due by over 180 days	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Gross carrying amount	27,402	3,899	1,845	2,329	35,475
Expected loss rate	0.07%	9.08%	45.42%	71.02%	
Loss allowance	(20)	(354)	(838)	(1,654)	(2,866)

At December 31, 2020	Current	Past due by 1 to 90 days	Past due by 91 to 180 days	Past due by over 180 days	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Gross carrying amount	24,189	1,837	248	2,132	28,406
Expected loss rate	0.06%	1.91%	16.94%	93.76%	
Loss allowance	(14)	(35)	(42)	(1,999)	(2,090)

At December 31, 2021	Current	Past due by 1 to 90 days	Past due by 91 to 180 days	Past due by over 180 days	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Gross carrying amount	25,478	942	273	1,698	28,391
Expected loss rate	0.04%	2.23%	3.66%	91.05%	
Loss allowance	(10)	(21)	(10)	(1,546)	(1,587)

At June 30, 2022	Current	Past due by 1 to 90 days	Past due by 91 to 180 days	Past due by over 180 days	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Gross carrying amount	26,261	2,942	522	1,833	31,558
Expected loss rate	0.04%	1.80%	31.8%	88.8%	
Loss allowance	(11)	(53)	(166)	(1,628)	(1,858)

(iii) Credit risk of other financial assets at amortized cost

The directors of the Group consider the probability of default upon initial recognition of asset and whether there has been significant increase in credit risk on an ongoing basis during the financial year. To assess whether there is a significant increase in credit risk the Group compares risk of a default occurring on the assets as at the reporting date with the risk of default as at the date of initial recognition. Especially the following indicators are incorporated:

- actual or expected significant adverse changes in business, financial economic conditions that are expected to cause a significant change to the third party's ability to meet its obligations;
- actual or expected significant changes in the operating results of the third party; and
- significant changes in the expected performance and behaviour of the third party, including changes in the payment status of the third party.

A default on a financial asset is when the counterparty fails to make contractual payments/repayable demanded.

Financial assets are written off when there is no reasonable expectation of recovery, such as a debtor failing to engage in a repayment plan with the Group. Where receivables have been written off, the Group continues to engage in enforcement activity to attempt to recover the receivable due. Where recoveries are made, these are recognized in profit or loss.

The Group reviews regularly the recoverable amount of each individual receivable to ensure that adequate impairment losses are made for irrecoverable amounts. Over the term of the financial assets, the Group accounts for its credit risk by appropriately providing for expected credit losses on a timely basis. In calculating the expected credit loss rates, the Group considers historical loss rates for each category of debtors, and adjusts for forward looking macroeconomic data.

The credit risk of the Group's other financial assets at amortized cost, which comprises deposits and other receivables, amounts due from joint ventures and amounts due from related companies arises from default of the counter party, with a maximum exposure equal to the carrying amount of the instrument. The credit quality has been assessed with reference to historical information and forward-looking information about the counterparties default rates and financial position of the counterparties. Given the track record of repayment in full, the directors of the Company are of the opinion that the risk of default by these counterparties is not significant and does not expect any losses from non-performance by the counterparties. Therefore, expected credit loss rate of the deposits and other receivables is assessed to be insignificant and no provision was made as at December 31, 2019, 2020 and 2021 and June 30, 2022.

The Group's maximum exposure to credit risk which will cause a financial loss to the Group arising from the amount of contingent liabilities in relation to financial guarantees provided by the Group is disclosed in Note 37.

(c) Liquidity risk

Cash flow forecasting is performed in the operating entities of the Group and aggregated by Group finance. Group finance monitors rolling forecasts of the Group's liquidity requirements to ensure it has sufficient cash to meet operational needs while maintaining sufficient headroom on its undrawn committed borrowing facilities at all times so that the Group does not breach borrowing limits or covenants (where applicable) on any of its borrowing facilities. Such forecasting takes into consideration the Group's debt financing plans, covenant compliance, compliance with internal balance sheet ratio targets and, if applicable external regulatory or legal requirements – for example, currency restrictions.

The table below analyzes the Group's financial liabilities into relevant maturity groupings based on the remaining period at the balance sheet dates to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

	Within 1 year or on demand *US$'000*	**Between 1 and 2 years** *US$'000*	**Between 2 and 5 years** *US$'000*
At December 31, 2019			
Trade payables	3,506	–	–
Accruals and other payables	10,897	–	–
Short-term bank borrowings	38,462	–	–
Interest payable on short-term bank borrowings	1,353	–	–
Lease liabilities	1,470	1,051	234
Interest payable on lease liabilities	75	39	2
Amount due to a related company	88,193	99,790	–
	143,956	100,880	236

	Within 1 year or on demand *US$'000*	Between 1 and 2 years *US$'000*	Between 2 and 5 years *US$'000*
At December 31, 2020			
Trade payables	1,364	–	–
Accruals and other payables	11,081	–	–
Short-term bank borrowings	39,898	–	–
Interest payable on short-term bank borrowings	541	–	–
Lease liabilities	922	496	61
Interest payable on lease liabilities	32	17	3
Loans from related companies	–	10,186	–
Interest payable on loans from related companies	306	–	–
	54,144	10,699	64
At December 31, 2021			
Trade payables	2,174	–	–
Accruals and other payables	9,877	–	–
Lease liabilities	1,483	1,327	1,172
Interest payable on lease liabilities	92	49	14
	13,626	1,376	1,186
At June 30, 2022			
Trade payables	3,875	–	–
Accruals and other payables	11,391	–	–
Amount due to a joint venture	129	–	–
Lease liabilities	1,396	1,315	1,342
Interest payable on lease liabilities	87	50	28
	16,878	1,365	1,370

3.2 Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

The Group monitors capital on the basis of the debt to asset ratio. The capital structure of the Group consists of borrowings and shareholders' equity. Capital is managed so as to maximize the return to shareholders while maintaining a capital base to allow the Group to operate effectively in the marketplace and sustain future development of the business. This ratio is calculated as total liabilities divided by total assets.

The Group's total liabilities and total assets positions and debt to asset ratio as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
Total liabilities (US$'000)	247,983	68,750	85,415	26,054
Total assets (US$'000)	95,692	103,646	268,527	278,780
Debt to asset ratio	259.1%	66.3%	31.8%	9.3%

The debt to asset ratio decreased from 259.1% as at December 31, 2019 to 66.3% as at December 31, 2020 as a result of additional contribution from shareholders. The ratio was decreased to 31.8% as at December 31, 2021 mainly due to the increase in total assets in relation to the cash proceeds received upon issuance of convertible redeemable preferred shares. The ratio was decreased to 9.3% as at June 30, 2022 mainly due to the capitalization of convertible redeemable preferred shares.

3.3 Fair value estimation

The table below analyzes the Group's financial instruments carried at fair value as at December 31, 2019, 2020 and 2021 and June 30, 2022 by level of the inputs to valuation techniques used to measure fair value. Such inputs are categorised into three levels within a fair value hierarchy as follows:

- **Level 1:** The fair value of financial instruments traded in active markets is based on quoted market prices at the end of the reporting period. These instruments are included in level 1.

- **Level 2:** The fair value of financial instruments that are not traded in an active market is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

- **Level 3:** If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

The following table presents the Group's assets and liabilities that are measured at fair value as at December 31, 2019, 2020 and 2021 and June 30, 2022:

	Level 1	Level 2	Level 3	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*
As at December 31, 2019				
Financial asset				
Financial asset at fair value through profit or loss				
– Life insurance policies	–	–	1,829	1,829
Financial liability				
Retirement benefit obligations	–	–	2,227	2,227

	Level 1	Level 2	Level 3	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*
As at December 31, 2020				
Financial asset				
Financial asset at fair value through profit or loss				
– Life insurance policies	–	–	2,048	2,048
Financial liability				
Retirement benefit obligations	–	–	2,541	2,541

	Level 1	Level 2	Level 3	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*
As at December 31, 2021				
Financial asset				
Financial asset at fair value through profit or loss				
– Life insurance policies	–	–	2,041	2,041
Financial liability				
Retirement benefit obligations	–	–	2,755	2,755

	Level 1	Level 2	Level 3	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*
As at June 30, 2022				
Financial assets				
Financial assets at fair value through profit or loss				
– Life insurance policies	–	–	1,793	1,793
– The Commodity Linked Fixed Rate Note	–	18,734	–	18,734
	–	18,734	1,793	20,527
Financial liability				
Retirement benefit obligations	–	–	2,208	2,208

The following table presented the changes in level item including financial assets at fair value through profit or loss during the Track Record Period.

The Group

	Financial assets at fair value through profit or loss			
	December 31, 2019	**December 31, 2020**	**December 31, 2021**	**June 30, 2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*
Beginning of year/period	1,745	1,829	2,048	2,041
Addition	341	390	407	20,180
Disposal	(333)	(194)	(166)	(16)
Fair value change	60	(76)	(29)	(1,347)
Currency translation differences	16	99	(219)	(331)
At end of year/period	1,829	2,048	2,041	20,527

The Company

	The Commodity Linked Fixed Rate Note	
	December 31, 2021	**June 30, 2022**
	US$'000	*US$'000*
Beginning of period	–	–
Addition	–	20,000
Fair value change	–	(1,266)
End of period	–	18,734

The change in level 3 instruments of convertible redeemable preferred shares and retirement benefit obligations are presented in Note 29 and 30 respectively.

There were no transfers between levels during the year/period.

(a) Financial instrument in Level 2

The fair value of the Commodity Linked Fixed Rate Note that is not traded in an active market is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates. If all significant inputs required to fair value of an instrument are observable, the instrument is included in level 2. Level 2 instrument of the Group's asset included the Commodity Linked Fixed Rate Note measured at fair value through profit or loss.

(b) Financial instrument in Level 3

If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. Life insurance policies under the Group's financial assets at fair value through profit or loss were included in level 3. The fair value of the financial assets at fair value through profit or loss is determined based on investment portion of the cash surrender value which is not an observable input.

Life insurance policies

A subsidiary in Japan entered into life insurance policies with an insurance company to insure the employees of the subsidiary and the subsidiary is the holder and beneficiary of these policies.

The subsidiary is required to pay monthly insurance premiums determined by the insurance company. The subsidiary may request a surrender to the policy at any time, such as upon employee resignation or retirement, and receive cash based on the cash surrender value of the policies at the date of surrender.

An independent valuation of the Group's financial assets at fair value through profit or loss was performed by a qualified valuer to determine the fair value of the life insurance policies as at December 31, 2019, 2020 and 2021 and June 30, 2022. These valuation results are then reported to the senior management of the Group for discussions in relation to the valuation processes and the reasonableness of valuation results. The fair value gains or losses are included in "other gains/(losses) – net" for the Track Record Period.

The valuation was determined using discounted cash flow ("DCF") projections based on significant unobservable inputs. These inputs include:

Discount rate	Reflecting current market assessments of the uncertainty in the amount and timing of cash flows
Mortality rate	Based on the life table revised in 2019, 2020, 2021 and 2022 published by the Ministry of Health, Labor and Welfare of Japan
Employee turnover rate	Based on a three year historical rate of the subsidiary in Japan
Surrender rate	Based on figures published by the insurance company

There were no changes to the valuation techniques during the Track Record Period.

Description	Unobservable inputs	Range of unobservable inputs at December 31 2019	Range of unobservable inputs at December 31 2020	Range of unobservable inputs at December 31, 2021	Range of unobservable inputs at June 30, 2022
Life insurance policies	Discount rate	0.1% – 0.4%	0.1% – 0.6%	0.1% – 0.8%	0.1% – 1.3%

The sensitivity of the life insurance policies to changes in the weighted principal assumptions is:

	Impact on financial assets at fair value through profit or loss		
	Change in assumption	Increase in assumption	Decrease in assumption
At December 31, 2019			
Discount rate	0.5%	Decrease by 7.77%	Increase by 8.54%
At December 31, 2020			
Discount rate	0.5%	Decrease by 7.93%	Increase by 8.74%
At December 31, 2021			
Discount rate	0.5%	Decrease by 5.9%	Increase by 6.4%
At June 30, 2022			
Discount rate	0.5%	Decrease by 5.4%	Increase by 5.8%

The sensitivity of other unobservable inputs are not expected to have significant impact on the fair value of financial assets at fair value through profit or loss as at December 31, 2019, 2020 and 2021 and June 30, 2022.

4 CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

(a) Impairment of financial assets

The loss allowances for financial assets are based on assumptions about risk of default and expected loss rates. The group uses judgement in making these assumptions and selecting the inputs to the impairment calculation, based on the Group's past history, existing market conditions as well as forward looking estimates at the end of each reporting period.

(b) Provision for inventories

The Group's management reviews the condition of inventories at each reporting date and makes provision for inventories that are identified as obsolete, slow-moving or no longer recoverable or suitable for use in production. The Group carries out the inventory review on a product-by-product basis and makes allowances by reference to the latest market prices and current market conditions.

(c) Useful lives of property, plant and equipment and intangible assets

The Group's management determines the estimated useful lives and related depreciation charges for the Group's property, plant and equipment with reference to the estimated periods that the Group intends to derive future economic benefits from the use of these assets. Management will revise the depreciation charges where useful lives are different to that of previously estimated, or it will write off or write down technically obsolete or non-strategic assets that have been abandoned or sold. Actual economic lives may differ from estimated useful lives. Periodic review could result in a change in depreciable lives and therefore depreciation expense in future periods.

The Group's intangible assets included capitalized development costs and customer relationship. Management determines the estimated useful lives and related amortization charges for the capitalized development costs with reference to the estimated periods that the Group intends to derive future economic benefits from the use of these assets. For customer relationship arising from business combination, management determines the estimated useful life and related amortization charges based on historical attrition rates of customers. Management will revise the amortization charges where useful lives are different to that of previously estimated, or it will write-off or write-down technically obsolete or non-strategic assets that have been abandoned or sold. Actual useful lives may differ from estimated useful lives. Periodic review could result in a change in depreciable lives and therefore amortization expense in future periods.

(d) Impairment of property, plant and equipment

Property, plant and equipment are reviewed for possible impairments whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The recoverable amounts are determined based on value-in-use calculation. The value-in-use calculation involves estimating the future cash inflows and outflows to be derived from continuing use of the asset and applying the appropriate discount rate to those future cash flows. The estimation of future cash flows and selection of discount rate require the use of judgments and estimates. Management believes that any reasonably foreseeable change in any of the above key elements in the value-in-use calculation would not result in material additional impairment charges.

(e) Research and development costs

Research costs are expensed as incurred. Costs incurred on development projects relating to the design and testing of new or improved products are recognized as an intangible asset when the technical feasibility and intention of completing the product under development has been demonstrated and the resources are available to do so, costs are identifiable and there is an ability to sell or use the asset that will generate probable future economic benefits.

Significant judgement is required in determining the capitalization of development costs. Development costs that are recognized as assets are amortized on the straight-line basis to reflect the pattern in which the related economic benefits are recognized. Development costs that do not meet the above criteria are expensed as incurred.

The research and development costs which do not meet these criteria and recognized in the consolidated statements of profit or loss are determined based on estimated budgeted costs, known services received and progress report from the service vendors. If the actual research and development expenses were different from the estimate, this would have an impact on the research and development expenses recognized in the following reporting period. The Group regularly reviews and revises the estimation of the amounts of the research and development costs recognized in the consolidated statements of profit or loss as the project progresses. Management regularly reviews the progress of the projects and the corresponding cost budgets.

(f) Income taxes

The Group is subject to income taxes in numerous jurisdictions. Significant judgement is required in determining the worldwide provision for income taxes. There are many transactions and calculations for which the ultimate tax determination is uncertain. The Group recognizes liabilities for anticipated tax audit issues based on estimates of whether additional taxes will be due. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

Deferred income tax assets relating to certain temporary differences and tax losses are recognized when management considers it is probable that future taxable profits will be available against which the temporary differences or tax losses can be utilized. When the expectation is different from the original estimate, such differences will impact the recognition of deferred income tax assets and taxation charges in the period in which such estimate is changed.

(g) Fair value of financial assets at fair value through profit or loss

The Group's subsidiary in Japan entered into life insurance policies with an insurance company to insure the employees of a subsidiary. These life insurance policies allow the subsidiary to request a surrender to the policy at any time, such as upon employee resignation or retirement, and receive cashback based on the cash surrender value of the policies at the date of surrender.

The fair value of these insurance contracts is determined by using valuation techniques. The Group uses its judgment to select the valuation method and make assumptions that are mainly based on market conditions existing at the end of each reporting period. Details of the assumptions and judgments used by the Group to determine the fair value of financial assets are disclosed in Note 3.3.

(h) Valuation of convertible redeemable preferred shares

The Preferred Shares issued by the Group are not traded in an active market and the respective fair value is determined by using valuation techniques. The Group has used the discounted cash flow method to determine the underlying equity value of the Group and adopted equity allocation model to determine the fair value of the Preferred Shares. Key assumptions, such as discount rate, risk-free interest rate, lack of marketability discount ("DLOM") and volatility are disclosed in Note 29. For Preferred Shares carried at amortized cost, management judgement and estimates in relation to the timing and manner of their settlement are also involved in determining the carrying amount of such preferred shares.

5 REVENUE AND SEGMENT INFORMATION

The CODM considers the business from a product perspective which is manufacturing, trading, sales and marketing of medical devices/instruments used for the treatment of coronary artery diseases. The CODM regularly reviews the financial information of the [**REDACTED**] which is the same as the Historical Financial Information of the Group, for the purposes of allocating resources and assessing its performance, so only one operating segment of the Group and, no separate segmental analysis is presented in these consolidated financial statements.

The amounts provided to the CODM with respect to total assets and total liabilities are measured in a manner consistent with that in the consolidated balance sheets.

The revenue recognized during the Track Record Period are as follows:

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Sales of goods – at point in time	96,342	88,472	116,462	57,339	68,851

Geographical information

The Group is organized on a worldwide basis. The analysis of revenue by geographical area is as follows:

	Europe, Middle East & Africa ("EMEA")	**Japan**	**Asia Pacific region, except Japan and the PRC ("APAC")**	**The PRC**	**United States**	**Total**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Year ended December 31, 2019						
Revenue	62,739	29,357	63,984	44,235	4,326	204,641
Less: inter-segment revenue	(35,318)	–	(37,015)	(35,966)	–	(108,299)
Revenue from external customers	27,421	29,357	26,969	8,269	4,326	96,342
Year ended December 31, 2020						
Revenue	64,586	28,164	63,023	38,910	7,288	201,971
Less: inter-segment revenue	(40,158)	–	(39,478)	(33,863)	–	(113,499)
Revenue from external customers	24,428	28,164	23,545	5,047	7,288	88,472

	Europe, Middle East & Africa ("EMEA")	Japan	Asia Pacific region, except Japan and the PRC ("APAC")	The PRC	United States	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Year ended December 31, 2021						
Revenue	78,936	29,807	79,027	56,744	7,468	251,982
Less: inter-segment revenue	(44,814)	–	(51,039)	(39,667)	–	(135,520)
Revenue from external customers	34,122	29,807	27,988	17,077	7,468	116,462
Six months ended June 30, 2022						
Revenue	35,115	17,134	41,368	31,341	7,012	131,970
Less: inter-segment revenue	(18,548)	–	(26,549)	(18,022)	–	(63,119)
Revenue from external customers	16,567	17,134	14,819	13,319	7,012	68,851
(Unaudited) Six months ended June 30, 2021						
Revenue	38,989	14,748	36,507	25,995	4,129	120,368
Less: inter-segment revenue	(21,088)	–	(22,886)	(19,055)	–	(63,029)
Revenue from external customers	17,901	14,748	13,621	6,940	4,129	57,339

The non-current assets information below is based on the location of assets other than financial instruments and deferred income tax assets.

	As at December 31,			As at June 30,
	2019	2020	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
EMEA	915	3,510	4,286	3,638
Japan	1,174	2,103	1,594	1,212
APAC	3,332	6,884	10,417	10,726
The PRC	9,957	9,011	8,906	9,035
United States	869	2,029	2,541	2,604
	16,247	23,537	27,744	27,215

Information about major customers

The revenue from external parties is derived from numerous external customers and the revenue reported to the CODM is measured in a manner consistent with that in the Historical Financial Information.

No external customers of the Group individually accounted for over 10% of the Group's revenue during the Track Record Period.

6 OTHER INCOME – NET

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Government grants *(Note)*	1,066	2,333	1,166	670	320
Others	96	73	219	4	73
	1,162	2,406	1,385	674	393

Note: Government grants mainly comprise subsidies received from the Government of the Hong Kong Special Administrative Region and various local governments in the PRC. There were no unfulfilled conditions and other contingencies attached to the receipts of those grants.

7 OTHER GAINS/(LOSSES) – NET

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net foreign exchange gains/(losses)	365	1,016	(903)	(453)	(1,197)
Losses on disposals of property, plant and equipment	(48)	(3)	(83)	(24)	–
Written off of property, plant and equipment	–	–	–	–	(311)
Realized losses on disposals of financial assets at fair value through profit or loss *(Note 18)*	(41)	(37)	(22)	(9)	(5)
Unrealized gains/(losses) of fair value change in financial asset at fair value through profit or loss *(Note 18)*	60	(76)	(29)	(33)	(1,347)
Gain on lease modification	2	–	–	–	2
Gain on disposals of subsidiaries	–	10	–	–	–
Others	–	(6)	17	6	4
	338	904	(1,020)	(513)	(2,854)

8 EXPENSES BY NATURE

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Cost of inventories recognized as expense (included write-down of inventories to net realizable value)	16,347	16,298	17,896	8,416	11,680
Employee benefit expenses *(Note 9)*	39,843	36,803	45,007	22,103	24,332
Depreciation of property, plant and equipment	2,388	2,474	2,255	1,180	953
Depreciation of right-of-use assets	1,585	1,441	1,288	627	755
Amortization of intangible assets	3	176	476	227	254
Short-term lease expense in respect of office premises	951	946	1,141	586	525
Royalty expenses	2,759	2,440	2,824	1,575	1,706
Auditors' remuneration	457	460	352	291	82
Marketing and advertising expenses	4,738	2,654	2,910	1,002	1,971
Legal and professional fees	2,511	3,277	2,146	1,386	1,749
(Reversal of clinical trial accruals)/clinical trial expenses	(2,599)	1,174	643	306	49
Travel and entertainment expenses	5,363	2,170	1,951	803	1,098
Testing material expenses	2,002	2,053	1,848	997	1,124
Commission expenses	1,795	1,251	1,352	686	669
Delivery and warehouse charge	1,738	1,874	2,579	1,189	1,377
Transportation expenses	694	509	571	287	278
Telecommunication expenses	390	320	297	158	138
Insurance expenses	565	617	581	344	381
[REDACTED]	–	–	[REDACTED]	[REDACTED]	[REDACTED]
Other expenses	6,916	7,082	6,731	2,803	3,350
	88,446	84,019	97,496	45,458	55,070

9 EMPLOYEE BENEFIT EXPENSE (INCLUDING DIRECTORS' REMUNERATION)

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Salaries, wages and allowances	34,913	31,926	36,270	17,597	19,998
Pension costs – defined contribution plans	2,845	3,871	5,006	2,774	2,525
Pension costs – defined benefit plans *(Note 30)*	346	164	337	172	153
Share options granted to directors and employees	–	–	1,339	670	368
Other staff benefits	1,739	842	2,055	890	1,288
	39,843	36,803	45,007	22,103	24,332

(a) Pension costs – defined contribution plans

There were no forfeited contributions (by employers on behalf of employees who leave the scheme prior to vesting fully in such contributions) to offset existing contributions under the defined contributions schemes.

(b) Directors' emoluments

The remuneration of individual director of the **[REDACTED]** paid or payable by the Group for the Track Record Period are set out below:

For the year ended December 31, 2019

Name of directors	Fees	Salaries	Discretionary bonuses	Allowance and benefits in kind	Employer's contribution to a retirement benefit scheme	Other emoluments paid or receivable in respect of director's other services in connection with the management of the affairs of the [REDACTED]	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Executive directors							
Mr. David Chien	–	308	26	–	2	–	336
Ms. Lau Kwai Ching Denise	–	277	23	–	2	–	302
Mr. Chen Wing Shing	–	252	53	6	2	–	313
Mr. Chow Ching Chung John	–	216	–	9	16	–	241
	–	1,053	102	15	22	–	1,192

For the year ended December 31, 2020

Name of directors	Fees	Salaries	Discretionary bonuses	Allowance and benefits in kind	Employer's contribution to a retirement benefit scheme	Other emoluments paid or receivable in respect of director's other services in connection with the management of the affairs of the [REDACTED]	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Executive directors							
Mr. David Chien	–	320	13	–	2	–	335
Ms. Lau Kwai Ching Denise	–	288	12	–	2	–	302
Mr. Chen Wing Shing	–	293	12	15	2	–	322
Mr. Chow Ching Chung John	–	224	–	9	16	–	249
	–	1,125	37	24	22	–	1,208

For the year ended December 31, 2021

Name of directors	Fees	Salaries	Discretionary bonuses	Allowance and benefits in kind	Employer's contribution to a retirement benefit scheme	Other emoluments paid or receivable in respect of director's other services in connection with the management of the affairs of the [REDACTED]	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Executive directors							
Mr. David Chien	–	326	27	–	2	–	355
Ms. Lau Kwai Ching Denise	–	294	24	–	2	–	320
Mr. Chen Wing Shing	–	299	149	17	2	29	496
Mr. Chow Ching Chung John	–	229	–	9	17	15	270
Mr. Zhou Yi	–	–	–	–	–	–	–
	–	1,148	200	26	23	44	1,441

For the six months ended June 30, 2022

Name of directors	Fees	Salaries	Discretionary bonuses	Allowance and benefits in kind	Employer's contribution to a retirement benefit scheme	Other emoluments paid or receivable in respect of director's other services in connection with the management of the affairs of the [REDACTED]	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Executive directors							
Mr. David Chien	–	385	32	–	1	–	418
Ms. Lau Kwai Ching Denise	–	231	19	–	1	–	251
Mr. Chen Wing Shing	–	177	15	11	1	15	219
Mr. Chow Ching Chung John	–	117	–	3	8	7	135
Mr. Zhou Yi	–	–	–	–	–	–	–
	–	910	66	14	11	22	1,023

For the six months ended June 30, 2021

Name of directors	Fees	Salaries	Discretionary bonuses	Allowance and benefits in kind	Employer's contribution to a retirement benefit scheme	Other emoluments paid or receivable in respect of director's other services in connection with the management of the affairs of the [REDACTED]	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
(Unaudited)							
Executive directors							
Mr. David Chien	–	163	14	–	1	–	178
Ms. Lau Kwai Ching Denise	–	147	12	–	1	–	160
Mr. Chen Wing Shing	–	149	12	9	1	16	187
Mr. Chow Ching Chung John	–	114	–	4	8	8	134
	–	573	38	13	11	24	659

The remuneration shown above represented remuneration received from the Group by these directors in their capacity as employees to the [**REDACTED**] and no directors waived any emolument during each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022.

No director fees were paid to these directors in their capacity as directors of the Company or the [**REDACTED**] and no emoluments were paid by the Company or the [**REDACTED**] to the directors as an inducement to join the Company or the Operating Companies, or as compensation for loss of office during each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022.

Mr. David Chien, Ms. Lau Kwai Ching Denise, Mr. Chen Wing Shing and Mr. Chow Ching Chung, John were appointed as the Company's executive director on July 22, 2021. Mr. Zhou Yi was appointed as the Company's director on September 28, 2021 and redesignated as the Company's non-executive director on [date]. Mr. Chan Yip Keung, Mr. Lau Ka Keung and Ms. Tam Lai Fan, Gloria were appointed as the Company's independent non-executive directors on [date]. During the Track Record Period, the non-executive directors and independent non-executive directors had not yet been appointed and did not receive any remuneration in their capacity as the Company's directors.

(c) Directors' retirement and termination benefits

None of the directors received any other retirement benefits or termination benefits during the Track Record Period.

(d) Consideration provided to third parties for making available directors' services

During the Track Record Period, no consideration was provided to or receivable by third parties for making available directors' services.

(e) Information about loans, quasi-loans and other dealings in favour of directors, controlled bodies corporate by and connected entities with such directors

There were no loans, quasi-loans and other dealings in favour of directors, controlled bodies corporate by and connected entities with such directors during the Track Record Period.

(f) Directors' material interests in transactions, arrangements or contracts

Save as disclosed in Note 39, no significant transactions, arrangements and contracts in relation to the Group's business to which the Group was a party and in which a director of the Group had a material interest, whether directly or indirectly, subsisted at the end of each reporting period or at any time during the Track Record Period.

(g) Five highest paid individuals

For each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022, the five individuals whose emoluments were the highest in the Group include nil, two, two, two and three directors, whose emoluments were reflected in Note 9(a). The emoluments paid to the remaining five, three, three, three and two individuals, respectively, are as follows:

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000 (Unaudited)*	*US$'000*
Salaries, wages and allowances	2,422	1,215	1,353	750	583
Share options granted	–	–	77	43	26
Pension costs – defined contribution plans	15	16	21	12	11
Pension costs – defined benefit plans	11	11	11	5	5
Other long-term benefits	17	18	20	10	9
	2,465	1,260	1,482	820	634

The emoluments of above individuals are within the following bands:

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
				(Unaudited)	
HK$1,000,001 – HK$1,500,000 (equivalent to US$128,205 – US$192,307)	–	–	–	1	–
HK$2,000,001 – HK$2,500,000 (equivalent to US$256,411 – US$320,513)	–	–	–	1	1
HK$2,500,001 – HK$3,000,000 (equivalent to US$320,514 – US$384,615)	2	1	1	1	1
HK$3,000,001 – HK$3,500,000 (equivalent to US$384,616 – US$448,718)	1	1	–	–	–
HK$3,500,001 – HK$4,000,000 (equivalent to US$448,719 – US$512,821)	–	–	–	–	–
HK$4,000,001 – HK$4,500,000 (equivalent to US$512,822 – US$576,923)	–	1	1	–	–
HK$4,500,001 – HK$5,000,000 (equivalent to US$576,924 – US$641,026)	1	–	1	–	–
HK$5,000,001 – HK$5,500,000 (equivalent to US$641,027 – US$705,128)	–	–	–	–	–
HK$5,500,001 – HK$6,000,000 (equivalent to US$705,129 – US$769,231)	1	–	–	–	–
	5	3	3	3	2

No incentive payment for joining the Group or compensation for loss of office was paid or payable to any of the five highest paid individuals during the Track Record Period.

10 FINANCE COSTS – NET

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000* (Unaudited)	*US$'000*
Finance income:					
– Interest income from bank deposits	20	11	12	6	249
– Interest income from a loan to an employee	1	1	–	–	–
	21	12	12	6	249
Finance costs:					
– Interest expense on bank borrowings	(381)	(1,258)	(525)	(403)	(11)
– Interest expense on lease liabilities	(120)	(77)	(76)	(40)	(57)
– Interest expense to related companies	–	(67)	(151)	(128)	–
– Unwinding of interests on convertible redeemable preferred shares	–	–	(4,853)	(476)	(1,336)
– Others	(2)	(3)	(2)	(1)	(3)
	(503)	(1,405)	(5,607)	(1,048)	(1,407)
Finance costs – net	(482)	(1,393)	(5,595)	(1,042)	(1,158)

11 INCOME TAX EXPENSE

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000* (Unaudited)	*US$'000*
Current income tax:					
Current income tax on profits for the year/period	562	688	2,556	1,333	1,106
(Over)/under-provision in prior year/period	(30)	61	(98)	(391)	(190)
	532	749	2,458	942	916
Deferred income tax:					
Relating to the origination and reversal of temporary differences *(Note 17)*	790	(565)	668	716	736
Recognition of previously unrecognized deferred income tax assets *(Note 17)*	(773)	–	–	–	–
	17	(565)	668	716	736
	549	184	3,126	1,658	1,652

The Group is primarily subject to the Hong Kong profits tax, PRC corporate income tax, Japan corporate income tax and the Netherlands corporate income tax.

(a) Hong Kong profits tax

The applicable profits tax rate in Hong Kong is 16.5%, 16.5%, 16.5% 16.5% and 16.5% for the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022 respectively.

(b) PRC corporate income tax

OrbusNeich Medical (Shenzhen) Company Limited ("OrbusNeich Shenzhen") is qualified as the National High and New Technology Enterprise ("HNTE"), which was valid for three years from January 1, 2017 to December 31, 2019 and further renewed the HNTE certificate on December 11, 2020 with the validity of three years therefrom. According to the CIT Law, the enterprise qualifying the HNTE status is entitled to the 15% reduced CIT rate subject to a record-filing to the in-charge tax bureau. OrbusNeich Shenzhen had completed the record-filing with Shenzhen local tax bureau. As such, the applicable CIT rate is 15%, 15%, 15%, 15% and 15% for the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022 respectively.

(c) Japan corporate income tax

The applicable corporate income tax in Japan is 33.58%, 33.58%, 33.58%, 30.62% and 33.58% for the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022 respectively.

(d) The Netherlands corporate income tax

For the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022, Netherlands corporate income tax has been provided for at the rate of 25%, 25%, 25%, 25% and 25.8% respectively on the estimated assessable profits of Netherlands subsidiaries.

The tax on the Group's profit/(loss) before income tax differs from the theoretical amount that would arise using the weighted average tax rate applicable to profits of the consolidated entities as follows:

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Profit/(loss) before income tax	7,507	7,255	(1,318)	4,979	9,689
Tax calculated at domestic tax rates applicable to profit/(loss) in the respective countries/regions	5,307	513	2,425	949	503
Income not subject to tax	(1,223)	(1,719)	(1,291)	(635)	(498)
Expenses not deductible for tax purposes	1,109	721	1,178	1,133	915
Effect of unrecognized temporary differences	(257)	402	(347)	(93)	370
Effect of unrecognized tax losses	1,717	323	1,763	824	1,226
Recognition of previously unrecognized deferred income tax assets	(773)	–	–	–	–
Utilization of previously unrecognized tax losses	(5,301)	(117)	(504)	(129)	(674)
(Over)/under-provision in prior years/periods	(30)	61	(98)	(391)	(190)
Income tax expense	549	184	3,126	1,658	1,652

12 Dividend

No dividend has been paid or declared by the Company for the Track Record Period.

13 Earnings/(loss) per share

(a) Basic earnings/(loss) per share

The basic earnings/(loss) per share is calculated based on the profit attributable to equity holders of the Company for the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022 divided by the weighted average number of shares in issue during the year. The weighted average number of ordinary shares used for such purpose has been retrospectively adjusted for the effect of the issuance of 2,884,499,620 shares of the Company in connection with the Reorganisation completed on September 28, 2021 deemed to have been in issue since January 1, 2019.

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
				(Unaudited)	
Profit/(loss) attributable to owners of the Company (US$'000)	6,958	7,071	(4,444)	3,321	8,037
Weighted average number of ordinary shares in issue (thousand shares)	2,884,500	2,884,500	2,884,500	2,884,500	2,884,500
Basic earnings/(loss) per share (US$ cents)	0.24	0.25	(0.15)	0.12	0.28

(b) Diluted earnings/(loss) per share

Diluted earnings/(loss) per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

For the years ended December 31, 2019 and 2020 there were no dilutive potential ordinary shares of the Company outstanding.

For the year ended December 31, 2021, the Company had share options (Note 27) and convertible redeemable preferred shares (Note 29) that are potential ordinary shares. As the Company incurred loss for the year ended December 31, 2021, these potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, the amount of diluted loss per share for the year ended December 31, 2021 were the same as basic loss per share of the year.

For the six months ended June 30, 2021, since the incremental earning per shares arising from convertible redeemable preferred shares is greater than the basic earning per share at the continuing operation, these potential ordinary shares were not included in the calculation of diluted earnings per share as their inclusion would be anti-dilutive. Accordingly, the amount of diluted earnings per share for the six months ended June 30, 2021 were the same as basic earnings per share of the period.

For the six months ended June 30, 2022, the diluted earnings per share have been calculated as follows:

Diluted earnings per share is calculated by dividing the profit attributable to owners of the Company by the weighted average number of ordinary shares outstanding during the financial year/period.

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
				(Unaudited)	
Profit/(loss) attributable to owners of the Company (US$'000)	6,958	7,071	(4,444)	3,321	8,037
Adjustment for convertible redeemable preferred shares	–	–	–	–	1,336
Adjusted profit/(losses) attributable to owners of the Company	6,958	7,071	(4,444)	3,321	9,373
Weighted average number of ordinary shares in issue (thousand shares)	2,884,500	2,884,500	2,884,500	2,884,500	2,884,500
Adjustments for:					
Weighted average number of convertible redeemable preferred shares and share options (thousand shares)	–	–	–	–	1,031,000
Weighted average number of ordinary shares for diluted earnings per share (thousand shares)	2,884,500	2,884,500	2,884,500	2,884,500	3,915,500
Diluted earnings/(loss) per share (US$ cents)	0.24	0.25	(0.15)	0.12	0.24

14 Property, plant and equipment

	Buildings	Leasehold improvements	Plant and machinery	Furniture, fixtures and equipment	Motor vehicles	Computer equipment	Construction-in-progress	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At January 1, 2019								
Cost	5,227	4,903	16,379	1,199	663	2,360	1,154	31,885
Accumulated depreciation	(3,988)	(2,466)	(10,018)	(662)	(562)	(1,898)	–	(19,594)
Net book amount	1,239	2,437	6,361	537	101	462	1,154	12,291

	Buildings	Leasehold improvements	Plant and machinery	Furniture, fixtures and equipment	Motor vehicles	Computer equipment	Construction-in-progress	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Year ended December 31, 2019								
Opening net book amount	1,239	2,437	6,361	537	101	462	1,154	12,291
Additions	–	163	837	862	90	177	101	2,230
Transfer	–	71	1,183	–	–	–	(1,254)	–
Disposals	–	(19)	(40)	(10)	(50)	(22)	–	(141)
Depreciation	(179)	(637)	(1,083)	(233)	(74)	(182)	–	(2,388)
Currency translation differences	–	1	1	–	–	–	–	2
Closing net book amount	1,060	2,016	7,259	1,156	67	435	1	11,994
At December 31, 2019								
Cost	5,227	4,622	17,872	1,947	691	2,269	1	32,629
Accumulated depreciation	(4,167)	(2,606)	(10,613)	(791)	(624)	(1,834)	–	(20,635)
Net book amount	1,060	2,016	7,259	1,156	67	435	1	11,994

	Buildings	Leasehold improvements	Plant and machinery	Furniture, fixtures and equipment	Motor vehicles	Computer equipment	Construction-in-progress	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At January 1, 2020								
Cost	5,227	4,622	17,872	1,947	691	2,269	1	32,629
Accumulated depreciation	(4,167)	(2,606)	(10,613)	(791)	(624)	(1,834)	–	(20,635)
Net book amount	1,060	2,016	7,259	1,156	67	435	1	11,994
Year ended December 31, 2020								
Opening net book amount	1,060	2,016	7,259	1,156	67	435	1	11,994
Acquisition of a subsidiary *(Note 38)*	–	4	–	–	–	–	–	4
Additions	–	24	664	155	20	119	17	999
Disposals	–	(1)	(5)	(104)	(4)	(2)	–	(116)
Depreciation	(179)	(664)	(1,128)	(303)	(31)	(169)	–	(2,474)
Currency translation differences	–	4	26	37	3	8	–	78
Closing net book amount	881	1,383	6,816	941	55	391	18	10,485

	Buildings	Leasehold improvements	Plant and machinery	Furniture, fixtures and equipment	Motor vehicles	Computer equipment	Construction-in-progress	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At December 31, 2020								
Cost	5,227	4,458	17,510	1,846	645	2,241	18	31,945
Accumulated depreciation	(4,346)	(3,075)	(10,694)	(905)	(590)	(1,850)	–	(21,460)
Net book amount	881	1,383	6,816	941	55	391	18	10,485

	Buildings	Leasehold improvements	Plant and machinery	Furniture, fixtures and equipment	Motor vehicles	Computer equipment	Construction-in-progress	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At January 1, 2021								
Cost	5,227	4,458	17,510	1,846	645	2,241	18	31,945
Accumulated depreciation	(4,346)	(3,075)	(10,694)	(905)	(590)	(1,850)	–	(21,460)
Net book amount	881	1,383	6,816	941	55	391	18	10,485
Year ended December 31, 2021								
Opening net book amount	881	1,383	6,816	941	55	391	18	10,485
Additions	–	5	208	660	–	129	49	1,051
Transfer	–	–	41	–	–	–	(41)	–
Disposals	–	(39)	(48)	(207)	–	(6)	–	(300)
Depreciation	(179)	(526)	(1,066)	(322)	(19)	(143)	–	(2,255)
Currency translation differences	–	(9)	(37)	(47)	(1)	(13)	–	(107)
Closing net book amount	702	814	5,914	1,025	35	358	26	8,874
At December 31, 2021								
Cost	5,227	4,123	17,240	2,084	393	2,176	26	31,269
Accumulated depreciation	(4,525)	(3,309)	(11,326)	(1,059)	(358)	(1,818)	–	(22,395)
Net book amount	702	814	5,914	1,025	35	358	26	8,874

	Buildings	Leasehold improvements	Plant and machinery	Furniture, fixtures and equipment	Motor vehicles	Computer equipment	Construction-in-progress	Total
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At January 1, 2022								
Cost	5,227	4,123	17,240	2,084	393	2,176	26	31,269
Accumulated depreciation	(4,525)	(3,309)	(11,326)	(1,059)	(358)	(1,818)	–	(22,395)
Net book amount	702	814	5,914	1,025	35	358	26	8,874
Six months ended June 30, 2022								
Opening net book amount	702	814	5,914	1,025	35	358	26	8,874
Additions	–	77	292	133	36	88	189	815
Transfer	–	–	123	–	–	–	(123)	–
Disposals	–	–	(10)	(89)	–	–	–	(99)
Depreciation	(89)	(112)	(490)	(184)	(8)	(70)	–	(953)
Written off	–	–	–	(311)	–	–	–	(311)
Currency translation differences	–	(11)	(37)	(36)	(5)	(18)	–	(107)
Closing net book amount	613	768	5,792	538	58	358	92	8,219
At June 30, 2022								
Cost	5,227	4,136	17,387	1,622	416	2,148	92	31,028
Accumulated depreciation	(4,614)	(3,368)	(11,595)	(1,084)	(358)	(1,790)	–	(22,809)
Net book amount	613	768	5,792	538	58	358	92	8,219

Depreciation expenses have been charged in the following categories in the consolidated statements of profit or loss:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Cost of sales	794	897	855	439	378
Selling and marketing expenses	82	70	77	39	39
General and administrative expenses	919	990	846	452	338
Research and development expenses	593	517	477	250	198
	2,388	2,474	2,255	1,180	953

15 Leases

(a) Amounts recognized in the consolidated balance sheets

The consolidated balance sheets show the following amounts relating to leases:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Right-of-use assets				
Buildings	2,350	1,065	3,681	3,732
Land use right	780	754	728	715
Motor vehicles	188	178	109	45
Office equipment	96	69	49	91
	3,414	2,066	4,567	4,583
Lease liabilities				
Current	1,470	922	1,483	1,396
Non-current	1,285	557	2,499	2,657
	2,755	1,479	3,982	4,053

Additions to the right-of-use assets during each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2022 were approximately US$378,000, US$278,000, US$2,119,000, and US$141,000, respectively.

(b) Amounts recognized in the consolidated statements of profit or loss

The consolidated statements of profit or loss shows the following amounts relating to leases:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Depreciation charge of right-of-use assets					
Land use right	26	26	26	13	13
Buildings	1,461	1,321	1,182	573	713
Motor vehicles	70	66	54	28	17
Office equipment	28	28	26	13	12
	1,585	1,441	1,288	627	755
Expense relating to short-term leases	951	946	1,141	586	525
Interest expense (included in finance cost)	120	77	76	40	57
Gain on lease modification	2	–	–	–	2

The total cash outflow for leases for each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022 was US$2,568,000, US$2,386,000, and US$2,514,000, US$1,333,000 and US$1,280,000.

(c) The Group's leasing activities and how these are accounted for

The Group leases office premises, warehouses, office equipment and motor vehicles. Rental contracts are typically made for fixed periods of 2 to 5 years but may have extension options as described in (d) below. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions.

The Group also obtained the land use right through lease contract with local government in the PRC with 50 years term.

(d) Extension and termination options

Extension and termination options are included in a number of property and equipment leases across the Group. These are used to maximize operational flexibility in terms of managing the assets used in the Group's operations.

16 INVESTMENT IN A SUBSIDIARY

The Company

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
Unlisted shares, at cost	30,265	30,633

The movements of investment in a subsidiary were as follows:

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
Beginning of period	–	30,265
Acquisition of a subsidiary under common control transaction	28,926	–
Share-based payment compensation to employees of subsidiaries	1,339	368
End of period	30,265	30,633

17 DEFERRED INCOME TAX

The analysis of deferred income tax assets are as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Deferred income tax assets	2,967	3,539	2,859	2,123

The gross movements on the deferred income tax account are as follows:

	December 31, 2019 *US$'000*	December 31, 2020 *US$'000*	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
Beginning of year/period	2,971	2,967	3,539	2,859
(Charged)/credited to the consolidated statements of profit or loss *(Note 11)*	(17)	565	(668)	(736)
Exchange difference	13	7	(12)	–
At end of year/period	2,967	3,539	2,859	2,123

The movements in deferred income tax assets during the year/period, without taking into consideration the offsetting of balances within the same tax jurisdiction, is as follows:

Deferred income tax assets	Unrealized profit on inventories *US$'000*	Tax losses *US$'000*	Decelerated tax depreciation *US$'000*	Total *US$'000*
At January 1, 2019	2,971	–	–	2,971
(Charged)/credited to the consolidated statements of profit or loss	(815)	773	25	(17)
Exchange difference	–	13	–	13
At December 31, 2019 and January 1, 2020	2,156	786	25	2,967
Credited/(charged) to the consolidated statements of profit or loss	934	(344)	(25)	565
Exchange difference	–	7	–	7
At December 31, 2020 and January 1, 2021	3,090	449	–	3,539
Charged to the consolidated statements of profit or loss	(314)	(354)	–	(668)
Exchange difference	–	(12)	–	(12)
At December 31, 2021 and January 1, 2022	2,776	83	–	2,859
Charged to the consolidated statements of profit or loss	(729)	(7)	–	(736)
At June 30, 2022	2,047	76	–	2,123

Deferred income tax assets are recognized for tax loss carry-forwards to the extent that the realization of the related tax benefit through future taxable profits is probable. The Group did not recognize deferred income tax assets of US$19,782,000, US$20,627,000, US$20,911,000 and US$21,082,000 in respect of losses amounting to approximately US$89,348,000, US$93,604,000, US$91,898,000 and US$92,152,000 at December 31, 2019, 2020 and 2021 and June 30, 2022, respectively.

The unrecognized estimated tax losses are analyzed by years from expiring as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
With no expiry date	10,968	14,724	9,555	9,004
Within 1 year	–	5	5	5
2 to 5 years	5,053	6,165	6,005	5,078
6 to 10 years	6,742	6,125	9,727	11,450
11 to 21 years	66,585	66,585	66,606	66,615
	89,348	93,604	91,898	92,152

For each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2022, the Group had deductible temporary differences of approximately US$10,609,000, US$12,539,000, US$10,834,000 and US$12,913,000 mainly arising from research and development tax credit, retirement benefit obligations and decelerated depreciation allowance. No deferred tax assets has been recognized in relation to such deductible temporary difference as it is not probable that taxable profit will be available again which the deductible temporary differences can be utilized.

Deferred income tax liabilities of approximately US$4,405,000, US$4,902,000, US$6,179,000 and US$6,771,000 have not been recognized for the withholding tax and other taxes that would be payable on the unremitted earnings of a subsidiary. Such amounts are permanently reinvested. Unremitted earnings totalled US$44,047,000, US$49,023,000, US$61,789,000 and US$67,706,000 at December 31, 2019, 2020 and 2021 and June 30, 2022.

18 FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

The Group

Financial assets measured at fair value through profit or loss include the following:

	December 31, 2019	December 31, 2020	December 31, 2021	June30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Life insurance policies	1,829	2,048	2,041	1,793
The Commodity Linked Fixed Rate Note	–	–	–	18,734
Total	1,829	2,048	2,041	20,527

During the six months ended June 30, 2022, the Company acquired the Commodity Linked Fixed Rate Note, which was issued by a reputable international investment bank. It was classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest. The accounting policy of the Commodity Linked Fixed Rate Note is disclosed in Note 2.9.

Amounts recognized in profit or loss

During the Track Record Period, the following gains/(losses) were recognized in the consolidated statements of profit or loss:

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Realized losses on disposals of financial assets at fair value through profit or loss	(41)	(37)	(22)	(9)	(5)
Unrealized gains/(losses) of fair value change in financial assets at fair value through profit or loss	60	(76)	(29)	(33)	(1,347)

The Company

	December 31, 2021	**June 30, 2022**
	US$'000	*US$'000*
The Commodity Linked Fixed Rate Note	–	18,734

Amounts recognized in profit or loss

	December 31, 2021	**June 30, 2022**
	US$'000	*US$'000*
Unrealized losses of fair value change in financial assets at fair value through profit or loss	–	1,266

Fair value measurements

For information about the methods and assumptions used in determining fair value, please refer to Note 3.3.

19 INTANGIBLE ASSETS

	Capitalized development costs	**Customer relationship**	**Total**
	US$'000	*US$'000*	*US$'000*
Year ended December 31, 2019			
Opening net book amount	–	–	–
Additions	338	–	338
Amortization charge	(3)	–	(3)
Closing net book amount	335	–	335

	Capitalized development costs *US$'000*	Customer relationship *US$'000*	Total *US$'000*
At December 31, 2019			
Cost	338	–	338
Accumulated amortization	(3)	–	(3)
Closing net book amount	335	–	335
Year ended December 31, 2020			
Opening net book amount	335	–	335
Acquisition of a subsidiary *(Note 38)*	–	1,176	1,176
Additions	2,609	–	2,609
Amortization charge	(133)	(43)	(176)
Exchange difference	22	–	22
Closing net book amount	2,833	1,133	3,966
At December 31, 2020			
Cost	2,969	1,176	4,145
Accumulated amortization	(136)	(43)	(179)
Closing net book amount	2,833	1,133	3,966
Year ended December 31, 2021			
Opening net book amount	2,833	1,133	3,966
Additions	894	–	894
Amortization charge	(345)	(131)	(476)
Exchange difference	(117)	–	(117)
Closing net book amount	3,265	1,002	4,267
At December 31, 2021			
Cost	3,737	1,176	4,913
Accumulated amortization	(472)	(174)	(646)
Closing net book amount	3,265	1,002	4,267
Six months ended June 30, 2022			
Opening net book amount	3,265	1,002	4,267
Additions	271	–	271
Amortization charge	(189)	(65)	(254)
Exchange difference	(146)	–	(146)
Closing net book amount	3,201	937	4,138
At June 30, 2022			
Cost	3,835	1,176	5,011
Accumulated amortization	(634)	(239)	(873)
Closing net book amount	3,201	937	4,138

Amortization expenses have been charged in the following categories in the consolidated statements of profit or loss:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Selling and marketing expenses	–	43	131	66	65
Research and development expenses	3	133	345	161	189
	3	176	476	227	254

20 GOODWILL

	US$'000
Opening net book amount as at January 1, 2020	–
Acquisition of a subsidiary *(Note 38)*	1,749
Closing net book amount as at December 31, 2020 and 2021 and June 30, 2022	1,749

The recoverable amount of the cash-generating unit ("CGU") relating to OrbusNeich (Switzerland) AG is determined based on value-in-use calculation. The calculation uses cash flow projections prepared based on financial budgets approved by the management covering a period of three years. Cash flows beyond the budget period is extrapolated using an estimated growth rate which does not exceed the long-term average growth rate in which the CGU operates.

The key parameters used for value-in-use calculations are as follows:

	At December 31, 2020	At December 31, 2021	At June 30, 2022
Revenue growth rate	-5.1% to 28.9%	20.2%	20.7% to 27.5%
Gross margin	56.0%	35.9%	35.9%
Profit margin	12.5% to 17.2%	9.8% to 10.9%	6.8% to 10.8%
Terminal growth rate	0.0%	0.0%	0.0%
Pre-tax discount rate	30.6%	32.9%	32.9%

The revenue growth rate for the forecast period and budgeted gross margin were determined by the management based on past performance and its expectation for market and product development.

As at December 31, 2020 and 2021 and June 30, 2022, the recoverable amount calculated based on the value-in-use calculation exceeded the carrying amount of the CGU by approximately US$184,000, US$178,000 and US$165,000, respectively. The directors of the Company performed sensitivity analysis based on the key assumptions and considered that a reasonable possible changes on the key assumptions would not cause the carrying amount of the CGU to exceed its recoverable amount.

With all other variables held constant, the management estimates the headroom would drop to zero as at December 31, 2020 and 2021 and June 30, 2022, respectively.

	At December 31, 2020	At December 31, 2021	At June 30, 2022
Revenue growth rate	Decrease to -8.6% to 25.4%	Decrease to 19.2%	Decrease to 19.6% to 26.0%
Gross margin	Decrease to 53.0%	Decrease to 35.2%	Decrease to 35.4%
Profit margin	Decrease to 11.3% to 15.3%	Decrease to 9.3% to 10.3%	Decrease to 6.5% to 10.3%
Pre-tax discount rate	Increase to 35.7%	Increase to 37.6%	Increase to 36.4%

In accordance with the Group's accounting policies, goodwill is tested for impairment on an annual basis at each year end. As at December 31, 2020 and 2021 and June 30, 2022, the management is not aware of any significant adverse changes on the development of the Group, which indicates that the carrying amount of the CGU exceeds the recoverable amount.

21 INTEREST IN A JOINT VENTURE

Interest in a joint venture

	December 31, 2019 *US$'000*	December 31, 2020 *US$'000*	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
Share of net assets:				
Beginning of year/period	–	–	5,051	4,844
Addition	–	5,097	–	–
Share of loss of a joint venture	–	(46)	(207)	(71)
End of year/period	–	5,051	4,844	4,773
Advance to a joint venture *(Note)*	–	–	3,044	3,044
	–	5,051	7,888	7,817

Note: During the year December 31, 2021, management reassessed the capital needs of the joint venture and reclassified the amount due from joint venture as part of the Group's net investment in such joint venture. The advance to a joint venture was non-trade in nature, unsecured, interest free and would not be demanded for repayment within 12 months from the end of the reporting period and prior to the [**REDACTED**]. The carrying amount approximate their fair values and are denominated in US$.

Nature of investment in a joint venture:

Name	Registered capital	Place of incorporation	Principal activities	Percentage of interest held December 31, 2019	2020	2021	June 30, 2022
OrbusNeich P+F Company Limited	US$50,000	BVI	Investment holding	–	50%	50%	50%

OrbusNeich P+F Company Limited and its subsidiaries are principal engaged in manufacturing and distribution of heart valve products.

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Current assets	–	460	734	504
Non-current assets	–	4,657	6,986	7,502
Current liabilities	–	(113)	(3,130)	(3,229)
Non-current liabilities	–	–	–	(329)
Net assets	–	5,004	4,590	4,448
Group's share of net assets	–	2,502	2,295	2,224
Goodwill	–	2,549	2,549	2,549
Carrying amount	–	5,051	4,844	4,773

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000* *(Unaudited)*	*US$'000*
Revenue	–	–	129	–	146
Loss for the year/period	–	(92)	(413)	(298)	(142)
Other comprehensive income	–	–	–	–	–
Total comprehensive loss	–	(92)	(413)	(298)	(142)

Commitment in respect of the joint venture:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Commitment to providing funding to a joint venture	–	5,642	5,251	4,845

There are no contingent liabilities relating to the Group's interest in the joint venture.

22 DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

The Group

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Deposits	846	892	970	905
Prepayments	1,102	961	1,179	2,511
Prepaid [**REDACTED**]	–	–	[**REDACTED**]	[**REDACTED**]
Deferred [**REDACTED**]	–	–	[**REDACTED**]	[**REDACTED**]
Other receivables	360	499	693	792
	2,308	2,352	3,723	5,181
Less non-current portion:				
Deposits and other receivables	(472)	(55)	(528)	(547)
Prepayments for property, plant and equipment	(504)	(16)	(195)	(505)
Prepayments for intangible assets	–	(204)	(204)	(204)
	(976)	(275)	(927)	(1,256)
Current portion	1,332	2,077	2,796	3,925

Deposits, prepayments and other receivables are denominated in the following currencies:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
US$	626	329	821	1,823
HK$	517	269	726	1,023
RMB	120	376	570	665
EUR	379	933	1,033	1,014
JPY	506	396	442	303
Other currencies	160	49	131	353
	2,308	2,352	3,723	5,181

The Company

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
Prepaid [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Deferred [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Other prepayments	–	202
Other receivables	–	118
	881	1,293

As at December 31, 2021 and June 30, 2022, the prepayments and other receivables are denominated in the following currencies:

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
US$	396	611
HK$	300	611
RMB	49	31
EUR	127	32
Other currencies	9	8
	881	1,293

The carrying amounts of deposits and other receivables approximate their fair values.

The deposits and other receivables do not contain impaired assets.

The maximum exposure to credit risk at each of the reporting dates is the carrying value of the deposits and other receivables. The Group does not hold any collateral as security.

23 INVENTORIES

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Raw materials	14,251	14,659	14,130	14,210
Work in progress	3,005	3,205	2,597	3,293
Finished goods	8,828	12,238	13,118	11,426
Inventories – gross	26,084	30,102	29,845	28,929
Less: Provision for inventories *(Note)*	(48)	(64)	(275)	(1,029)
	26,036	30,038	29,570	27,900

Note: The cost of inventories recognized as expense and included in 'cost of sales' amounting to approximately US$16,299,000, US$16,282,000, US$17,640,000, US$8,397,000 and US$10,843,000 for each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022, respectively. Provision for inventories amounting to US$48,000, US$16,000, US$256,000, US$19,000 and US$837,000 for each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022, respectively was included in the cost of sales.

24 TRADE RECEIVABLES

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Trade receivables *(Note)*	35,475	28,406	28,391	31,558
Loss allowance	(2,866)	(2,090)	(1,587)	(1,858)
Trade receivables, net	32,609	26,316	26,804	29,700

Note: At December 31, 2019, 2020 and 2021 and June 30, 2022, trade receivables from a related party amounted to approximately US$4,400,000, US$2,170,000, Nil and Nil respectively, as disclosed in Note 39(b).

The majority of the Group's sales are with credit terms of 30 to 180 days. The carrying amounts of trade receivables approximate their fair values.

The ageing analysis of the trade receivables based on invoice date, before provision for impairment, is as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
0 to 30 days	10,221	7,935	11,493	10,790
31 to 60 days	6,483	6,409	6,770	8,180
61 to 90 days	7,189	5,435	4,704	4,592
Over 90 days	11,582	8,627	5,424	7,996
	35,475	28,406	28,391	31,558

Movements in the loss allowance of trade receivables are as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Beginning of year/period	1,514	2,866	2,090	1,587
Movement in loss allowance	1,407	(931)	(109)	402
Trade receivables written off during the year/period as uncollectible	(26)	(15)	(265)	–
Currency translation difference	(29)	170	(129)	(131)
End of year/period	2,866	2,090	1,587	1,858

The Group applies the HKFRS 9 simplified approach to measure expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

Information about the impairment of trade receivables and the Group's exposure to credit risk can be found in Note 3.1(b)(ii).

The carrying amounts of the Group's trade receivables, net are denominated in the following currencies:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
US$	12,658	9,100	5,608	9,048
HK$	1,731	2,204	2,767	2,557
JPY	8,525	8,879	9,209	8,813
EUR	6,242	3,144	4,631	4,173
Other currencies	3,453	2,989	4,589	5,109
	32,609	26,316	26,804	29,700

25 CASH AND CASH EQUIVALENTS, PLEDGED AND SHORT-TERM BANK DEPOSITS

The Group

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Cash at banks and on hand	13,631	15,112	175,886	131,619
Short-term bank deposit *(Note a)*	–	–	–	20,000
Pledged bank deposit *(Note b)*	–	–	–	15,000
	13,631	15,112	175,886	166,619

Notes:

(a) Short-term bank deposits were deposits with original maturities over three months and less than one year and denominated in US$.

(b) Pledged bank deposit represents comfort cash to be maintained with the relevant bank for the banking facilities of the Group and is denominated in US$ (Note 34).

Cash at banks and on hand include the following for the purposes of the consolidated statements of cash flows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Cash and bank balances	13,631	15,112	175,886	86,619
Time deposits with original maturity of less than three months	–	–	–	45,000
	13,631	15,112	175,886	131,619

Cash and cash equivalents are denominated in the following currencies:

	December 31, 2019 *US$'000*	December 31, 2020 *US$'000*	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
US$	3,123	3,315	164,118	112,229
HK$	2,432	314	454	790
RMB	624	722	1,307	3,292
JPY	4,023	6,528	4,291	4,795
EUR	2,110	1,910	1,525	5,723
Other currencies	1,319	2,323	4,191	4,790
	13,631	15,112	175,886	131,619

The conversion of RMB denominated balances into foreign currencies and the remittance of such foreign currencies denominated bank balances and cash out of PRC are subject to the relevant rules and regulations of foreign exchange control promulgated by the PRC government.

As at December 31, 2019, 2020 and 2021 and June 30, 2022, the Group held RMB denominated cash and bank balances totalling approximately US$624,000, US$722,000, US$1,307,000, and US$3,292,000 which were kept in the PRC, the conversion and remittance of which are subject to these rules and regulations.

The Company

	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
Cash at banks	149,104	60,831
Short-term bank deposit *(Note)*	–	20,000
	149,104	80,831

Note: Short-term bank deposits were deposits with original maturities over three months and less than one year and denominated in US$.

Cash at banks include the following:

	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
Cash at banks	149,104	15,831
Time deposits with original maturity of less than three months	–	45,000
	149,104	60,831

Cash and cash equivalents are denominated in the following currencies:

	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
US$	149,100	60,829
HK$	4	2
	149,104	60,831

Interest rates of short-term bank deposit and pledged bank deposit ranged from 0.8% to 1.6% per annum for the six months ended June 30, 2022.

The carrying amounts of cash and cash equivalents, pledged and short-term bank deposits approximate their fair values.

26 SHARE CAPITAL

The Group and Company

	Number of shares	*US$'000*
Authorized:		
Upon incorporation	500,000,000	50
Increase in authorized share capital *(Note b)*	5,500,000,000	550
At December 31, 2021 and June 30, 2022	6,000,000,000	600
Represented by:		
Ordinary shares	5,018,814,933	502
Series A preferred shares *(Note 29)*	234,784,854	23
Series A-2 preferred shares *(Note 29)*	746,400,213	75
At December 31, 2021 and June 30, 2022	6,000,000,000	600
Issued and fully paid:		
Upon incorporation	1	–
Issue of shares *(Note c)*	2,884,499,620	288
At December 31, 2021 and June 30, 2022	2,884,499,621	288

Notes:

(a) The Company was incorporated on July 22, 2021 with 1 ordinary share of US$0.0001 issued and allotted to initial subscriber. On the same day, the initial subscriber transferred one ordinary share at par to Harmony Tree Limited.

(b) Pursuant to a sole shareholder's resolution dated September 28, 2021:

(i) The authorized share capital of the Company was increased to US$600,000 by creation of additional 5,500,000,000 shares of a par value of US$0.0001 each. The authorized share capital became US$600,000, divided into 6,000,000,000 shares of a par value of US$0.0001 each.

(ii) Subsequently, the aforementioned authorized share capital of the Company was reclassified and redesignated into (i) 5,018,814,933 ordinary shares of a par value of US$0.0001 each, (ii) 234,784,854 convertible series A preferred shares of a par value of US$0.0001 each and (iii) 746,400,213 convertible series A-2 preferred shares of a par value of US$0.0001 each.

(c) Pursuant to director's written resolutions dated September 28, 2021, the Company issued 2,884,499,620 ordinary shares of par value of US$0.0001 each to the shareholders of COSMIC in exchange for 1,878,278,823 ordinary shares of par value of US$0.0001 each of COSMIC.

27 SHARE OPTIONS

(a) Share option scheme established by ONM BVI

OrbusNeich Medical Company Limited ("ONM BVI") set up two incentive plans: (1) Class A share option scheme and (2) 2008 Omnibus incentive plan. The directors and selected employees of the Group are eligible to purchase the ordinary share of ONM BVI under these two incentive plans.

Class A share option scheme was established by ONM BVI on May 20, 2005 which remained in force for 10 years and expired on May 19, 2015. No share option can be further granted thereunder, where outstanding share options under the scheme remain valid and exercisable starting 6 years from the grant date. The exercise price of the granted options and vesting condition are determined by the board of directors of ONM BVI and stated in the agreement for such grant, and the exercise price shall not be less the par value of the share of ONM BVI. As at December 31, 2018, 2019 and 2020, the weighted average exercise price were US$0.40, US$0.40 and US$0.40 respectively. All share options are vested during the Track Record Period.

2008 Omnibus incentive plan was established by ONM BVI on December 15, 2008 which remained in force for 10 years and expired on December 14, 2018. No share option can be further granted thereunder, where outstanding share options under the scheme remain valid and exercisable starting 10 years from the grant date. This plan provides for the grant of stock options, stock appreciation rights, restricted stocks, stock units, unrestricted stocks and dividend equivalent rights. Except for stock options, no other awards were granted since its establishment. The exercise price of the granted options and vesting condition are determined by the board of directors of ONM BVI and stated in the agreement for such grant, and the exercise price shall not be less the par value of the share of ONM BVI. As at December 31, 2018, 2019 and 2020, the weighted average exercise price were US$0.40, US$0.40 and US$0.40 respectively. All share options are vested during the Track Record Period.

The outstanding options exercisable were 11,724,587 as at December 31, 2019. During the year ended December 31, 2020, all vested share options were cancelled and no outstanding options as at December 31, 2020 and 2021 were exercisable.

No share option was exercised and granted during the Track Record Period.

(b) Share option scheme established by the Company

ONM Group Ltd., a subsidiary of the Company, set up a share incentive plan: 2020 share option scheme on January 1, 2021 in which the directors and selected employees of the Group are eligible to purchase the ordinary shares of ONM Group Ltd..

On September 28, 2021, due to the Reorganization, the Company renamed the amended scheme as 2021 share option scheme, in which the directors and selected employees of the Group are eligible to purchase the ordinary shares of the Company, instead of ONM Group Ltd..

The share option scheme remained in force for 10 years and expired on January 1, 2031. Outstanding share options under the scheme remain valid and exercisable starting 10 years from the grant date. The exercise price of the granted options and vesting condition are determined by the board of directors of ONM Group Ltd. and stated in the agreement for such grant. The options are vested over periods of one to four years from the grant date and the exercise price of each option ranged from US$0.1 to US$0.2.

During the year ended December 31, 2021, 49,814,500 share options with average exercise price of US$0.18 per share option were issued. There is no share option exercised for the year ended December 31, 2021 and six months ended June 30, 2022.

Share options outstanding at the end of the year/period have the following expiry date and exercise prices:

Expiry date	Exercise price in US$ per share option	Options As at December 31, 2021	Options As at June 30, 2022
2031	0.10	384,500	384,500
2031	0.15	18,150,000	18,150,000
2031	0.20	31,280,000	31,280,000
		49,814,500	49,814,500

The weighted average fair value of options granted during the year ended December 31, 2021 determined using the Polynomial option price model was US$0.0538 per option. The significant input into the model were exercise prices of US$0.10, US$0.15 or US$0.20, spot price of the Company of US$0.128 per share, expected volatility of 56.37% based on the historical volatilities of the comparable companies, 0% expected dividend yield, an expected option life of 10 years and risk-free rate of 0.92%. See Note 9 for the total expense recognized in the consolidated statement of profit or loss for share options granted to directors and selected employees.

28 OTHER RESERVES AND ACCUMULATED LOSSES

	Other reserve *US$'000 (Note (d))*	Currency translation reserve *US$'000*	Statutory reserve *US$'000 (Note (c))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
At January 1, 2019	–	(12,305)	2,503	2,957	(152,188)	(159,033)
Profit for the year	–	–	–	–	6,958	6,958
Other comprehensive income/(loss):						
– Remeasurements of post-employment benefit obligations	–	–	–	–	40	40
– Currency translation differences	–	(256)	–	–	–	(256)
Total other comprehensive (loss)/income, net of tax	–	(256)	–	–	40	(216)
Total comprehensive (loss)/income	–	(256)	–	–	6,998	6,742
Transaction with owner:						
– Employee share option scheme: lapse of share options	–	–	–	(62)	62	–
At December 31, 2019	–	(12,561)	2,503	2,895	(145,128)	(152,291)

	Other reserve *US$'000 (Note (d))*	Currency translation reserve *US$'000*	Statutory reserve *US$'000 (Note (c))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
At January 1, 2020	–	(12,561)	2,503	2,895	(145,128)	(152,291)
Profit for the year	–	–	–	–	7,071	7,071
Other comprehensive (loss)/income:						
– Remeasurements of post-employment benefit obligations	–	–	–	–	(134)	(134)
– Realization of accumulated exchange difference upon dissolution of a subsidiary	–	17	–	–	–	17
– Currency translation differences	–	1,246	–	–	–	1,246
Total other comprehensive income/(loss), net of tax	–	1,263	–	–	(134)	1,129
Total comprehensive income	–	1,263	–	–	6,937	8,200
Transactions with owner:						
– Deemed contribution *(Note 1.2)*	187,828	–	–	–	–	187,828
– Deemed distribution to shareholders *(Note (a))*	(8,841)	–	–	–	–	(8,841)
– Employee share option scheme: lapse of share options	–	–	–	(290)	290	–
Total transactions with owner	178,987	–	–	(290)	290	178,987
At December 31, 2020	178,987	(11,298)	2,503	2,605	(137,901)	34,896

	Other reserve *US$'000 (Note (d))*	Currency translation reserve *US$'000*	Statutory reserve *US$'000 (Note (c))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
At January 1, 2021	178,987	(11,298)	2,503	2,605	(137,901)	34,896
Loss for the year	–	–	–	–	(4,444)	(4,444)
Other comprehensive loss:						
– Remeasurements of post-employment benefit obligations	–	–	–	–	(340)	(340)
– Realization of accumulated exchange difference upon dissolution of subsidiaries	–	(8)	–	–	–	(8)
– Currency translation differences	–	(3,394)	–	–	–	(3,394)
Total other comprehensive loss, net of tax	–	(3,402)	–	–	(340)	(3,742)
Total comprehensive loss	–	(3,402)	–	–	(4,784)	(8,186)
Transactions with owners:						
– Issuance of shares pursuant to share swap *(Note 26(c))*	(288)	–	–	–	–	(288)
– Reclassification of Series A-2 Preferred Shares upon completion of the Reorganization *(Note (b))*	167,193	–	–	–	–	167,193
– Changes in value of Series A Preferred Shares upon completion of the Reorganization	(12,130)	–	–	–	–	(12,130)
– Employee share option scheme: value of employee services	–	–	–	1,339	–	1,339
Total transactions with owners	154,775	–	–	1,339	–	156,114
At December 31, 2021	333,762	(14,700)	2,503	3,944	(142,685)	182,824

	Other reserve *US$'000 (Note (d))*	Currency translation reserve *US$'000*	Statutory reserve *US$'000 (Note (c))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
At January 1, 2022	333,762	(14,700)	2,503	3,944	(142,685)	182,824
Profit for the period	–	–	–	–	8,037	8,037
Other comprehensive (loss)/income:						
– Remeasurements of post-employment benefit obligations	–	–	–	–	246	246
– Currency translation differences	–	(4,084)	–	–	–	(4,084)
Total other comprehensive (loss)/income, net of tax	–	(4,084)	–	–	246	(3,838)
Total comprehensive (loss)/income	–	(4,084)	–	–	8,283	4,199
Transactions with owners:						
– Reclassification from financial liabilities to equity for Series A Preferred Shares *(Note (e))*	65,047	–	–	–	–	65,047
– Employee share option scheme: value of employee services	–	–	–	368	–	368
Total transactions with owners	65,047	–	–	368	–	65,415
At June 30, 2022	398,809	(18,784)	2,503	4,312	(134,402)	252,438

	Other reserve *US$'000 (Note (d))*	Currency translation reserve *US$'000*	Statutory reserve *US$'000 (Note (c))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
(Unaudited)						
At January 1, 2021	178,987	(11,298)	2,503	2,605	(137,901)	34,896
Loss for the period	–	–	–	–	3,321	3,321
Other comprehensive loss:						
– Remeasurements of post-employment benefit obligations	–	–	–	–	(38)	(38)
– Realization of accumulated exchange difference upon dissolution of subsidiaries	–	(8)	–	–	–	(8)
– Currency translation differences	–	(2,056)	–	–	–	(2,056)
Total other comprehensive loss, net of tax	–	(2,064)	–	–	(38)	(2,102)
Total comprehensive (loss)/income	–	(2,064)	–	–	3,283	1,219
Transactions with owners:						
– Employee share option scheme: value of employee services	–	–	–	670	–	670
Total transactions with owners	–	–	–	670	–	670
At June 30, 2021	178,987	(13,362)	2,503	3,275	(134,618)	36,785

The Company

	Other reserve *US$'000 (Note (d))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
Balance as at date of incorporation	–	–	–	–
Loss for the period	–	–	(5,606)	(5,606)
Transactions with owners:				
– Other reserve arising from the Reorganization	28,638	–	–	28,638
– Reclassification of Series A-2 Preferred Shares upon completion of the Reorganization *(Note (b))*	167,193	–	–	167,193
– Changes in value of Series A Preferred Shares upon completion of the Reorganization	(12,130)	–	–	(12,130)
– Employee share option scheme: value of employee services	–	1,339	–	1,339
Total transactions with owners	183,701	1,339	–	185,040
At December 31, 2021	183,701	1,339	(5,606)	179,434

	Other reserve *US$'000 (Note (d))*	Share-based compensation reserve *US$'000*	Accumulated losses *US$'000*	Total *US$'000*
At January 1, 2022	183,701	1,339	(5,606)	179,434
Loss for the period	–	–	(5,144)	(5,144)
Transactions with owners:				
– Reclassification from financial liabilities to equity for Series A Preferred Shares *(Note (e))*	65,047	–	–	65,047
– Employee share option scheme: value of employee services	–	368	–	368
Total transactions with owners	65,047	368	–	65,415
At June 30, 2022	248,748	1,707	(10,750)	239,705

Notes:

(a) Deemed distribution of US$8,841,000 represents the difference between the investment cost of ONM Group Ltd. and the paid-up capital of the shares issued by COSMIC upon the acquisition.

(b) Following the completion of the Reorganization on September 28, 2021, the carrying amount of series A-2 preferred shares of US$167,193,000 was reclassified to equity as (i) the Company only has the obligation to deliver its ordinary shares, and (ii) all the activities that may cause adjustment to the conversion ratio of such preferred shares are within the control of the Company.

(c) Statutory reserve is non-distributable and the transfers of these funds are in accordance with law and regulations in the PRC. The subsidiary established in the PRC is required to make appropriations to certain statutory reserves from profit for the year after offsetting accumulated losses from prior years and before any profit distribution to equity holders. The percentages to be appropriated to different statutory reserves are determined according to the relevant regulations in the PRC or at the discretion of the directors of the subsidiary. Such statutory reserves can only be used to offset accumulated losses, to increase capital, or for special bonus or collective welfare of employees. These statutory reserves cannot be distributed to equity holders of the subsidiary.

(d) The amount as at December 31, 2021 includes 746,400,213 issued Series A-2 Preferred Shares amounting to US$167,193,000. The amount as at June 30, 2022 includes 746,400,213 and 234,784,854 issued Series A and Series A-2 Preferred Shares amounting to US$167,193,000 and US$65,047,000, respectively. The rights and preferences of the Series A and Series A-2 Preferred Shares have been disclosed in Note 29.

(e) During the six months ended June 30, 2022, upon the fulfillment of condition attached in the Series A shares subscription agreement (i.e. the fulfillment of profit target for the year ended December 31, 2021), the conversion adjustment right granted to the holders of Series A Preferred Shares are terminated and therefore all the activities that may cause adjustment to the conversion ratio of the Series A Preferred Shares are within the control of the Company. As such, the Series A Preferred Shares amounting to US$65,047,000 were reclassified from liability to equity and accounted for as other reserve.

29 CONVERTIBLE REDEEMABLE PREFERRED SHARES

On April 27, 2021, pursuant to the initial series A preferred shares subscription agreement, ONM Group Ltd., a subsidiary of the Company issued 234,784,854 series A preferred shares to the Series A Investors. On June 10, 2021, ONM Group Ltd., entered into a share subscription agreement, to issue series A-2 preferred shares to the Series A-2 Investors. Such 746,400,213 series A-2 preferred shares were issued in July 2021 and August 2021 at a consideration of US$167,500,000.

The series A and series A-2 preferred shares are hybrid instruments which contain financial liability hosts and embedded derivatives. The embedded derivatives have been bifurcated from the financial liability hosts and measured at fair value with changes in fair value recognized in the consolidated statements of profit or loss.

Upon the completion of the Reorganization on September 28, 2021, (i) the series A preferred shares held by the Series A Investors were swapped into Series A Preferred Shares of the Company ("Series A Preferred Shares") and (ii) the series A-2 preferred shares held by the Series A-2 Investors were swapped into Series A-2 Preferred Shares of the Company ("Series A-2 Preferred Shares").

In conjunction with the above event, the Company derecognized the financial liability host and embedded derivative for series A convertible redeemable preferred shares, and instead recognized a new financial liability at amortized cost amounting to US$62,374,000, measured at the present value of the expected redemption amount. The Company also reclassified the financial liability host and embedded derivative for series A-2 convertible redeemable preferred shares to equity. Due to the derecognition and reclassification, a loss of US$559,000 was charged to profit or loss.

In April 2022, the condition attached in the Series A share subscription agreement has been fulfilled, as such the financial liabilities in relation to the Series A preferred shares has been reclassified from financial liabilities to equity.

The key terms of the Series A and A-2 Convertible Redeemable Preferred Shares (collectively referred to as "Preferred Shares") at December 31, 2021 and June 30, 2022 are summarized as follows:

(a) Conversion

Pursuant to the agreement dated September 28, 2021, each Preferred Share may, at the option of the holders, be converted at any time into ordinary shares of the Company at an initial conversion ratio of 1:1 subject to adjustment for Preferred Shares conversion price.

In addition, each Preferred Share shall automatically be converted into ordinary shares of the Company based on the then-effective applicable conversion price upon:

(i) the closing of a Qualified [**REDACTED**], or

(ii) the written approval of the Preferred Shares preferred majority to convert all Preferred Shares into ordinary shares of the Company.

"Qualified [**REDACTED**]" shall mean an [**REDACTED**] ("[**REDACTED**]") and commencement of [**REDACTED**] of the shares of the Company on [**REDACTED**] or another stock exchange of similar standing of the shares of the Company at the pre-[**REDACTED**] market capitalization that (i) implies a valuation of the Series A-2 Preferred Shares held by the investors immediately prior to the [**REDACTED**] no less than 100% of the aggregate purchase price paid by such investor for such Series A-2 Preferred Shares if the [**REDACTED**] is consummated within the next 24 months from July 20, 2021 ("Series A-2 Original Issue Date") or (ii) is equal to or exceed US$1,000 million if the [**REDACTED**] is consummated after the second anniversary of the Series A-2 Original Issue Date.

(b) Redemption

If the Company fails to complete the Qualified [**REDACTED**] or Qualified Trade Sale before April 27, 2025, each holder of the Preferred Shares shall have the right (the "Put Right") to sell to Harmony Tree Limited all or a portion of the Preferred Shares held by such holder by sending a written request for exercise of its Put Right to the Company within thirty (30) business days. The purchase price of each Preferred Share shall be one hundred percent (100%) of the original issue price, plus all accrued or declared but unpaid dividends on such Preferred Share and an amount that would accrue on the purchase price at a compound interest rate of 8% per annum.

"Qualified Trade Sale" shall mean a Trade Sale, either (i) any consolidation, amalgamation or merger of the Company with or into any other Person or other corporate reorganization, in which the shareholders of the Company immediately prior to such consolidation, amalgamation, merger or reorganization, own less than fifty percent (50%) of the voting power of the Company immediately after such consolidation, merger, amalgamation or reorganization, or any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; (ii) sale, transfer or other disposition of all or substantially all of the assets, or intellectual property of the Company and its subsidiaries; or (iii) the exclusive licensing of all or substantially all of the Company and its subsidiaries' proprietary rights, that results in (i) a valuation of the Series A-2 Preferred Shares held by the investors immediately prior to the consummation of a Trade Sale no less than 100% of the aggregate purchase price paid by such investors for such Series A-2 Preferred Shares if the Trade Sale is consummated within the next twenty four (24) months from the date of the closing or (ii) a market capitalization of the Company that is equal to or exceed US$1,000 million if the trade sale is consummated after the second anniversary of the Series A-2 Original Issue Date.

(c) Voting rights

Each Preferred Share has voting rights equivalent to the number of ordinary shares into which such Preferred Shares could be then convertible.

(d) Liquidation preferences

Upon the occurrence of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the assets of the Company legally available for distribution shall be distributed among the holders of the issued and outstanding shares (on an as-converted basis) in the following order and manner:

Each holder of Preferred Shares shall be entitled to receive, on parity with each other, an amount equal to one hundred percent of the original issue price, plus all accrued or declared but unpaid dividends on such preferred share.

The remaining assets of the Company available for distribution shall be distributed ratably among all members according to the relative number of ordinary shares of the Company held by such member (treating all Preferred Shares as if they had been converted to ordinary shares of the Company immediately prior to such liquidation, dissolution or winding up of the Company).

If any holder of Preferred Shares fails to receive the amounts in full, each holder of ordinary shares of the Company (excluding the ordinary shares of the Company converted from the Preferred Shares) shall severally and jointly transfer all of the assets or cash it received from the Company.

The movements of the convertible redeemable preferred shares are set out as below:

	Financial liability at amortized cost *US$'000*	**Bifurcated embedded derivatives** *US$'000*	**Total** *US$'000*
At January 1, 2021	–	–	–
Issuance of series A preferred shares	34,482	518	35,000
Issuance of series A-2 preferred shares	165,895	1,605	167,500
Transaction costs incurred	(3,535)	–	(3,535)
Accrued interest	4,853	–	4,853
Fair value losses	–	14,397	14,397
Loss on derecognition of financial liability charged to profit or loss	559	–	559
Derecognition of series A preferred shares upon completion of the Reorganization	(35,238)	(15,006)	(50,244)
Derecognition of series A-2 preferred shares upon completion of the Reorganization	(165,679)	(1,514)	(167,193)
Recognition of Series A Preferred Shares upon completion of the Reorganization	62,374	–	62,374
At December 31, 2021	63,711	–	63,711
At January 1, 2022	63,711	–	63,711
Accrued interest	1,336	–	1,336
Reclassification of Series A Preferred Shares to equity	(65,047)	–	(65,047)
At June 30, 2022	–	–	–

The Group adopted the equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions are set as below:

	April 27, 2021	**July 20, 2021**	**September 28, 2021**
Discount rate	8.40%	8.28%	8.78%
Risk-free interest rate	0.62%	0.49%	0.69%
DLOM	24%	24%	24%
Volatility	45.53%	47.95%	51.24%

Discount rate was estimated by cost of debt as at the valuation date. The directors estimated the risk-free interest rate based on the yield of United States treasury active curves with maturity life close to the Qualified [**REDACTED**] timing as of valuation date. The DLOM was estimated based on the option-pricing method. Volatility was estimated based on annualized standard deviation of the daily return embedded in historical stock prices of comparable companies with a time horizon close to the expected term. Probability weight among redemption, liquidation and [**REDACTED**] scenarios was based on the ONM Group Ltd.'s best estimates.

30 RETIREMENT BENEFIT OBLIGATIONS

The defined benefit retirement plan of the subsidiary in Japan is an unfunded pension plans for full-time employees upon retirement or resignation. The level of benefits provided depends on the employees' length of service. The defined benefit retirement plan is measured at present values which are determined with reference to the valuation performed by an independent qualified professional valuer. The valuation was carried out by projected unit credit method.

The amounts recognized in the consolidated balance sheets are determined as follows:

	December 31, 2019 *US$'000*	**December 31, 2020** *US$'000*	**December 31, 2021** *US$'000*	**June 30, 2022** *US$'000*
Present value of unfunded obligations	2,227	2,541	2,755	2,208

The movements in the retirement benefit obligations during the Track Record Period are as follows:

	Present value of obligations			
	December 31, 2019 *US$'000*	**December 31, 2020** *US$'000*	**December 31, 2021** *US$'000*	**June 30, 2022** *US$'000*
Beginning of year/period	2,229	2,227	2,541	2,755
Current service cost	345	164	337	153
Interest expense	1	–	2	–
	346	164	339	153
Remeasurements:				
– (Gain)/loss from change in financial assumptions	(1)	13	(13)	(38)
– Experience (gain)/loss	(39)	121	353	(208)
	(40)	134	340	(246)
Currency translation differences	20	111	(269)	(448)
Payments from plans	(328)	(95)	(196)	(6)
At end of year/period	2,227	2,541	2,755	2,208

The significant actuarial assumptions were as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
Discount rate (per annum)	0.08%	0.18%	0.16%	0.38%
Turnover rate (average)	12.81%	15.38%	15.49%	15.49%

Assumptions regarding future mortality are set based on actuarial advice in accordance with published statistics and experience in the territory.

The sensitivity of the defined benefit obligation to changes in the weighted principal assumptions is:

		Impact on defined benefit obligation	
	Change in assumption	Increase in assumption	Decrease in assumption
At December 31, 2019			
Discount rate	0.2% or 0.4%	Decrease by 3.2% or 6.3%	Increase by 3.2% or 6.3%
At December 31, 2020			
Discount rate	0.3% or 0.5%	Decrease by 2.7% or 4.4%	Increase by 2.8% or 4.8%
At December 31, 2021			
Discount rate	0.2% or 0.3%	Decrease by 1.5% or 2.2%	Increase by 1.5% or 2.3%
At June 30, 2022			
Discount rate	0.2% or 0.6%	Decrease by 1.5% or 4.3%	Increase by 1.5% or 4.6%

The above sensitivity analyses are based on a change in an assumption while holding all other assumptions constant. In practice, this is unlikely to occur, and changes in some of the assumptions may be correlated. When calculating the sensitivity of the defined benefit obligation to significant actuarial assumptions the same method (present value of the defined benefit obligation calculated with the projected unit credit method at the end of the reporting period) has been applied as when calculating the pension liability recognized within the consolidated balance sheets.

The sensitivity of other unobservable inputs are not expected to have significant impact on the defined benefit obligation as at December 31, 2019, 2020 and 2021 and June 30, 2022.

The methods and types of assumptions used in preparing the sensitivity analysis did not change compared to the previous year.

Expected contributions to the defined benefit scheme by the Group for the twelve months ending June 30, 2023 are approximately US$244,000.

The weighted average duration of the defined benefit obligation is 8.5 years, 9 years, 7.7 years and 7.6 years for each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2022, respectively. The expected maturity analysis of undiscounted defined benefit obligation is as follows:

	Within 1 year *US$'000*	Between 1 and 2 years *US$'000*	Between 2 and 5 years *US$'000*	Over 5 years *US$'000*
At December 31, 2019				
Defined benefit obligation	245	143	666	4,728
At December 31, 2020				
Defined benefit obligation	312	180	730	4,554
At December 31, 2021				
Defined benefit obligation	256	324	867	3,608
At June 30, 2022				
Defined benefit obligation	220	221	540	1,292

31 LOANS FROM RELATED COMPANIES

As at December 31, 2020, the loan from Belinfer Corporation, a related company is secured by the ownership and assets of all subsidiaries and bears interest at 1% per annum. The repayment of the loan would not be demanded within 12 months from the end of the reporting period.

On February 16, 2021, the loan from Belinfer Corporation was assigned to Harmony Tree Limited. The loan from Harmony Tree Limited is unsecured and interest free. The loan has been settled during the year ended December 31, 2021.

As at December 31, 2020, the loan from Neich Capital Company Limited, a related company was unsecured and bears interest at 5% per annum. The repayment of the loan would not be demanded within 12 months from the end of the reporting period. The loan has been settled during the year ended December 31, 2021.

The carrying amounts of loans are denominated in US$ and approximate their fair values.

32 TRADE PAYABLES

	December 31, 2019 *US$'000*	December 31, 2020 *US$'000*	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
Trade payables	3,506	1,364	2,174	3,875

The carrying amounts of trade payables approximate their fair values.

Credit terms granted by creditors generally range from 30 to 90 days.

As at December 31, 2019, 2020 and 2021 and June 30, 2022, the ageing analysis of the trade payables based on invoice date is as follows:

	December 31, 2019 *US$'000*	December 31, 2020 *US$'000*	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
0 to 30 days	2,176	1,131	1,797	3,172
31 to 60 days	554	226	299	446
61 to 90 days	305	5	46	184
Over 90 days	471	2	32	73
	3,506	1,364	2,174	3,875

Trade payables are denominated in the following currencies:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
US$	2,141	634	1,536	3,141
EUR	870	501	362	347
RMB	331	180	243	335
Other currencies	164	49	33	52
	3,506	1,364	2,174	3,875

33 ACCRUALS AND OTHER PAYABLES

The Group

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Accrued expenses	9,996	9,804	8,961	10,153
Accrued [**REDACTED**]	–	–	[**REDACTED**]	[**REDACTED**]
Other payables	3,027	2,957	1,576	1,595
	13,023	12,761	11,866	14,217

The carrying amounts of accruals and other payables approximate their fair values and are denominated in the following currencies:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
US$	3,041	3,053	2,031	4,041
EUR	4,532	3,142	2,438	2,144
RMB	3,166	2,667	3,851	4,337
JPY	1,363	1,537	1,460	1,280
HK$	421	955	1,394	1,673
Other currencies	500	1,407	692	742
	13,023	12,761	11,866	14,217

The Company

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
Accrued [**REDACTED**]	[**REDACTED**]	[**REDACTED**]

The carrying amounts of accruals approximate their fair values and are denominated in the following currencies:

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
US$	326	1,363
EUR	9	39
RMB	10	88
JPY	3	9
HK$	981	970
	1,329	2,469

34 BANK BORROWINGS

At December 31, 2019 and 2020, the Group's bank borrowings were repayable within 1 year.

The weighted average effective interest rate of these short-term bank borrowings were 3.77%, 3.30%, 1.98% and 2.75% per annum for each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2022, respectively.

For the years ended December 31, 2019 and 2020, these short-term bank borrowings were secured by: (1) certain properties held by the directors; (2) corporate guarantee given by a related company and (3) personal guarantee given by a Controlling Shareholder and a related party. The controlling shareholder of the related company is also one of the Controlling Shareholders of the Group. These guarantees have been released during the year ended December 31, 2021.

For the six months ended June 30, 2022, the Group has banking facilities from two financial institutions amounting to US$15,000,000 and US$30,000,000 respectively. Both facilities were secured by (i) the corporate guarantee given by the Company, and (ii) a personal guarantee given by the Controlling Shareholders. The US$30,000,000 banking facility was additionally secured by the corporate guarantee given by OrbusNeich Medical Group Limited. Further, the US$30,000,000 banking facility required the Group to maintain a US$15,000,000 deposit as comfort cash with the relevant bank (Note 25). Upon [**REDACTED**] of the Company, the corporate guarantee given by OrbusNeich Medical Group Limited and the personal guarantee given by the Controlling Shareholders will be released.

The carrying amounts of the Group's short-term bank borrowings approximate their fair value and are denominated in the following currencies:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
HK$	38,462	38,462	–	–
RMB	–	1,436	–	–
	38,462	39,898	–	–

The Group has the following undrawn borrowing facilities at the end of the reporting period:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Total available and undrawn facilities	7,840	13,566	109	45,000

35 NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Cash generated from operations:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Profit/(loss) before income tax	7,507	7,255	(1,318)	4,979	9,689
Adjustments for:					
Depreciation of property, plant and equipment	2,388	2,474	2,255	1,180	953
Depreciation of right-of-use assets	1,585	1,441	1,288	627	755
Amortization of intangible assets	3	176	476	227	254
Losses on disposals of property, plant and equipment	48	3	83	24	–
Written off of property, plant and equipment	–	–	–	–	311
Gain on lease modification	(2)	–	–	–	(2)
Losses on disposals of financial assets at fair value through profit or loss	41	37	22	9	5
Gain on disposal of subsidiaries	–	(10)	–	–	–
Realization of accumulated exchange differences upon dissolution of subsidiaries	–	17	(8)	(8)	–
Net unrealized foreign exchange (gain)/losses	(179)	(1,682)	480	(231)	1,391
Provision for inventories	48	16	256	19	837
Net impairment losses/(reversal of impairment losses) on financial assets	1,407	(931)	(109)	(158)	402
Pension costs – defined benefit plans	346	164	337	172	153
Share options granted to directors and employees	–	–	1,339	670	368

	Year ended December 31,			Six months ended June 30,	
	2019	**2020**	**2021**	**2021**	**2022**
	US$'000	*US$'000*	*US$'000*	*US$'000* (Unaudited)	*US$'000*
Unrealized (gains)/losses of fair value change in financial assets at fair value through profit or loss	(60)	76	29	33	1,347
Interest income	(21)	(12)	(12)	(6)	(249)
Interest expense	503	1,405	5,607	1,048	1,407
Loss on derecognition of financial liability charged to profit or loss	–	–	559	–	–
Fair value loss of convertible redeemable preferred shares	–	–	14,397	6,030	–
Share of losses of investment in a joint venture	–	46	207	149	71
	13,614	10,475	25,888	14,764	17,692
Changes in working capital:					
Increase in inventories	(1,264)	(1,931)	(1,587)	(1,254)	(1,225)
(Increase)/decrease in trade receivables	(3,156)	8,637	(1,718)	403	(5,727)
Decrease/(increase) in deposits, prepayments and other receivables	2,498	(193)	(776)	(614)	(1,055)
(Decrease)/increase in trade payables	(928)	(2,188)	842	2,183	1,727
(Decrease)/increase in accruals and other payables	(6,487)	(1,230)	(514)	(781)	2,578
Decrease in retirement benefit obligations	(328)	(95)	(196)	(34)	(6)
(Increase)/decrease in amounts due from/to joint ventures	–	(36)	79	(164)	118
(Increase)/decrease in amounts due from related companies	–	(149)	326	326	–
Cash generated from operations	3,949	13,290	22,344	14,829	14,102

(b) In the consolidated statements of cash flows, proceeds from disposals of property, plant, and equipment comprise:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net book amount *(Note 14)*	141	116	300	40	99
Non-cash transaction: transfer of motor vehicle to a related company	(48)	–	–	–	–
Losses on disposals of property, plant and equipment *(Note 7)*	(48)	(3)	(83)	(24)	–
Proceeds from disposals of property, plant and equipment	45	113	217	16	99

(c) In the consolidated statements of cash flows, proceeds from disposals of financial assets at fair value through profit or loss comprise:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Net book amount	333	194	166	43	16
Losses on disposals of financial assets at fair value through profit or loss *(Note 7)*	(41)	(37)	(22)	(9)	(5)
Proceeds from disposals of financial assets at fair value through profit or loss	292	157	144	34	11

(d) Significant non-cash transactions

During the Track Record Period, the Group had the following non-cash transactions:

(i) During the year ended December 31, 2020, ONM BVI waived the balances due from ONM Group Ltd. and its subsidiaries of US$178,987,000 as capital contribution to ONM Group Ltd..

(ii) During the year ended December 31, 2020, pursuant to the Assignment of Shareholder Loan agreement dated July 31, 2020, the shareholder's loan from Belinfer Corporation amounting to US$5,168,000 was transferred from ONM BVI to Cosmic Ascent Limited and was partly offset by the current account with Belinfer of US$177,000.

(iii) During the year ended December 31, 2020, there was modification to the lease for office premises and the Group derecognized right-of use assets and lease liabilities of US$216,000.

(iv) During the year ended December 31, 2021, there was modification to the lease for office premises and the Group recognized right-of use assets and lease liabilities of US$1,751,000.

(v) During the six months ended June 30, 2022, there was modification to the lease for office premises and the Group recognized right-of-use assets of US$724,000 and lease liabilities of US$722,000, respectively.

(e) Analysis of changes in financing activities during the Track Record Period:

	Liabilities from financing activities				
	Bank borrowings *US$'000*	**Amount due to a related company** *US$'000*	**Loans from related companies** *US$'000*	**Convertible redeemable preferred shares** *US$'000*	**Lease liabilities** *US$'000*
At January 1, 2019	–	223,242	–	–	3,889
Lease addition	–	–	–	–	378
Lease disposal	–	–	–	–	(20)
Cash inflow from financing activities	38,462	–	–	–	–
Cash outflow from financing activities	–	(35,259)	–	–	(1,497)
Accrued interest	381	–	–	–	120
Interest paid	(381)	–	–	–	(120)
Foreign exchange adjustments	–	–	–	–	5
At December 31, 2019	38,462	187,983	–	–	2,755
At January 1, 2020	38,462	187,983	–	–	2,755
Lease addition	–	–	–	–	278
Lease disposal	–	–	–	–	(3)
Acquisition of subsidiary *(Note 38)*	334	–	–	–	–
Cash inflow from financing activities	4,513	–	5,128	–	–
Cash outflow from financing activities	(3,411)	(4,005)	–	–	(1,363)
Accrued interest	1,258	–	67	–	77
Interest paid	(1,258)	–	–	–	(77)
Foreign exchange adjustments	–	–	–	–	28
Other non-cash movements	–	(183,978)	4,991	–	(216)
At December 31, 2020	39,898	–	10,186	–	1,479
At January 1, 2021	39,898	–	10,186	–	1,479
Lease addition	–	–	–	–	2,119
Cash inflow from financing activities	3,057	–	230	198,965	–
Cash outflow from financing activities	(42,955)	–	(10,416)	–	(1,297)
Accrued interest	525	–	151	4,853	76
Interest paid	(525)	–	(151)	–	(76)
Change in fair value	–	–	–	14,397	–
Foreign exchange adjustments	–	–	–	–	(70)
Other non-cash movements	–	–	–	(154,504)	1,751
At December 31, 2021	–	–	–	63,711	3,982

	Liabilities from financing activities				
	Bank borrowings	Amount due to a related company	Loans from related companies	Convertible redeemable preferred shares	Lease liabilities
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At January 1, 2022	–	–	–	63,711	3,982
Lease addition	–	–	–	–	141
Cash inflow from financing activities	5,000	–	–	–	–
Cash outflow from financing activities	(5,000)	–	–	–	(698)
Accrued interest	11	–	–	1,336	57
Interest paid	(11)	–	–	–	(57)
Foreign exchange adjustments	–	–	–	–	(94)
Other non-cash movements	–	–	–	(65,047)	722
At June 30, 2022	–	–	–	–	4,053
(Unaudited)					
At January 1, 2021	39,898	–	10,186	–	1,479
Lease addition	–	–	–	–	1,175
Cash inflow from financing activities	3,057	–	230	34,681	–
Cash outflow from financing activities	(7,077)	–	(5,022)	–	(707)
Accrued interest	403	–	128	476	40
Interest paid	(403)	–	–	–	(40)
Foreign exchange adjustments	–	–	–	–	(39)
Other non-cash movements	–	–	–	6,030	893
At June 30, 2021	35,878	–	5,522	41,187	2,801

36 COMMITMENTS

Capital expenditures contracted for at the end of the year/period but not yet incurred are as follows:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Contracted but not provided for:				
Property, plant and equipment	–	–	74	210

37 CONTINGENT LIABILITIES

As at December 31, 2019, OrbusNeich Medical Company Limited (業聚醫療有限公司), a subsidiary of the Company provided ONM BVI with cross guarantees up to approximately US$3,846,000 in respect of a banking facility granted to the subsidiary and ONM BVI. The facility was also secured by personal guarantee given by a director of the Company and a related party; and pledge of properties held by the director.

No facility was utilized by ONM BVI as at December 31, 2019. In the opinion of the directors of the Company, the fair values of these financial guarantees were not significant at initial recognition as the directors considered the possibilities of default by the related company were remote. The guarantee was released during the year ended December 31, 2020.

As at December 31, 2020, OrbusNeich Medical Company Limited (業聚醫療有限公司), a subsidiary of the Company provides Neich Capital Company Limited, a related company, with cross guarantees up to approximately US$3,846,000 in respect of a banking facility granted to the subsidiary and Neich Capital Company Limited. The facility was also secured by personal guarantee given by a director of the Company and a related party; and pledge of properties held by the director.

No facility was utilized by Neich Capital Company Limited as at December 31, 2020. In the opinion of the director of the Company, the fair values of these financial guarantees were not significant at initial recognition as the director considered the possibilities of default by the related company were remote. These guarantees have been released during the year ended December 31, 2021.

38 BUSINESS COMBINATION

In August 2020, the Group acquired 100% of the issued share capital of OrbusNeich (Switzerland) AG from independent third parties. The acquisition will increase the Group's market share in this industry and complement the Group's existing medical trading.

Details of the purchase consideration, the net assets acquired and goodwill are as follows:

	US$'000
Consideration paid as at acquisition date	
Cash	3,320
Consideration payable	699
	4,019
Recognized amounts of identifiable assets acquired, liabilities assumed	
Property, plant and equipment	4
Intangible assets: customer relationship	1,176
Inventories	471
Trade receivables	388
Deposits, prepayments and other receivables	47
Cash and cash equivalents	1,080
Accruals and other payables	(336)
Current income tax liabilities	(226)
Bank borrowings	(334)
Total identifiable net assets	2,270
Goodwill	1,749
Net assets acquired	4,019
Net cash outflow arising from the acquisitions	
Cash and cash equivalents acquired	1,080
Less: cash consideration	(3,320)
	(2,240)

The goodwill was attributable to synergies expected to arise from the Group's acquisition of the new subsidiary. The acquired business contributed approximately US$1,324,000 and US$179,000 of revenues and net profit, respectively to the Group for the year ended December 31, 2020.

If the acquisition had occurred on January 1, 2020, the consolidated revenue and profit for the year ended December 31, 2020 would have been US$3,419,000 and US$578,000 respectively.

Acquisition related costs were not significant and have been charged to general and administrative expenses in the consolidated statements of profit or loss for the year ended December 31, 2020.

39 RELATED PARTY TRANSACTIONS

Parties are considered to be related to the Group if the party has the ability, directly or indirectly, to exercise significant influence over the Group in making financial and operating decisions. Related parties may be individuals (being members of key management personnel, significant shareholder and/or their close family members) or other entities and include entities which are under the significant influence of related parties of the Group where those parties are individuals. Parties are also considered to be related if they are subject to common control.

Name of related parties	Relationship with the Company
Harmony Tree Limited	Ultimate holding company
OrbusNeich P+F Company Limited	A joint venture
OrbusNeich P&F (Hong Kong) Company Limited	A subsidiary of the joint venture
Belinfer Corporation	Controlled by the Controlling Shareholder
OrbusNeich Medical Company Limited ("ONM BVI")	Controlled by the Controlling Shareholder
Neich Capital Company Limited	Controlled by the Controlling Shareholder
Neich Holdings Limited	Controlled by the Controlling Shareholder
A distributor of the Group	50% owned by a cousin of Mr. David Chien, one of the Controlling Shareholders

The following is a summary of the significant transactions carried out between the Group and its related parties in the ordinary course of business during each of the years ended December 31, 2019, 2020 and 2021 and six months ended June 30, 2021 and 2022, and balances arising from related party transactions as at December 31, 2019, 2020 and 2021 and June 30, 2022.

(a) Transactions with related parties

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000* (*Unaudited*)	*US$'000*
Sales of goods to a related party:					
– A distributor of the Group *(Note (i))*	8,269	5,012	940	940	–
Service fee received from a related party:					
– OrbusNeich P&F (Hong Kong) Company Limited *(Note (i))*	–	29	125	61	86
Transfer of motor vehicle to a related company:					
– Belinfer Corporation *(Note (ii))*	48	–	–	–	–

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
				(Unaudited)	
Short-term lease charged by a related company					
– Neich Holdings Limited *(Note (i))*	100	100	45	50	–
Interest expense on loans from related companies					
– Belinfer Corporation *(Note (iii))*	–	21	–	–	–
– Neich Capital Company Limited *(Note (iii))*	–	46	151	128	–
	–	67	151	128	–

(i) The transactions were carried out at rate mutually-agreed between the related parties involved in the transactions and the Group.

(ii) The transaction was entered into at terms agreed between parties involved and the consideration was equal to net book amount of the motor vehicle on the date of transfer.

(iii) The terms of the loans from related companies are set out in Note 31.

(b) Year-end balances with related parties

The Group

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Amounts due from joint ventures				
– OrbusNeich P&F (Hong Kong) Company Limited *(Note (i))*	–	81	11	–
– OrbusNeich P&F (Hong Kong) Company Limited *(Note (ii))*	–	–	–	22
– OrbusNeich P+F Company Limited *(Note (ii))*	–	9	–	–
	–	90	11	22
Advance to a joint venture				
– OrbusNeich P+F Company Limited *(Note 21)*	–	–	3,044	3,044

	December 31, 2019 *US$'000*	December 31, 2020 *US$'000*	December 31, 2021 *US$'000*	June 30, 2022 *US$'000*
Amounts due from related companies *(Note (ii))*				
– Belinfer Corporation	177	–	–	–
– OrbusNeich Medical Company Limited (BVI)	–	326	–	–
	177	326	–	–
Loans from related companies *(Note (iii))*				
– Belinfer Corporation	–	5,012	–	–
– Neich Capital Company Limited	–	5,174	–	–
	–	10,186	–	–
Amount due to a related company *(Note (iv))*				
– OrbusNeich Medical Company Limited (BVI)	187,983	–	–	–
Amount due to a joint venture				
– OrbusNeich P&F (Hong Kong) Company Limited *(Note (i))*	–	–	–	129
Trade receivable from a related party *(Note (v))*				
– A distributor of the Group	4,400	2,170	–	–

(i) The amount due from/to a joint venture was trade in nature, unsecured, interest free and repayable on demand. The carrying amounts approximate their fair values and are denominated in US$ and Singapore dollar.

(ii) The amounts due from a joint venture and related companies were non-trade in nature, unsecured, interest-free and repayable on demand. The carrying amounts approximate their fair values and are denominated in US$.

(iii) The loans from related companies were non-trade in nature and the terms of the loans are set out in Note 31.

(iv) The amount due to a related company was non-trade in nature, unsecured, interest-free and repayable on demand, except for the balances of US$99,790,000 in December 31, 2019, which would not be demanded within 12 months from the end of the reporting period. The carrying amounts approximate their fair values and are denominated in US$.

(v) The balances of trade receivables from a related party were unsecured, trade in nature, interest free and are denominated in US$.

The Company

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
Amounts due from subsidiaries		
– OrbusNeich Medical Group Limited	64,544	64,451
– OrbusNeich Medical Company Limited (業聚醫療有限公司)	–	46,520
	64,544	110,971
Amount due to a subsidiary		
– OrbusNeich Medical Company Limited (業聚醫療有限公司)	32	–

The amounts due from/to subsidiaries as at December 31, 2021 and June 30, 2022 was non-trade in nature, unsecured, interest-free and repayable on demand. The carrying amounts approximate their fair values and are denominated in US$.

(c) Key management compensation

Key management includes the directors and certain member of the management. The compensation paid or payable to key management for employee services is shown below:

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	US$'000	*US$'000*	*US$'000*	*US$'000* (*Unaudited*)	*US$'000*
Salaries, wages and allowances	3,866	2,877	3,202	1,612	1,890
Share-based payment expense	–	–	155	87	77
Pension costs – defined contribution plans	37	39	45	23	23
Pension costs – defined benefit plans	11	11	11	5	5
Other long-term benefits	17	18	19	10	9
	3,931	2,945	3,432	1,737	2,004

(d) For the years ended December 31, 2019 and 2020, these short-term bank borrowings were secured by certain assets held by the directors and corporate guarantee given by a related company and personal guarantee given by a Controlling Shareholder and a related party. The Controlling Shareholder of the related company is also a Controlling Shareholder of the Group. These guarantees have been released during the year ended December 31, 2021.

For the six months ended June 30, 2022, the Group has banking facilities from two financial institutions amounting to US$15,000,000 and US$30,000,000 respectively. Both facilities were secured by (i) the corporate guarantee given by the Company, and (ii) a personal guarantee given by the Controlling Shareholders. The US$30,000,000 banking facility was additionally secured by the corporate guarantee given by OrbusNeich Medical Group Limited. Further, the US$30,000,000 banking facility required the Group to maintain a US$15,000,000 deposit as comfort cash with the relevant bank (Note 25). Upon [**REDACTED**] of the Company, the corporate guarantee given by OrbusNeich Medical Group Limited and the personal guarantee given by the Controlling Shareholders will be released.

40 FINANCIAL INSTRUMENTS BY CATEGORY

The Group holds the following financial instruments:

	December 31, 2019	December 31, 2020	December 31, 2021	June 30, 2022
	US$'000	*US$'000*	*US$'000*	*US$'000*
Financial assets				
Financial assets at fair value through profit or loss	1,829	2,048	2,041	20,527
Financial assets at amortized cost				
– Trade receivables	32,609	26,316	26,804	29,700
– Deposits and other receivables	1,206	1,391	1,663	1,697
– Advance to a joint venture	–	–	3,044	–
– Amounts due from joint ventures	–	90	11	22
– Amounts due from related companies	177	326	–	–
– Pledged bank deposit	–	–	–	15,000
– Short-term bank deposit	–	–	–	20,000
– Cash and cash equivalents	13,631	15,112	175,886	131,619
	47,623	43,235	207,408	198,038
	49,452	45,283	209,449	218,565
Financial liabilities				
Financial liabilities at amortized cost				
– Trade payables	3,506	1,364	2,174	3,875
– Accruals and other payables	10,897	11,081	9,877	11,391
– Lease liabilities	2,755	1,479	3,982	4,053
– Loans from related companies	–	10,186	–	–
– Amount due to a related company	187,983	–	–	–
– Amount due to a joint venture	–	–	–	129
– Bank borrowings	38,462	39,898	–	–
– Convertible redeemable preferred shares	–	–	63,711	–
	243,603	64,008	79,744	19,448

The Company holds the following financial instruments:

	December 31, 2021	June 30, 2022
	US$'000	*US$'000*
Financial assets		
Financial assets at amortized cost		
– Other receivables	–	118
– Amounts due from subsidiaries	64,544	110,971
– Short-term bank deposit	–	20,000
– Cash and cash equivalents	149,104	60,831
	213,648	191,920
Financial liabilities		
Financial liabilities at amortized cost		
– Convertible redeemable preferred shares	63,711	–
– Accruals and other payables	1,329	2,469
– Amount due to a subsidiary	32	–
	65,072	2,469

41 EVENTS AFTER THE REPORTING PERIOD

[As of the date of this report, there is no material subsequent event occurred during the period from June 30, 2022.]

III SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company or any of the companies now comprising the Group in respect of any period subsequent to June 30, 2022 and up to the date of this report.

The information set out in this Appendix II does not form part of the Accountant's Report from PricewaterhouseCoopers, Certified Public Accountants, the reporting accountant of the Company, as set out in Appendix I to this document, and is included herein for illustrative purpose only. The unaudited pro forma financial information should be read in conjunction with the section entitled "Financial Information" in this document and the Accountant's Report set out in Appendix I to this document.

A. UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited pro forma statement of adjusted consolidated net tangible assets of the Group prepared in accordance with Rule 4.29 of the Listing Rules are set out below to illustrate the effect of the [**REDACTED**] on the consolidated net tangible assets of the Group attributable to the owners of the Company as at June 30, 2022 as if the [**REDACTED**] had taken place on June 30, 2022.

The unaudited pro forma adjusted consolidated net tangible assets has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group as at June 30, 2022 or at any future dates following the [**REDACTED**].

	Audited consolidated net tangible assets of the Group attributable to owners of the Company as at June 30, 2022	**Estimated net [REDACTED] from the [REDACTED]**	**Unaudited pro forma adjusted net tangible assets attributable to owners of the Company as at June 30, 2022**	**Unaudited pro forma adjusted net tangible assets per Share**	
	Note 1	*Note 2*		*Note 3*	*Note 4*
	US$'000	*US$'000*	*US$'000*	*US$*	*HK$*
Based on an [**REDACTED**] of HK$[**REDACTED**] per Share	246,839	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Based on an [**REDACTED**] of HK$[**REDACTED**] per Share	246,839	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]

Notes:

1. The audited consolidated net tangible assets attributable to owners of the Company as at June 30, 2022 is extracted from the Accountant's Report set forth in Appendix I to this document, which is based on the audited consolidated net assets of our Group attributable to the owners of the Company as at June 30, 2022 of approximately US$252,726,000 with an adjustment for the intangible assets and goodwill attributable to the owners of the Company as at June 30, 2022 of approximately US$4,138,000 and US$1,749,000, respectively.

2. The estimated net [**REDACTED**] from the [**REDACTED**] are based on [**REDACTED**] and the indicative [**REDACTED**] of HK$[**REDACTED**] per [**REDACTED**] and HK$[**REDACTED**] per [**REDACTED**], being the low end to high end of the indicative [**REDACTED**], respectively, after deduction of the [**REDACTED**] fees and other related expenses, excluding [**REDACTED**] of approximately US$[**REDACTED**] which has been charged to the consolidated statement of profit and loss up to June 30, 2022.

3. The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after the adjustments referred to in the preceding paragraphs and on the basis that a total of [**REDACTED**] Shares were in issue (including Shares in issue as of the date of this document and those Shares to be [**REDACTED**] pursuant to the [**REDACTED**]) assuming that the Share Consolidation and the [**REDACTED**] had been completed on June 30, 2022, and all Preferred Shares are automatically converted into Ordinary Shares on a 1:1 basis, but taking no account of any Shares (a) which may be alloted and issued pursuant to the exercise of options which were granted under Shares Incentive Schemes; or (b) which may be alloted and issued or repurchased by the Company pursuant to the general mandates granted to the Directors to allot and issue or repurchase Shares as described in the section headed "Share Capital" in this document.

4. For the purpose of this unaudited pro forma adjusted consolidated net tangible assets, the translations between U.S. dollars and Hong Kong dollars were made at the rate of HK$[7.8250] to US$1.00, as set out in "Information about this Document and the [**REDACTED**]" to this document. No representation is made that U.S. dollars amounts have been, could have been or may be converted to Hong Kong dollars, or vice versa, at that rate.

5. No other adjustment has been made to the unaudited pro forma adjusted net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to June 30, 2022.

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

Set out below is a summary of certain provisions of the Memorandum and Articles of Association of the Company and of certain aspects of Cayman company law.

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on July 22, 2021 under the Companies Act (As Revised) of the Cayman Islands (the "**Companies Act**"). The Company's constitutional documents consist of its Amended and Restated Memorandum of Association (the "**Memorandum**") and its Amended and Restated Articles of Association (the "**Articles**").

1. MEMORANDUM OF ASSOCIATION

(a) The Memorandum states, inter alia, that the liability of members of the Company is limited to the amount, if any, for the time being unpaid on the shares respectively held by them and that the objects for which the Company is established are unrestricted (including acting as an investment company), and that the Company shall have and be capable of exercising all the functions of a natural person of full capacity irrespective of any question of corporate benefit, as provided in section 27(2) of the Companies Act and in view of the fact that the Company is an exempted company that the Company will not trade in the Cayman Islands with any person, firm or corporation except in furtherance of the business of the Company carried on outside the Cayman Islands.

(b) The Company may by special resolution alter its Memorandum with respect to any objects, powers or other matters specified therein.

2. ARTICLES OF ASSOCIATION

The Articles were [conditionally] adopted on [●] [with effect from the [**REDACTED**]]. The following is a summary of certain provisions of the Articles:

(a) Shares

(i) Classes of shares

The share capital of the Company consists of ordinary shares.

(ii) Variation of rights of existing shares or classes of shares

Subject to the Companies Act, if at any time the share capital of the Company is divided into different classes of shares, all or any of the special rights attached to the shares or any class of shares may (unless otherwise provided for by the terms of issue of that class) be varied, modified or abrogated either with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a separate general meeting of the

holders of the shares of that class. To every such separate general meeting the provisions of the Articles relating to general meetings will *mutatis mutandis* apply, but so that the necessary quorum (other than at an adjourned meeting) shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of that class and at any adjourned meeting two holders present in person or by proxy (whatever the number of shares held by them) shall be a quorum. Every holder of shares of the class shall be entitled to one vote for every such share held by him.

Any special rights conferred upon the holders of any shares or class of shares shall not, unless otherwise expressly provided in the rights attaching to the terms of issue of such shares, be deemed to be varied by the creation or issue of further shares ranking *pari passu* therewith.

(iii) Alteration of capital

The Company may by ordinary resolution of its members:

(i) increase its share capital by the creation of new shares;

(ii) consolidate all or any of its capital into shares of larger amount than its existing shares;

(iii) divide its shares into several classes and attach to such shares any preferential, deferred, qualified or special rights, privileges, conditions or restrictions as the Company in general meeting or as the directors may determine;

(iv) subdivide its shares or any of them into shares of smaller amount than is fixed by the Memorandum; or

(v) cancel any shares which, at the date of passing of the resolution, have not been taken and diminish the amount of its capital by the amount of the shares so cancelled.

The Company may reduce its share capital or any capital redemption reserve or other undistributable reserve in any way by special resolution.

(iv) Transfer of shares

All transfers of shares may be effected by an instrument of transfer in the usual or common form or in a form prescribed by The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") or in such other form as the board may approve and which may be under hand or, if the transferor or transferee is a clearing house or its nominee(s), by hand or by machine imprinted signature or by such other manner of execution as the board may approve from time to time.

Notwithstanding the foregoing, for so long as any shares are listed on the Stock Exchange, titles to such listed shares may be evidenced and transferred in accordance with the laws applicable to and the rules and regulations of the Stock Exchange that are or shall be applicable to such listed shares. The register of members in respect of its listed shares (whether the principal register or a branch register) may be kept by recording the particulars required by Section 40 of the Companies Act in a form otherwise than legible if such recording otherwise complies with the laws applicable to and the rules and regulations of the Stock Exchange that are or shall be applicable to such listed shares.

The instrument of transfer shall be executed by or on behalf of the transferor and the transferee provided that the board may dispense with the execution of the instrument of transfer by the transferee. The transferor shall be deemed to remain the holder of the share until the name of the transferee is entered in the register of members in respect of that share.

The board may, in its absolute discretion, at any time transfer any share upon the principal register to any branch register or any share on any branch register to the principal register or any other branch register.

The board may decline to recognise any instrument of transfer unless a fee (not exceeding the maximum sum as the Stock Exchange may determine to be payable) determined by the Directors is paid to the Company, the instrument of transfer is properly stamped (if applicable), it is in respect of only one class of share and is lodged at the relevant registration office or registered office or such other place at which the principal register is kept accompanied by the relevant share certificate(s) and such other evidence as the board may reasonably require to show the right of the transferor to make the transfer (and if the instrument of transfer is executed by some other person on his behalf, the authority of that person so to do).

The registration of transfers may be suspended and the register closed on giving notice by advertisement in any newspaper or by any other means in accordance with the requirements of the Stock Exchange, at such times and for such periods as the board may determine. The register of members must not be closed for periods exceeding in the whole thirty (30) days in any year. The period of thirty (30) days may be extended for a further period or periods not exceeding thirty (30) days in respect of any year if approved by members by ordinary resolution.

Subject to the above, fully paid shares are free from any restriction on transfer and free of all liens in favour of the Company.

(v) Power of the Company to purchase its own shares

The Company is empowered by the Companies Act and the Articles to purchase its own shares subject to certain restrictions and the board may only exercise this power on behalf of the Company subject to any applicable requirements imposed from time to time by the Stock Exchange.

The board may accept the surrender for no consideration of any fully paid share.

(vi) Power of any subsidiary of the Company to own shares in the Company

There are no provisions in the Articles relating to ownership of shares in the Company by a subsidiary.

(vii) Calls on shares and forfeiture of shares

The board may from time to time make such calls upon the members in respect of any monies unpaid on the shares held by them respectively (whether on account of the nominal value of the shares or by way of premium). A call may be made payable either in one lump sum or by installments. If the sum payable in respect of any call or instalment is not paid on or before the day appointed for payment thereof, the person or persons from whom the sum is due shall pay interest on the same at such rate not exceeding twenty per cent. (20%) per annum as the board may agree to accept from the day appointed for the payment thereof to the time of actual payment, but the board may waive payment of such interest wholly or in part. The board may, if it thinks fit, receive from any member willing to advance the same, either in money or money's worth, all or any part of the monies uncalled and unpaid or installments payable upon any shares held by him, and upon all or any of the monies so advanced the Company may pay interest at such rate (if any) as the board may decide.

If a member fails to pay any call on the day appointed for payment thereof, the board may serve not less than fourteen (14) clear days' notice on him requiring payment of so much of the call as is unpaid, together with any interest which may have accrued and which may still accrue up to the date of actual payment and stating that, in the event of non-payment at or before the time appointed, the shares in respect of which the call was made will be liable to be forfeited.

If the requirements of any such notice are not complied with, any share in respect of which the notice has been given may at any time thereafter, before the payment required by the notice has been made, be forfeited by a resolution of the board to that effect. Such forfeiture will include all dividends and bonuses declared in respect of the forfeited share and not actually paid before the forfeiture.

A person whose shares have been forfeited shall cease to be a member in respect of the forfeited shares but shall, notwithstanding, remain liable to pay to the Company all monies which, at the date of forfeiture, were payable by him to the Company in respect of the shares, together with (if the board shall in its discretion so require) interest thereon from the date of forfeiture until the date of actual payment at such rate not exceeding twenty per cent. (20%) per annum as the board determines.

(b) Directors

(i) Appointment, retirement and removal

At each annual general meeting, one third of the Directors for the time being (or if their number is not a multiple of three, then the number nearest to but not less than one third) shall retire from office by rotation provided that every Director shall be subject to retirement at an annual general meeting at least once every three years. The Directors to retire by rotation shall include any Director who wishes to retire and not offer himself for re-election. Any further Directors so to retire shall be those who have been longest in office since their last re-election or appointment but as between persons who became or were last re-elected Directors on the same day those to retire will (unless they otherwise agree among themselves) be determined by lot.

Neither a Director nor an alternate Director is required to hold any shares in the Company by way of qualification. Further, there are no provisions in the Articles relating to retirement of Directors upon reaching any age limit.

The Directors have the power to appoint any person as a Director either to fill a casual vacancy on the board or as an addition to the existing board. Any Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election.

A Director (including a managing or other executive Director) may be removed by an ordinary resolution of the Company before the expiration of his term of office (but without prejudice to any claim which such Director may have for damages for any breach of any contract between him and the Company) and members of the Company may by ordinary resolution appoint another in his place. Unless otherwise determined by the Company in general meeting, the number of Directors shall not be less than two. There is no maximum number of Directors.

The office of director shall be vacated if:

(aa) he resigns by notice in writing delivered to the Company;

(bb) he becomes of unsound mind or dies;

(cc) without special leave, he is absent from meetings of the board for six (6) consecutive months, and the board resolves that his office is vacated;

(dd) he becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors;

(ee) he is prohibited from being a director by law; or

(ff) he ceases to be a director by virtue of any provision of law or is removed from office pursuant to the Articles.

The board may appoint one or more of its body to be managing director, joint managing director, or deputy managing director or to hold any other employment or executive office with the Company for such period and upon such terms as the board may determine and the board may revoke or terminate any of such appointments. The board may delegate any of its powers, authorities and discretions to committees consisting of such Director or Directors and other persons as the board thinks fit, and it may from time to time revoke such delegation or revoke the appointment of and discharge any such committees either wholly or in part, and either as to persons or purposes, but every committee so formed must, in the exercise of the powers, authorities and discretions so delegated, conform to any regulations that may from time to time be imposed upon it by the board.

(ii) Power to allot and issue shares and warrants

Subject to the provisions of the Companies Act and the Memorandum and Articles and to any special rights conferred on the holders of any shares or class of shares, any share may be issued (a) with or have attached thereto such rights, or such restrictions, whether with regard to dividend, voting, return of capital, or otherwise, as the Directors may determine, or (b) on terms that, at the option of the Company or the holder thereof, it is liable to be redeemed.

The board may issue warrants or convertible securities or securities of similar nature conferring the right upon the holders thereof to subscribe for any class of shares or securities in the capital of the Company on such terms as it may determine.

Subject to the provisions of the Companies Act and the Articles and, where applicable, the rules of the Stock Exchange and without prejudice to any special rights or restrictions for the time being attached to any shares or any class of shares, all unissued shares in the Company are at the disposal of the board, which may offer, allot, grant options over or otherwise dispose of them to such persons, at such times, for such consideration and on such terms and conditions as it in its absolute discretion thinks fit, but so that no shares shall be issued at a discount to their nominal value.

Neither the Company nor the board is obliged, when making or granting any allotment of, offer of, option over or disposal of shares, to make, or make available, any such allotment, offer, option or shares to members or others with registered addresses in

any particular territory or territories being a territory or territories where, in the absence of a registration statement or other special formalities, this would or might, in the opinion of the board, be unlawful or impracticable. Members affected as a result of the foregoing sentence shall not be, or be deemed to be, a separate class of members for any purpose whatsoever.

(iii) Power to dispose of the assets of the Company or any of its subsidiaries

There are no specific provisions in the Articles relating to the disposal of the assets of the Company or any of its subsidiaries. The Directors may, however, exercise all powers and do all acts and things which may be exercised or done or approved by the Company and which are not required by the Articles or the Companies Act to be exercised or done by the Company in general meeting.

(iv) Borrowing powers

The board may exercise all the powers of the Company to raise or borrow money, to mortgage or charge all or any part of the undertaking, property and assets and uncalled capital of the Company and, subject to the Companies Act, to issue debentures, bonds and other securities of the Company, whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

(v) Remuneration

The ordinary remuneration of the Directors is to be determined by the Company in general meeting, such sum (unless otherwise directed by the resolution by which it is voted) to be divided amongst the Directors in such proportions and in such manner as the board may agree or, failing agreement, equally, except that any Director holding office for part only of the period in respect of which the remuneration is payable shall only rank in such division in proportion to the time during such period for which he held office. The Directors are also entitled to be prepaid or repaid all travelling, hotel and incidental expenses reasonably expected to be incurred or incurred by them in attending any board meetings, committee meetings or general meetings or separate meetings of any class of shares or of debentures of the Company or otherwise in connection with the discharge of their duties as Directors.

Any Director who, by request, goes or resides abroad for any purpose of the Company or who performs services which in the opinion of the board go beyond the ordinary duties of a Director may be paid such extra remuneration as the board may determine and such extra remuneration shall be in addition to or in substitution for any ordinary remuneration as a Director. An executive Director appointed to be a managing

director, joint managing director, deputy managing director or other executive officer shall receive such remuneration and such other benefits and allowances as the board may from time to time decide. Such remuneration may be either in addition to or in lieu of his remuneration as a Director.

The board may establish or concur or join with other companies (being subsidiary companies of the Company or companies with which it is associated in business) in establishing and making contributions out of the Company's monies to any schemes or funds for providing pensions, sickness or compassionate allowances, life assurance or other benefits for employees (which expression as used in this and the following paragraph shall include any Director or past Director who may hold or have held any executive office or any office of profit with the Company or any of its subsidiaries) and ex-employees of the Company and their dependents or any class or classes of such persons.

The board may pay, enter into agreements to pay or make grants of revocable or irrevocable, and either subject or not subject to any terms or conditions, pensions or other benefits to employees and ex-employees and their dependents, or to any of such persons, including pensions or benefits additional to those, if any, to which such employees or ex-employees or their dependents are or may become entitled under any such scheme or fund as is mentioned in the previous paragraph. Any such pension or benefit may, as the board considers desirable, be granted to an employee either before and in anticipation of, or upon or at any time after, his actual retirement.

The board may resolve to capitalise all or any part of any amount for the time being standing to the credit of any reserve or fund (including a share premium account and the profit and loss account) whether or not the same is available for distribution by applying such sum in paying up unissued shares to be allotted to (i) employees (including directors) of the Company and/or its affiliates (meaning any individual, corporation, partnership, association, joint-stock company, trust, unincorporated association or other entity (other than the Company) that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, the Company) upon exercise or vesting of any options or awards granted under any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the members in general meeting, or (ii) any trustee of any trust to whom shares are to be allotted and issued by the Company in connection with the operation of any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the members in general meeting.

(vi) Compensation or payments for loss of office

Pursuant to the Articles, payments to any Director or past Director of any sum by way of compensation for loss of office or as consideration for or in connection with his retirement from office (not being a payment to which the Director is contractually entitled) must be approved by the Company in general meeting.

(vii) Loans and provision of security for loans to Directors

The Company must not make any loan, directly or indirectly, to a Director or his close associate(s) if and to the extent it would be prohibited by the Companies Ordinance (Chapter 622 of the laws of Hong Kong) as if the Company were a company incorporated in Hong Kong.

(viii) Disclosure of interests in contracts with the Company or any of its subsidiaries

A Director may hold any other office or place of profit with the Company (except that of the auditor of the Company) in conjunction with his office of Director for such period and upon such terms as the board may determine, and may be paid such extra remuneration therefor in addition to any remuneration provided for by or pursuant to the Articles. A Director may be or become a director or other officer of, or otherwise interested in, any company promoted by the Company or any other company in which the Company may be interested, and shall not be liable to account to the Company or the members for any remuneration, profits or other benefits received by him as a director, officer or member of, or from his interest in, such other company. The board may also cause the voting power conferred by the shares in any other company held or owned by the Company to be exercised in such manner in all respects as it thinks fit, including the exercise thereof in favour of any resolution appointing the Directors or any of them to be directors or officers of such other company, or voting or providing for the payment of remuneration to the directors or officers of such other company.

No Director or proposed or intended Director shall be disqualified by his office from contracting with the Company, either with regard to his tenure of any office or place of profit or as vendor, purchaser or in any other manner whatsoever, nor shall any such contract or any other contract or arrangement in which any Director is in any way interested be liable to be avoided, nor shall any Director so contracting or being so interested be liable to account to the Company or the members for any remuneration, profit or other benefits realised by any such contract or arrangement by reason of such Director holding that office or the fiduciary relationship thereby established. A Director who to his knowledge is in any way, whether directly or indirectly, interested in a contract or arrangement or proposed contract or arrangement with the Company must declare the

nature of his interest at the meeting of the board at which the question of entering into the contract or arrangement is first taken into consideration, if he knows his interest then exists, or in any other case, at the first meeting of the board after he knows that he is or has become so interested.

A Director shall not vote (nor be counted in the quorum) on any resolution of the board approving any contract or arrangement or other proposal in which he or any of his close associates is materially interested, but this prohibition does not apply to any of the following matters, namely:

(aa) the giving of any security or indemnity either:–

(aaa) to the Director or his close associate(s) in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries; or

(bbb) to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or his close associate(s) has himself/themselves assumed responsibility in whole or in part and whether alone or jointly under a guarantee or indemnity or by the giving of security;

(bb) any proposal concerning an offer of shares or debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase where the Director or his close associate(s) is/are or is/are to be interested as a participant in the underwriting or sub-underwriting of the offer;

(cc) any proposal or arrangement concerning the benefit of employees of the Company or its subsidiaries including:–

(aaa) the adoption, modification or operation of any employees' share scheme or any share incentive or share option scheme under which the Director or his close associate(s) may benefit; or

(bbb) the adoption, modification or operation of a pension fund or retirement, death or disability benefits scheme which relates to the Directors, his close associate(s) and employee(s) of the Company or any of its subsidiaries and does not provide in respect of any Director, or his close associate(s), as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates;

(dd) any contract or arrangement in which the Director or his close associate(s) is/are interested in the same manner as other holders of shares or debentures or other securities of the Company by virtue only of his/their interest in shares or debentures or other securities of the Company.

(c) Proceedings of the Board

The board may meet for the despatch of business, adjourn and otherwise regulate its meetings as it considers appropriate. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairman of the meeting shall have an additional or casting vote.

(d) Alterations to constitutional documents and the Company's name

The Articles may be rescinded, altered or amended by the Company in general meeting by special resolution. The Articles state that a special resolution shall be required to alter the provisions of the Memorandum, to amend the Articles or to change the name of the Company.

(e) Meetings of members

(i) Special and ordinary resolutions

A special resolution of the Company must be passed by a majority of not less than three-fourths of the votes cast by such members as, being entitled so to do, vote in person or, in the case of such members as are corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice has been duly given in accordance with the Articles.

Under the Companies Act, a copy of any special resolution must be forwarded to the Registrar of Companies in the Cayman Islands within fifteen (15) days of being passed.

An ordinary resolution is defined in the Articles to mean a resolution passed by a simple majority of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice has been duly given in accordance with the Articles.

(ii) Voting rights and right to demand a poll

Subject to any special rights or restrictions as to voting for the time being attached to any shares, at any general meeting on a poll every member present in person or by proxy or, in the case of a member being a corporation, by its duly authorised representative shall have one vote for every fully paid share of which he is the holder but

so that no amount paid up or credited as paid up on a share in advance of calls or installments is treated for the foregoing purposes as paid up on the share. A member entitled to more than one vote need not use all his votes or cast all the votes he uses in the same way.

At any general meeting a resolution put to the vote of the meeting is to be decided by way of a poll save that the chairman of the meeting may in good faith, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands in which case every member present in person (or being a corporation, is present by a duly authorized representative), or by proxy(ies) shall have one vote provided that where more than one proxy is appointed by a member which is a clearing house (or its nominee(s)), each such proxy shall have one vote on a show of hands. Votes (whether on a show of hands or by way of poll) may be cast by such means, electronic or otherwise, as the Directors or the chairman of the meeting may determine.

Any corporation which is a member may by resolution of its directors or other governing body authorise such person as it thinks fit to act as its representative at any general meeting of the Company or at any meeting of any class of members.

The person so authorised shall be entitled to exercise the same powers on behalf of such corporation as the corporation could exercise if it were an individual member and such corporation shall for the purposes of the Articles be deemed to be present in person at any such meeting if a person so authorised is present thereat.

If a recognised clearing house (or its nominee(s)) is a member of the Company it may authorise such person or persons as it thinks fit to act as its representative(s) at any meeting of the Company or at any meeting of any class of members of the Company provided that, if more than one person is so authorised, the authorisation shall specify the number and class of shares in respect of which each such person is so authorised. A person authorised pursuant to this provision shall be deemed to have been duly authorised without further evidence of the facts and be entitled to exercise the same powers on behalf of the recognised clearing house (or its nominee(s)) as if such person was the registered holder of the shares of the Company held by that clearing house (or its nominee(s)) including, the right to speak and to vote, and where a show of hands is allowed, the right to vote individually on a show of hands.

All members have the right to speak and vote at a general meeting except where a member is required, by the rules of the Stock Exchange, to abstain from voting to approve the matter under consideration.

Where the Company has any knowledge that any member is, under the rules of the Stock Exchange, required to abstain from voting on any particular resolution of the Company or restricted to voting only for or only against any particular resolution of the Company, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

(iii) Annual general meetings and extraordinary general meetings

The Company must hold an annual general meeting of the Company every financial year and such general meeting must be held within six (6) months after the end of the Company's financial year unless a longer period would not infringe the rules of the Stock Exchange.

Extraordinary general meetings may be convened on the requisition of one or more members holding, at the date of deposit of the requisition, not less than one-tenth of the paid up capital of the Company having the right of voting at general meetings, on a one vote per share basis. Such requisition shall be made in writing to the board or the secretary for the purpose of requiring an extraordinary general meeting to be called by the board for the transaction of any business or resolution specified in such requisition. Such meeting shall be held within 2 months after the deposit of such requisition. If within 21 days of such deposit, the board fails to proceed to convene such meeting, the requisitionist(s) himself/herself (themselves) may do so in the same manner, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the board shall be reimbursed to the requisitionist(s) by the Company.

Notwithstanding any provisions in the Articles, any general meeting or any class meeting may be held by means of such telephone, electronic or other communication facilities as to permit all persons participating in the meeting to communicate with each other, and participation in such a meeting shall constitute presence at such meeting.

(iv) Notices of meetings and business to be conducted

An annual general meeting must be called by notice of not less than twenty-one (21) clear days. All other general meetings must be called by notice of at least fourteen (14) clear days. The notice is exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and must specify the time and place of the meeting and particulars of resolutions to be considered at the meeting and, in the case of special business, the general nature of that business.

In addition, notice of every general meeting must be given to all members of the Company other than to such members as, under the provisions of the Articles or the terms of issue of the shares they hold, are not entitled to receive such notices from the Company, and also to, among others, the auditors for the time being of the Company.

Any notice to be given to or by any person pursuant to the Articles may be served on or delivered to any member of the Company personally, by post to such member's registered address or by advertisement in newspapers in accordance with the requirements of the Stock Exchange. Subject to compliance with Cayman Islands law and the rules of the Stock Exchange, notice may also be served or delivered by the Company to any member by electronic means.

All business that is transacted at an extraordinary general meeting and at an annual general meeting is deemed special, save that in the case of an annual general meeting, each of the following business is deemed an ordinary business:

(aa) the declaration and sanctioning of dividends;

(bb) the consideration and adoption of the accounts and balance sheet and the reports of the directors and the auditors;

(cc) the election of directors in place of those retiring;

(dd) the appointment of auditors and other officers; and

(ee) the fixing of the remuneration of the directors and of the auditors.

(v) Quorum for meetings and separate class meetings

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the appointment of a chairman.

The quorum for a general meeting shall be two members present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy or, for quorum purposes only, two persons appointed by the clearing house as authorized representative or proxy, and entitled to vote. In respect of a separate class meeting (other than an adjourned meeting) convened to sanction the modification of class rights the necessary quorum shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of that class.

(vi) Proxies

Any member of the Company entitled to attend and vote at a meeting of the Company is entitled to appoint another person as his proxy to attend and vote instead of him. A member who is the holder of two or more shares may appoint more than one proxy to represent him and vote on his behalf at a general meeting of the Company or at a class meeting. A proxy need not be a member of the Company and is entitled to exercise the same powers on behalf of a member who is an individual and for whom he acts as proxy

as such member could exercise. In addition, a proxy is entitled to exercise the same powers on behalf of a member which is a corporation and for which he acts as proxy as such member could exercise as if it were an individual member. Votes may be given either personally (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy.

(f) Accounts and audit

The board shall cause true accounts to be kept of the sums of money received and expended by the Company, and the matters in respect of which such receipt and expenditure take place, and of the property, assets, credits and liabilities of the Company and of all other matters required by the Companies Act or necessary to give a true and fair view of the Company's affairs and to explain its transactions.

The accounting records must be kept at the registered office or at such other place or places as the board decides and shall always be open to inspection by any Director. No member (other than a Director) shall have any right to inspect any accounting record or book or document of the Company except as conferred by law or authorised by the board or the Company in general meeting. However, an exempted company must make available at its registered office in electronic form or any other medium, copies of its books of account or parts thereof as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act of the Cayman Islands.

A copy of every balance sheet and profit and loss account (including every document required by law to be annexed thereto) which is to be laid before the Company at its general meeting, together with a printed copy of the Directors' report and a copy of the auditors' report, shall not less than twenty-one (21) days before the date of the meeting and at the same time as the notice of annual general meeting be sent to every person entitled to receive notices of general meetings of the Company under the provisions of the Articles; however, subject to compliance with all applicable laws, including the rules of the Stock Exchange, the Company may send to such persons summarised financial statements derived from the Company's annual accounts and the directors' report instead provided that any such person may by notice in writing served on the Company, demand that the Company sends to him, in addition to summarised financial statements, a complete printed copy of the Company's annual financial statement and the directors' report thereon.

At the annual general meeting or at a subsequent extraordinary general meeting in each year, the members shall by ordinary resolution appoint an auditor to audit the accounts of the Company and such auditor shall hold office until the next annual general meeting. Moreover, the members may, at any general meeting, by ordinary resolution remove the auditor at any time before the expiration of his terms of office and shall by ordinary resolution at that meeting appoint another auditor for the remainder of his term. The remuneration of the auditors shall be fixed and approved by the Company by an ordinary resolution passed at a general meeting or in such manner as the members may by ordinary resolution determine.

The financial statements of the Company shall be audited by the auditor in accordance with generally accepted auditing standards which may be those of a country or jurisdiction other than the Cayman Islands. The auditor shall make a written report thereon in accordance with generally accepted auditing standards and the report of the auditor must be submitted to the members in general meeting.

(g) Dividends and other methods of distribution

The Company in general meeting may declare dividends in any currency to be paid to the members but no dividend shall be declared in excess of the amount recommended by the board.

The Articles provide dividends may be declared and paid out of the profits of the Company, realised or unrealised, or from any reserve set aside from profits which the directors determine is no longer needed. With the sanction of an ordinary resolution dividends may also be declared and paid out of share premium account or any other fund or account which can be authorised for this purpose in accordance with the Companies Act.

Except in so far as the rights attaching to, or the terms of issue of, any share may otherwise provide, (i) all dividends shall be declared and paid according to the amounts paid up on the shares in respect whereof the dividend is paid but no amount paid up on a share in advance of calls shall for this purpose be treated as paid up on the share and (ii) all dividends shall be apportioned and paid pro rata according to the amount paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. The Directors may deduct from any dividend or other monies payable to any member or in respect of any shares all sums of money (if any) presently payable by him to the Company on account of calls or otherwise.

Whenever the board or the Company in general meeting has resolved that a dividend be paid or declared on the share capital of the Company, the board may further resolve either (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up, provided that the members entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment, or (b) that members entitled to such dividend will be entitled to elect to receive an allotment of shares credited as fully paid up in lieu of the whole or such part of the dividend as the board may think fit.

The Company may also upon the recommendation of the board by an ordinary resolution resolve in respect of any one particular dividend of the Company that it may be satisfied wholly in the form of an allotment of shares credited as fully paid up without offering any right to members to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other sum payable in cash to the holder of shares may be paid by cheque or warrant sent through the post addressed to the holder at his registered address, or in the case of joint holders, addressed to the holder whose name stands first in the register of the Company in respect of the shares at his address as appearing in the register or addressed

to such person and at such addresses as the holder or joint holders may in writing direct. Every such cheque or warrant shall, unless the holder or joint holders otherwise direct, be made payable to the order of the holder or, in the case of joint holders, to the order of the holder whose name stands first on the register in respect of such shares, and shall be sent at his or their risk and payment of the cheque or warrant by the bank on which it is drawn shall constitute a good discharge to the Company. Any one of two or more joint holders may give effectual receipts for any dividends or other moneys payable or property distributable in respect of the shares held by such joint holders.

Whenever the board or the Company in general meeting has resolved that a dividend be paid or declared the board may further resolve that such dividend be satisfied wholly or in part by the distribution of specific assets of any kind.

All dividends or bonuses unclaimed for one year after having been declared may be invested or otherwise made use of by the board for the benefit of the Company until claimed and the Company shall not be constituted a trustee in respect thereof. All dividends or bonuses unclaimed for six years after having been declared may be forfeited by the board and shall revert to the Company.

No dividend or other monies payable by the Company on or in respect of any share shall bear interest against the Company.

(h) Inspection of corporate records

Pursuant to the Articles, the register and branch register of members maintained in Hong Kong shall be open to inspection for at least two (2) hours during business hours by members without charge, or by any other person upon a maximum payment of HK$2.50 or such lesser sum specified by the board, at the registered office or such other place at which the register is kept in accordance with the Companies Act or, upon a maximum payment of HK$1.00 or such lesser sum specified by the board, at the office where the branch register of members is kept, unless the register is closed in accordance with the Articles.

(i) Rights of minorities in relation to fraud or oppression

There are no provisions in the Articles relating to rights of minority shareholders in relation to fraud or oppression. However, certain remedies are available to members of the Company under Cayman Islands law, as summarised in paragraph 3(f) of this Appendix.

(j) Procedures on liquidation

Unless otherwise provided by the Companies Act, a resolution that the Company be wound up by the court or be wound up voluntarily shall be a special resolution.

Subject to any special rights, privileges or restrictions as to the distribution of available surplus assets on liquidation for the time being attached to any class or classes of shares:

(i) if the Company is wound up and the assets available for distribution amongst the members of the Company shall be more than sufficient to repay the whole of the capital paid up at the commencement of the winding up, the excess shall be distributed *pari passu* amongst such members in proportion to the amount paid up on the shares held by them respectively; and

(ii) if the Company is wound up and the assets available for distribution amongst the members as such shall be insufficient to repay the whole of the paid-up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up, or which ought to have been paid up, at the commencement of the winding up on the shares held by them respectively.

If the Company is wound up (whether the liquidation is voluntary or by the court) the liquidator may, with the authority of a special resolution and any other sanction required by the Companies Act divide among the members in specie or kind the whole or any part of the assets of the Company whether the assets shall consist of property of one kind or shall consist of properties of different kinds and the liquidator may, for such purpose, set such value as he deems fair upon any one or more class or classes of property to be divided as aforesaid and may determine how such division shall be carried out as between the members or different classes of members. The liquidator may, with the like authority, vest any part of the assets in trustees upon such trusts for the benefit of members as the liquidator, with the like authority, shall think fit, but so that no contributory shall be compelled to accept any shares or other property in respect of which there is a liability.

(k) Subscription rights reserve

The Articles provide that to the extent that it is not prohibited by and is in compliance with the Companies Act, if warrants to subscribe for shares have been issued by the Company and the Company does any act or engages in any transaction which would result in the subscription price of such warrants being reduced below the par value of a share, a subscription rights reserve shall be established and applied in paying up the difference between the subscription price and the par value of a share on any exercise of the warrants.

3. CAYMAN ISLANDS COMPANY LAW

The Company is incorporated in the Cayman Islands subject to the Companies Act and, therefore, operates subject to Cayman Islands law. Set out below is a summary of certain provisions of Cayman company law, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of Cayman company law and taxation, which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar:

(a) Company operations

As an exempted company, the Company's operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the amount of its authorised share capital.

(b) Share capital

The Companies Act provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the premiums on those shares shall be transferred to an account, to be called the "share premium account". At the option of a company, these provisions may not apply to premiums on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium.

The Companies Act provides that the share premium account may be applied by the company subject to the provisions, if any, of its memorandum and articles of association in (a) paying distributions or dividends to members; (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares; (c) the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Act); (d) writing-off the preliminary expenses of the company; and (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business.

The Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands (the "**Court**"), a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

(c) Financial assistance to purchase shares of a company or its holding company

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company to another person for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and acting in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

(d) Purchase of shares and warrants by a company and its subsidiaries

A company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a shareholder and the Companies Act expressly provides that it shall be lawful for the rights attaching to any shares to be varied, subject to the provisions of the company's articles of association, so as to provide that such shares are to be or are liable to be so redeemed. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. However, if the articles of association do not authorise the manner and terms of purchase, a company cannot purchase any of its own shares unless the manner and terms of purchase have first been authorised by an ordinary resolution of the company. At no time may a company redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any issued shares of the company other than shares held as treasury shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

Shares purchased by a company is to be treated as cancelled unless, subject to the memorandum and articles of association of the company, the directors of the company resolve to hold such shares in the name of the company as treasury shares prior to the purchase. Where shares of a company are held as treasury shares, the company shall be entered in the register of members as holding those shares, however, notwithstanding the foregoing, the company is not to be treated as a member for any purpose and must not exercise any right in respect of the treasury shares, and any purported exercise of such a right shall be void, and a treasury share must not be voted, directly or indirectly, at any meeting of the company and must not be counted in determining the total number of issued shares at any given time, whether for the purposes of the company's articles of association or the Companies Act.

A company is not prohibited from purchasing and may purchase its own warrants subject to and in accordance with the terms and conditions of the relevant warrant instrument or certificate. There is no requirement under Cayman Islands law that a company's memorandum

or articles of association contain a specific provision enabling such purchases and the directors of a company may rely upon the general power contained in its memorandum of association to buy and sell and deal in personal property of all kinds.

Under Cayman Islands law, a subsidiary may hold shares in its holding company and, in certain circumstances, may acquire such shares.

(e) Dividends and distributions

The Companies Act permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account. With the exception of the foregoing, there are no statutory provisions relating to the payment of dividends. Based upon English case law, which is regarded as persuasive in the Cayman Islands, dividends may be paid only out of profits.

No dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the company's assets (including any distribution of assets to members on a winding up) may be made to the company, in respect of a treasury share.

(f) Protection of minorities and shareholders' suits

The Courts ordinarily would be expected to follow English case law precedents which permit a minority shareholder to commence a representative action against or derivative actions in the name of the company to challenge (a) an act which is ultra vires the company or illegal, (b) an act which constitutes a fraud against the minority and the wrongdoers are themselves in control of the company, and (c) an irregularity in the passing of a resolution which requires a qualified (or special) majority.

In the case of a company (not being a bank) having a share capital divided into shares, the Court may, on the application of members holding not less than one fifth of the shares of the company in issue, appoint an inspector to examine into the affairs of the company and to report thereon in such manner as the Court shall direct.

Any shareholder of a company may petition the Court which may make a winding up order if the Court is of the opinion that it is just and equitable that the company should be wound up or, as an alternative to a winding up order, (a) an order regulating the conduct of the company's affairs in the future, (b) an order requiring the company to refrain from doing or continuing an act complained of by the shareholder petitioner or to do an act which the shareholder petitioner has complained it has omitted to do, (c) an order authorising civil proceedings to be brought in the name and on behalf of the company by the shareholder

petitioner on such terms as the Court may direct, or (d) an order providing for the purchase of the shares of any shareholders of the company by other shareholders or by the company itself and, in the case of a purchase by the company itself, a reduction of the company's capital accordingly.

Generally claims against a company by its shareholders must be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

(g) Disposal of assets

The Companies Act contains no specific restrictions on the power of directors to dispose of assets of a company. However, as a matter of general law, every officer of a company, which includes a director, managing director and secretary, in exercising his powers and discharging his duties must do so honestly and in good faith with a view to the best interests of the company and exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

(h) Accounting and auditing requirements

A company must cause proper books of account to be kept with respect to (i) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place; (ii) all sales and purchases of goods by the company; and (iii) the assets and liabilities of the company.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

An exempted company must make available at its registered office in electronic form or any other medium, copies of its books of account or parts thereof as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act of the Cayman Islands.

(i) Exchange control

There are no exchange control regulations or currency restrictions in the Cayman Islands.

(j) Taxation

Pursuant to the Tax Concessions Act of the Cayman Islands, the Company has obtained an undertaking:

(1) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciation shall apply to the Company or its operations; and

(2) that the aforesaid tax or any tax in the nature of estate duty or inheritance tax shall not be payable on or in respect of the shares, debentures or other obligations of the Company.

The undertaking for the Company is for a period of twenty years from 26 July 2021.

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save for certain stamp duties which may be applicable, from time to time, on certain instruments executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are a party to a double tax treaty entered into with the United Kingdom in 2010 but otherwise is not party to any double tax treaties.

(k) Stamp duty on transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

(l) Loans to directors

There is no express provision in the Companies Act prohibiting the making of loans by a company to any of its directors.

(m) Inspection of corporate records

The notice of registered office is a matter of public record. A list of the names of the current directors and alternate directors (if applicable) is made available by the Registrar of Companies for inspection by any person on payment of a fee. The register of mortgages is open to inspection by creditors and members.

Members of the Company have no general right under the Companies Act to inspect or obtain copies of the register of members or corporate records of the Company. They will, however, have such rights as may be set out in the Company's Articles.

(n) Register of members

An exempted company may maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as the directors may, from time to time, think fit. The register of members shall contain such particulars as required by Section 40 of the Companies Act. A branch register must be kept in the same manner in which a principal register is by the Companies Act required or permitted to be kept. The company shall cause to be kept at the place where the company's principal register is kept a duplicate of any branch register duly entered up from time to time.

There is no requirement under the Companies Act for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection. However, an exempted company shall make available at its registered office, in electronic form or any other medium, such register of members, including any branch register of members, as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act of the Cayman Islands.

(o) Register of Directors and Officers

The Company is required to maintain at its registered office a register of directors and officers which is not available for inspection by the public. A copy of such register must be filed with the Registrar of Companies in the Cayman Islands and any change must be notified to the Registrar within thirty (30) days of any change in such directors or officers.

(p) Beneficial Ownership Register

An exempted company is required to maintain a beneficial ownership register at its registered office that records details of the persons who ultimately own or control, directly or indirectly, 25% or more of the equity interests or voting rights of the company or have rights to appoint or remove a majority of the directors of the company. The beneficial ownership register is not a public document and is only accessible by a designated competent authority of the Cayman Islands. Such requirement does not, however, apply to an exempted company with its shares listed on an approved stock exchange, which includes the Stock Exchange. Accordingly, for so long as the shares of the Company are [**REDACTED**] on the Stock Exchange, the Company is not required to maintain a beneficial ownership register.

(q) Winding up

A company may be wound up (a) compulsorily by order of the Court, (b) voluntarily, or (c) under the supervision of the Court.

The Court has authority to order winding up in a number of specified circumstances including where the members of the company have passed a special resolution requiring the company to be wound up by the Court, or where the company is unable to pay its debts, or where it is, in the opinion of the Court, just and equitable to do so. Where a petition is presented by members of the company as contributories on the ground that it is just and equitable that the company should be wound up, the Court has the jurisdiction to make certain other orders as an alternative to a winding-up order, such as making an order regulating the conduct of the company's affairs in the future, making an order authorising civil proceedings to be brought in the name and on behalf of the company by the petitioner on such terms as the Court may direct, or making an order providing for the purchase of the shares of any of the members of the company by other members or by the company itself.

A company (save with respect to a limited duration company) may be wound up voluntarily when the company so resolves by special resolution or when the company in general meeting resolves by ordinary resolution that it be wound up voluntarily because it is unable to pay its debts. In the case of a voluntary winding up, such company is obliged to cease to carry on its business (except so far as it may be beneficial for its winding up) from the time of passing the resolution for voluntary winding up or upon the expiry of the period or the occurrence of the event referred to above.

For the purpose of conducting the proceedings in winding up a company and assisting the Court therein, there may be appointed an official liquidator or official liquidators; and the court may appoint to such office such person, either provisionally or otherwise, as it thinks fit, and if more persons than one are appointed to such office, the Court must declare whether any act required or authorised to be done by the official liquidator is to be done by all or any one or more of such persons. The Court may also determine whether any and what security is to be given by an official liquidator on his appointment; if no official liquidator is appointed, or during any vacancy in such office, all the property of the company shall be in the custody of the Court.

As soon as the affairs of the company are fully wound up, the liquidator must make a report and an account of the winding up, showing how the winding up has been conducted and how the property of the company has been disposed of, and thereupon call a general meeting of the company for the purposes of laying before it the account and giving an explanation thereof. This final general meeting must be called by at least 21 days' notice to each contributory in any manner authorised by the company's articles of association and published in the Gazette.

(r) Reconstructions

There are statutory provisions which facilitate reconstructions and amalgamations approved by (i) a majority in number representing seventy-five per cent. (75%) in value of creditors, or (ii) seventy-five per cent. (75%) in value of shareholders or class of shareholders, as the case may be, as are present at a meeting called for such purpose and thereafter sanctioned by the Court. Whilst a dissenting shareholder would have the right to express to the Court his view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Court is unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management.

The Companies Act also contains statutory provisions which provide that a company may present a petition to the Court for the appointment of a restructuring officer on the grounds that the company (a) is or is likely to become unable to pay its debts within the meaning of section 93 of the Companies Act; and (b) intends to present a compromise or arrangement to its creditors (or classes thereof) either, pursuant to the Companies Act, the law of a foreign country or by way of a consensual restructuring. The petition may be presented by a company acting by its directors, without a resolution of its shareholders or an express power in its articles of association. On hearing such a petition, the Court may, among other things, make an order appointing a restructuring officer or make any other order as the Court thinks fit.

(s) Take-overs

Where an offer is made by a company for the shares of another company and, within four (4) months of the offer, the holders of not less than ninety per cent. (90%) of the shares which are the subject of the offer accept, the offeror may at any time within two (2) months after the expiration of the said four (4) months, by notice in the prescribed manner require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Court within one (1) month of the notice objecting to the transfer. The burden is on the dissenting shareholder to show that the Court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority shareholders.

(t) Indemnification

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Court to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

(u) Economic Substance Requirements

Pursuant to the International Tax Cooperation (Economic Substance) Act, 2018 of the Cayman Islands ("**ES Act**") that came into force on 1 January 2019, a "relevant entity" is required to satisfy the economic substance test set out in the ES Act. A "relevant entity" includes an exempted company incorporated in the Cayman Islands as is the Company; however, it does not include an entity that is tax resident outside the Cayman Islands. Accordingly, for so long as the Company is a tax resident outside the Cayman Islands, including in Hong Kong, it is not required to satisfy the economic substance test set out in the ES Act.

4. GENERAL

Conyers Dill & Pearman, the Company's special legal counsel on Cayman Islands law, have sent to the Company a letter of advice summarising certain aspects of Cayman Islands company law. This letter, together with a copy of the Companies Act, is available on display as referred to in the paragraph headed "Documents Delivered to the Registrar of Companies and Available on Display" in Appendix V to this document. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

We were incorporated in the Cayman Islands on July 22, 2021 under the Companies Act as an exempted company with limited liability. Accordingly, our corporate structure and Articles of Association are subject to the relevant laws of the Cayman Islands. A summary of certain aspects of the Cayman Islands Company Law and a summary of certain provisions of our Articles of Associations are set out in the section headed "Summary of the Constitution of the Company and Cayman Islands Company Law" in Appendix III to this document.

Our registered place of business in Hong Kong is at Units 303 & 305, 3/F, Building 20E, Hong Kong Science Park, Shatin, N.T., Hong Kong. We were registered as a non-Hong Kong Company under Part 16 of the Companies Ordinance on September 15, 2021. David CHIEN of Units 303 & 305, 3/F, Building 20E, Hong Kong Science Park, Shatin, N.T., Hong Kong has been appointed as our authorized representative for the acceptance of service of process and notices in Hong Kong.

2. Changes in the Share Capital of Our Company

As of the date of incorporation of our Company, our authorized share capital was US$50,000 divided into 500,000,000 Shares of US$0.0001 each. Upon its incorporation, one nil-paid Share was allotted and issued to an initial subscriber who is an Independent Third Party and on the same day, the initial subscriber transferred one Share to Harmony Tree Limited.

On September 28, 2021, the Shareholder of our Company resolved to increase our authorized share capital to US$600,000 divided into 6,000,000,000 Shares of US$0.0001 each.

Save as disclosed above and as mentioned in "– 4. Resolutions of the Shareholders of the Company Passed on [●]" below, there has been no alteration in the share capital of our Company since its incorporation.

3. Changes in the Share Capital of Our Subsidiary

Our subsidiaries are set out in the Accountant's Report, the text of which is set out in Appendix I to this document. The following alteration in the share capital of our subsidiaries have taken place within the two years immediately preceding the date of this document:

ONM Group Ltd.

On October 29, 2020, the director and shareholder of ONM Group Ltd. resolved to, among others, (i) increase the authorized share capital of ONM Group Ltd. by US$600,000 and (ii) diminish and cancel the authorized share capital of HK$380,000. As a result of the foregoing resolutions, the denomination of ONM Group Ltd. was changed from Hong Kong dollars to U.S. dollars, and the authorized share capital of ONM Group Ltd. consists of US$600,000 divided into 6,000,000,000 ordinary shares with par value of US$0.0001 each.

ONM Japan

On June 25, 2021, the share capital of ONM Japan was further increased to JPY644,450,000 divided into 21,800 shares, with an additional 20,000 fully-paid shares allotted and issued to ONM HK.

On September 3, 2021, the share capital of ONM Japan was reduced to JPY90 million.

Save as disclosed above, there has been no alteration in the share capital of our subsidiaries within the two years immediately preceding the date of this document.

4. Resolutions of the Shareholders of the Company Passed on [●]

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on [●], it was resolved, among others:

(a) the Memorandum and Articles of Association were approved and adopted, and will come into effect upon [**REDACTED**];

(b) the Post-[**REDACTED**] Share Option Scheme was approved and adopted, and will come into effect upon [**REDACTED**];

(c) conditional on (1) the [**REDACTED**] granting the [**REDACTED**] of, and permission to [**REDACTED**] in, the Shares in issue and to be issued as mentioned in this document; and (2) the obligations of the [**REDACTED**] under the [**REDACTED**] Agreements becoming unconditional and the [**REDACTED**] Agreements not being terminated in accordance with the terms therein or otherwise:

(i) the [**REDACTED**] was approved and our Directors were authorized to effect the same, and to allot and issue the [**REDACTED**] pursuant to the [**REDACTED**];

(ii) the proposed [**REDACTED**] was approved, and our Directors were authorized to implement such [**REDACTED**];

(iii) all the issued and unissued Preferred Shares be re-designated and re-classified as ordinary Shares, having the rights and restrictions as set out in the Amended and Restated Memorandum and Articles of Association (the "**Share Redesignation**"), with effect immediately prior to the [**REDACTED**], was approved; and

(iv) the consolidation of every five shares with par value of US$0.0001 each in the Company's issued and unissued share capital into one share of the corresponding class with par value of US$0.0005 each (the "**Share Consolidation**"), with effect immediately upon completion of the Share Redesignation, was approved;

(d) a general unconditional mandate was granted to our Directors to allot, issue and deal with Shares, and to make or grant offers, agreements, or options which might require such Shares to be allotted and issued or dealt with at any time subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, shall not exceed 20% of the aggregate nominal value of the share capital of our Company in issue immediately following completion of the [**REDACTED**].

This mandate does not cover Shares to be allotted, issued, or dealt with under a rights issue or scrip dividend scheme or similar arrangements, or a specific authority granted by our Shareholders or under the Share Incentive Schemes. This general mandate to issue Shares will remain in effect until:

(i) the conclusion of the next annual general meeting of our Company;

(ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or

(iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting of our Company;

whichever is the earliest;

(e) a general unconditional mandate was granted to our Directors to exercise all powers of our Company to repurchase Shares with an aggregate nominal value of not more than 10% of the aggregate nominal value of the share capital of our Company in issue immediately following completion of the [**REDACTED**] (excluding Shares which may be allotted and issued under the Share Incentive Schemes).

This mandate only relates to repurchase made on the [**REDACTED**] or on any other stock exchange on which the Shares may be [**REDACTED**] (and which is recognized by the SFC and the Stock Exchange for this purpose) and made in accordance with all applicable laws and regulations and the requirements of the Listing Rules. This general mandate to repurchase Shares will remain in effect until:

(i) the conclusion of the next annual general meeting of our Company;

(ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or

(iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting of our Company;

whichever is the earliest; and

(f) the general unconditional mandate as mentioned in paragraph (d) above would be extended by the addition to the aggregate nominal value of the Shares which may be allotted and issued or agreed to be allotted and issued by our Directors pursuant to such general mandate of an amount representing the aggregate nominal value of the Shares purchased by our Company pursuant to the mandate to repurchase Shares referred to in paragraph (e) above (up to 10% of the aggregate nominal value of the Shares in issue immediately following completion of the [**REDACTED**], excluding any Shares which may fall to be allotted and issued under the Share Incentive Scheme).

5. Restrictions on Repurchase

This section sets out information required by the Stock Exchange to be included in this document concerning the repurchase by us of our own Shares.

(a) Provisions of the Listing Rules

The Listing Rules permit companies with a primary [**REDACTED**] on the [**REDACTED**] to repurchase their own Shares on the [**REDACTED**] subject to certain restrictions, the more important of which are summarized below:

(i) Shareholders' Approval

All proposed repurchase of Shares (which must be fully paid up in the case of shares) by a company with a primary [**REDACTED**] on the [**REDACTED**] must be approved in advance by an ordinary resolution of the shareholders, either by way of general mandate or by specific approval of a particular transaction.

(ii) Source of Funds

Repurchases must be funded out of funds legally available for the purpose in accordance with the constitutive documents of a [**REDACTED**] company, the laws of the jurisdiction in which the listed company is incorporated or otherwise established. A [**REDACTED**] company may not repurchase its own securities on the [**REDACTED**] for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange from time to time.

Subject to the foregoing, any repurchases by a [**REDACTED**] company may be made out of the funds which would otherwise be available for dividend or distribution or out of the proceeds of a new issue of shares made for the purpose of the repurchase. Any amount of premium payable on the purchase over the par value of the shares to be repurchased must be out of the funds which would otherwise be available for dividend or distribution or from sums standing to the credit of our share premium account.

(b) Reasons for Repurchase

Our Directors believe that it is in the best interest of us and our Shareholders for our Directors to have general authority from the Shareholders to enable us to repurchase Shares in the market. Such repurchases may, depending on market conditions and funding arrangements at the time, lead to an enhancement of the net asset value per Share and/or earnings per Share and will only be made where our Directors believe that such repurchases will benefit us and our Shareholders.

(c) Funding of Repurchases

In repurchasing securities, we may only apply funds legally available for such purpose in accordance with the Amended and Restated Memorandum and Articles of Association, the Companies Law or other applicable laws of Cayman Islands and the Listing Rules. On the basis of our current financial condition as disclosed in this document and taking into account our current working capital position, our Directors consider that, if the Repurchase Mandate were to be exercised in full, it might have a material adverse effect on our working capital and/or our gearing position as compared with the position disclosed in this document. However, our Directors do not propose to exercise the repurchase mandate to such an extent as would, in the circumstances, have a material adverse effect on our working capital requirements or the gearing levels which in the opinion of our Directors are from time to time appropriate for us.

(d) General

Exercise in full of the current repurchase mandate, on the basis of [**REDACTED**] Shares in issue after completion of the [**REDACTED**] (without taking into account of the Shares that may be allotted and issued under the Share Incentive Schemes), could accordingly result in up to [**REDACTED**] Shares being repurchased by us during the period prior to:

(i) the conclusion of our next annual general meeting;

(ii) the expiration of the period within which the next annual general meeting of our Company is required by any applicable law or the Articles of Association to be held; or

(iii) the date on which the repurchase mandate is varied or revoked by an ordinary resolution of our Shareholders in general meeting,

whichever is the earliest.

None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their close associates (as defined in the Listing Rules) currently intends to sell any Shares to us or our subsidiaries. Our Directors have undertaken with the Stock Exchange that, so far as the same may be applicable, they will exercise the repurchase mandate in accordance with the Listing Rules, the Amended and Restated Memorandum and Articles of Association, the Companies Law or any other applicable laws of the Cayman Islands.

If, as a result of a repurchase of our Shares pursuant to the repurchase mandate, a Shareholder's proportionate interest in our voting rights is increased, such increase will be treated as an acquisition for the purpose of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of us and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code. Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the repurchase mandate.

No core connected person, as defined in the Listing Rules, has notified us that he/she or it has a present intention to sell his/her or its Shares to us, or has undertaken not to do so, if the repurchase mandate is exercised.

B. FURTHER INFORMATION ABOUT THE BUSINESS OF THE COMPANY

1. Summary of Material Contracts

The following contracts (not being contracts entered into in the ordinary course of business) were entered into by our Group within the two years preceding the date of this document and are or may be material:

(a) [**REDACTED**].

2. Our Material Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, our material registered trademarks were as follows:

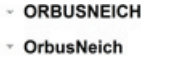
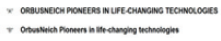
No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
1	业聚	PRC	ONM Shenzhen	3870582	10	May 27, 2025
2.		PRC	ONM Shenzhen	3051519	10	March 20, 2023*
3.	业聚	PRC	ONM Shenzhen	32081106	44	March 20, 2029
4.		PRC	ONM Shenzhen	32081105	35	August 20, 2029
5.		PRC	ONM Shenzhen	32081104	41	July 6, 2029
6.	NEICH	PRC	ONM Shenzhen	6616247	10	June 13, 2030
7.	NEICH	PRC	ONM Shenzhen	6616246	44	April 27, 2030
8.		PRC	ONM Shenzhen	41134756	44	June 6, 2031
9.	Combo	PRC	ONM Singapore	22656654	10	April 13, 2028
10.	COMBO	PRC	ONM Singapore	62468883	10	September 27, 2032
11.	COMBO ORBUSNEICH	PRC	ONM Singapore	28633892	5	January 06, 2029
12.	Dual Therapy Stent	PRC	ONM Singapore	10750993	44	August 13, 2023*
13.	COMBO ORBUSNEICH	PRC	ONM Singapore	28633894	10	December 20, 2028
14.	康博	PRC	ONM Singapore	34102021	5	November 06, 2029
15.		PRC	ONM Singapore	6616257	10	March 27, 2030

* We intend to renew the trademark and are in the process of preparing for renewal application.

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
16.		PRC	ONM Singapore	6616256	44	April 27, 2030
17.	OrbusNeich	PRC	ONM Singapore	6616249	10	March 27, 2030
18.	OrbusNeich	PRC	ONM Singapore	6616248	44	April 27, 2030
19.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	PRC	ONM Singapore	32081112	10	March 27, 2029
20.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	PRC	ONM Singapore	32081111	35	March 27, 2029
21.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	PRC	ONM Singapore	32081110	41	March 27, 2029
22.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	PRC	ONM Singapore	32081109	44	March 27, 2029
23.	JADE	PRC	ONM Singapore	28633899	10	July 06, 2029
24.	JADE	PRC	ONM Singapore	62488027	10	October 6, 2032
25.		PRC	ONM Singapore	63340485	10	October 6, 2032
26.	SAPPHIRE	PRC	ONM Singapore	6616258	44	April 27, 2030
27.	SAPPHIRE	PRC	ONM Singapore	28633896	10	June 20, 2029
28.		PRC	ONM Singapore	16713706	10	August 06, 2027
29.		PRC	ONM Singapore	16713707	44	June 06, 2026
30.	SAPPHIRE ORBUSNEICH	PRC	ONM Singapore	28633895	10	December 27, 2028
31.	SCOREFLEX	PRC	ONM Singapore	6513210	10	March 20, 2030
32.	SCOREFLEX	PRC	ONM Singapore	6513211	44	November 27, 2030
33.		PRC	ONM Singapore	6616251	10	March 27, 2030
34.		PRC	ONM Singapore	6616356	44	April 27, 2030

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
35.	SCOREFLEX TRIO	PRC	ONM Singapore	48283561	10	March 06, 2031
36.	TELEPORT	PRC	ONM Singapore	21005174	10	October 13, 2027
37.	TELEPORT	PRC	ONM Singapore	21005175	44	October 13, 2027
38.	TELEPORT NEURO	PRC	ONM Singapore	61184812	10	June 6, 2032
39.	TELEPORT NEURO	PRC	ONM Singapore	61213089	44	June 13, 2032
40.	TELEPORT XT	PRC	ONM Singapore	62787092	10	August 27, 2032
41.	TELEPORT XT	PRC	ONM Singapore	62789607	44	August 27, 2032
42.	业聚	PRC	ONM Singapore	55577231	42	November 27, 2031
43.	SCOREFLEX TRIO	PRC	ONM Singapore	48283560	44	March 6, 2031
44.	Combo	PRC	ONM Singapore	8110992	44	April 20, 2031
45.	Combo Stent	PRC	ONM Singapore	8110991	10	March 20, 2031
46.	Combo	European Union	ONM Singapore	008945552	10, 44	March 11, 2030
47.	Combo	European Union	ONM Singapore	013152831	5	August 7, 2024
48.	Dual Therapy Stent	European Union	ONM Singapore	010794576	10, 44	April 10, 2032
49.	NEICH	European Union	ONM Shenzhen	006744635	10, 44	March 11, 2028
50.	ORBUS	European Union	ONM Singapore	002326619	10	August 2, 2031
51.	OrbusNeich	European Union	ONM Singapore	006670319	10, 44	February 14, 2028
52.		European Union	ONM Singapore	004311858	10, 44	March 24, 2025
53.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	European Union	ONM Singapore	017923859	10, 35, 41, 44	June 26, 2028
54.	Jade OrbusNeich	European Union	ONM Singapore	017538711	10	November 29, 2027
55.		European Union	ONM Singapore	013361597	10, 44	October 15, 2024
56.	SAPPHIRE	European Union	ONM Singapore	006669601	10, 44	February 14, 2028
57.		European Union	ONM Singapore	006795421	10, 44	April 1, 2028

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
58.	SCOREFLEX	European Union	ONM Singapore	006349054	10, 44	October 10, 2027
59.	SCOREFLEX TRIO	European Union	ONM Singapore	018225848	10, 44	April 15, 2030
60.	TELEPORT	European Union	ONM Singapore	015746051	10	August 16, 2026
61.	TELEPORT	European Union	ONM Singapore	017949885	44	September 4, 2028
62.		European Union	ONM Singapore	018641392	10, 44	January 20, 2032
63.		European Union	ONM Singapore	18554372	10, 35, 41, 42, 44	September 8, 2031
64.		European Union	ONM Singapore	18505340	10, 44	July 1, 2031
65.		European Union	ONM Singapore	18555189	10, 44	September 9, 2031
66.	Combo	Germany	ONM Singapore	013152831	5	August 7, 2024
67.	COMBO	Germany	ONM Singapore	008945552	10, 44	March 11, 2030
68.	Dual Therapy Stent	Germany	ONM Singapore	010794576	10, 44	April 10, 2032
69.	ORBUS	Germany	ONM Singapore	002326619	10	August 2, 2031
70.	NEICH	Germany	ONM Shenzhen	006744635	10, 44	March 11, 2028
71.		Germany	ONM Singapore	004311858	10, 44	March 24, 2025
72.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	Germany	ONM Singapore	0017923859	10, 35, 41, 44	June 26, 2028
73.	OrbusNeich	Germany	ONM Singapore	006670319	10, 44	February 14, 2028
74.	JADE OrbusNeich	Germany	ONM Singapore	017538711	10	November 29, 2027
75.	SAPPHIRE	Germany	ONM Singapore	006669601	10, 44	February 14, 2028
76.	SCOREFLEX	Germany	ONM Singapore	006349054	10, 44	October 10, 2027

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
77.		Germany	ONM Singapore	006795421	10, 44	April 1, 2028
78.	SCOREFLEX TRIO	Germany	ONM Singapore	018225848	10, 44	April 15, 2030
79.	TELEPORT	Germany	ONM Singapore	017949885	44	September 4, 2028
80.	TELEPORT	Germany	ONM Singapore	015746051	10	August 16, 2026
81.	"A"  "B" 	Hong Kong	ONM Singapore	304316797	10, 44	October 26, 2027
82.		Hong Kong	ONM Singapore	304316805	10, 44	October 26, 2027
83.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	Hong Kong	ONM Singapore	304569661	35, 41	June 19, 2028
84.		Hong Kong	ONM Singapore	304317714	10, 44	October 29, 2027
85.		Hong Kong	ONM Singapore	305297365	10, 44	June 7, 2030
86.	"A" 祥豐 "B" 祥丰	Hong Kong	ONM Singapore	304316814	10, 44	October 26, 2027
87.	JADE	Hong Kong	ONM Singapore	303784663	10, 44	May 22, 2026
88.	SAPPHIRE	Hong Kong	ONM Singapore	303814966	10, 44	June 21, 2026
89.	SAPPHIRE	Hong Kong	ONM Singapore	304186567	10, 44	June 26, 2027
90.	TELEPORT	Hong Kong	ONM Singapore	303878399	10, 44	August 21, 2026
91.		Hong Kong	ONM Singapore	305657536	10, 35, 42, 44	June 14, 2031
92.		Hong Kong	ONM Singapore	305731768	10, 16, 35, 42, 44	August 29, 2031
93.		Hong Kong	ONM Singapore	305731777	10, 16, 35, 42, 44	August 29, 2031
94.		Hong Kong	ONM Singapore	305797144	10, 16, 35, 42, 44	November 9, 2031
95.		Hong Kong	ONM Singapore	305765932	10, 16, 35, 42, 44	October 5, 2031

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
96.	業聚醫療业聚医疗 OrbusNeich OrbusNeich	Hong Kong	ONM Singapore	305765941	10, 16, 35, 42, 44	October 5, 2031
97.	TELEPORT XT	Hong Kong	ONM Singapore	305887379	10, 44	February 21, 2032
98.	Teleport XT	Hong Kong	ONM Singapore	305887388	10, 44	February 21, 2032
99.	TELEPORT XT MICROCATHETER	Hong Kong	ONM Singapore	305887405	10, 44	February 21, 2032
100.	TELEPORT NEURO MICROCATHETER	Hong Kong	ONM Singapore	305887414	10, 44	February 21, 2032
101.	JADE PTA BALLOON CATHETER	Hong Kong	ONM Singapore	305887423	10, 44	February 21, 2032
102.	SCOREFLEX TRIO	Hong Kong	ONM Singapore	305680233	10, 44	July 7, 2031
103.	scoreflex TRIO	Hong Kong	ONM Singapore	305690359	10, 44	July 18, 2031
104.	EZGuide	Japan	ONM Singapore	6551297	10, 44	May 2, 2032
105.	COMBO	Japan	ONM Singapore	5813161	10, 44	December 11, 2025
106.	COMBO コンボ	Japan	ONM Singapore	6059938	10	July 6, 2028
107.	Dual Therapy Stent	Japan	ONM Singapore	5564623	10, 44	March 8, 2023*
108.	NEICH	Japan	ONM Shenzhen	5180153	10, 44	November 14, 2028
109.	OrbusNeich	Japan	ONM Singapore	5180154	10, 44	November 14, 2028
110.	OrbusNeich	Japan	ONM Singapore	5168959	10, 44	September 26, 2028
111.	ORBUSNEICH PIONEERS IN LIFE-CHANGING TECHNOLOGIES	Japan	ONM Singapore	6152034	10, 35, 41, 44	June 14, 2029
112.	JADE	Japan	ONM Singapore	6078472	10, 44	September 7, 2028
113.	SAPPHIRE II PRO Coronary Dilatation Catheter	Japan	ONM Singapore	5954545	10, 44	June 16, 2027

* We intend to renew the trademark and are in the process of preparing for renewal application.

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
114.	SAPPHIRE	Japan	ONM Singapore	5234166	44	May 29, 2029
115.	SAPPHIRE	Japan	ONM Singapore	5903792	10	December 9, 2026
116.	SAPPHIRE サファイア	Japan	ONM Singapore	6117095	10	January 25, 2029
117.	SCOREFLEX	Japan	ONM Singapore	5140046	10, 44	June 13, 2028
118.	scoreflex	Japan	ONM Singapore	5267164	10, 44	September 18, 2029
119.	SCOREFLEX TRIO	Japan	ONM Singapore	6383777	10, 44	April 28, 2031
120.	scoreflex TRIO	Japan	ONM Singapore	6625024	10, 44	October 7, 2032
121.	TELEPORT	Japan	ONM Singapore	5940687	10, 44	April 14, 2027
122.	JADE PTA BALLOON CATHETER	Japan	ONM Singapore	2022/13 (designated under International Registration No. 1656328)	10, 44	February 23, 2032
123.	OrbusNeich	Japan	ONM Singapore	2021-366102 (designated under International Registration No. 1622555)	10, 35, 41, 42, 44	September 15, 2031
124.	COMBO AB-SES	Japan	ONM Singapore	6537125	5, 10	March 30, 2032
125.	OrbusNeich	Switzerland	ONM Singapore	000726799	10,44	September 10, 2028
126.	COMBO	United States	ONM Singapore	5105463	5	December 20, 2026
127.	ORBUSNEICH	United States	ONM Singapore	4552384	10, 44	June 17, 2024
128.	JADE	United States	ONM Singapore	5503573	10	June 26, 2028
129.	SAPPHIRE	United States	ONM Singapore	4700026	10, 44	March 10, 2025
130.	SCOREFLEX	United States	ONM Singapore	5052752	10, 44	October 4, 2026
131.	TELEPORT	United States	ONM Singapore	6102329	10	July 14, 2030

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
132.	Teleport Microcatheter	United States	ONM Singapore	6096966	10	July 7, 2030
133.	scoreflex	United States	ONM Singapore	6487346	10	September 14, 2031
134.	OrbusNeich	United States	ONM Singapore	4552385	10, 44	June 17, 2024
135.	OrbusNeich	Taiwan	ONM Singapore	02220264	10, 35, 42, 44	April 30, 2032
136.	業聚	Taiwan	ONM Singapore	02220265	10, 35, 42, 44	April 30, 2032
137.	COMBO	WIPO (designating Singapore Malaysia and Vietnam)	ONM Singapore	1 662 540	5, 10, 44	April 5, 2032
138.	JADE	WIPO (designating Singapore Malaysia and Vietnam)	ONM Singapore	1 661 902	10, 44	March 23, 2032
139.	SAPPHIRE	WIPO (designating Singapore Malaysia and Vietnam)	ONM Singapore	1 682 609	10, 44	July 20, 2032
140.	scoreflex TRIO Balloon Dilatation Catheter	WIPO (designating Singapore Malaysia and Vietnam)	ONM Singapore	1 671 935	10, 44	June 2, 2032
141.	JADE	United Kingdom	ONM Singapore	UK00003756635	10, 44	February 18, 2032
142.	JADE PTA BALLOON CATHETER	United Kingdom	ONM Singapore	UK00003756632	10, 44	February 18, 2032
143.	Teleport Neuro Microcatheter	United Kingdom	ONM Singapore	UK00003756636	10, 44	February 18, 2032

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
144.	Teleport Neuro Microcatheter	United Kingdom	ONM Singapore	UK00003756638	10, 44	February 18, 2032
145.	SAPPHIRE	Benelux	ONM Singapore	1461742	44	March 23, 2032

As of the Latest Practicable Date, we have applied for the registration of the following trademarks which we consider to be material to our business:

No.	Trademark	Place of registration	Name of applicant	Application no.	Class	Application date
1	scoreflex TRIO	Japan	ONM Singapore	2021-082928	10, 44	July 2, 2021
2	OrbusNeich	Japan	ONM Singapore	2022352600 (designated under International Registration No. 1645795)	10, 35, 41, 42, 45	January 13, 2022
3	OrbusNeich	Japan	ONM Singapore	2022351999 (designated under International Registration No. 1643715)	10	January 12, 2022
4	EZGUIDE	United States	ONM Singapore	88893065	10	April 29, 2020
5	OrbusNeich	United States	ONM Singapore	90731722	5, 10, 41, 44	May 24, 2021
6	PIONEERS IN LIFE-CHANGING TECHNOLOGIES	United States	ONM Singapore	90757847	5, 10, 41, 44	June 7, 2021
7	scoreflex TRIO	United States	ONM Singapore	90849981	10	July 27, 2021
8	JADE PTA BALLOON CATHETER	United States	ONM Singapore	97150148	10	December 1, 2021
9	业聚	PRC	ONM Singapore	55736856	41	April 30, 2021

No.	Trademark	Place of registration	Name of applicant	Application no.	Class	Application date
10	OrbusNeich 业聚医疗	PRC	ONM Singapore	59285145	10	September 16, 2021
11	OrbusNeich 业聚医疗	PRC	ONM Singapore	59285609	35	September 16, 2021
12	OrbusNeich 业聚医疗	PRC	ONM Singapore	59281345	42	September 16, 2021
13	OrbusNeich 业聚医疗	PRC	ONM Singapore	59273954	44	September 16, 2021
14	OrbusNeich 业聚医疗	PRC	ONM Singapore	59263855	10	September 16, 2021
15	OrbusNeich 业聚医疗	PRC	ONM Singapore	59271019	35	September 16, 2021
16	OrbusNeich 业聚医疗	PRC	ONM Singapore	59271046	42	September 16, 2021
17	OrbusNeich 业聚医疗	PRC	ONM Singapore	59279577	44	September 16, 2021
18	SAPPHIRE NEURO	PRC	ONM Singapore	61211539	10	December 7, 2021
19	SAPPHIRE NEURO	PRC	ONM Singapore	61201950	44	December 7, 2021
20	scoreflex TRIO	PRC	ONM Singapore	57757330	10	July 16, 2021
21	scoreflex TRIO	PRC	ONM Singapore	57757330	44	July 16, 2021
22	Teleport Neuro Microcatheter	PRC	ONM Singapore	62144908	10	January 13, 2022
23	Teleport Neuro Microcatheter	PRC	ONM Singapore	62123497	44	January 13, 2022
24	COMBO	PRC	ONM Singapore	62469174	44	January 29, 2022
25	业聚	PRC	ONM Singapore	55591624	35	April 26, 2021
26	Teleport XT Microcatheter	PRC	ONM Singapore	62785808	10	February 23, 2022
27	Teleport XT Microcatheter	PRC	ONM Singapore	62789351	44	February 23, 2022
28	TELEPORT XT MICROCATHETER	PRC	ONM Singapore	62793520	10	February 23, 2022
29	TELEPORT XT MICROCATHETER	PRC	ONM Singapore	62803183	44	February 23, 2022

No.	Trademark	Place of registration	Name of applicant	Application no.	Class	Application date
30	SAPPHIRE NEURO	Hong Kong	ONM Singapore	305887937	10, 44	February 23, 2022
31		European Union	ONM Singapore	18555184	10, 44	September 9, 2021
32		European Union	ONM Singapore	18641395	10, 44	January 20, 2022
33	JADE	European Union	ONM Singapore	18657145	10, 44	February 16, 2022
34		European Union	ONM Singapore	018657178	10, 44	February 16, 2022
35	业聚	Malaysia	ONM Singapore	TM2021036291	10, 35, 41, 42, 44	December 23, 2021
36		Malaysia	ONM Singapore	TM2022004186 (designated under International Registration No. 1645795)	10, 35, 41, 42, 44	January 13, 2022
37		Malaysia	ONM Singapore	TM2022003475 (designated under International Registration No. 1643715)	10	January 12, 2022
38	业聚	Singapore	ONM Singapore	40202129435V	10, 35, 41, 42, 44	December 3, 2021
39		Singapore	ONM Singapore	40202203632W (designated under International Registration No. 1645795)	10, 35, 41, 42, 44	January 13, 2022

No.	Trademark	Place of registration	Name of applicant	Application no.	Class	Application date
40	OrbusNeich	Singapore	ONM Singapore	40202203046U (designated under International Registration No. 1643715)	10	January 12, 2022
41	TELEPORT	WIPO (designating Singapore Malaysia and Vietnam)	ONM Singapore	1657184	10, 44	March 23, 2022

(b) Patents

As of the Latest Practicable Date, our material granted patents were as follows:

No.	Title	Place of registration	Name of registered proprietor	Patent no.	Expiry date
1	Bioabsorbable Polymeric Composition For A Medical Device	European Patent Convention	ONM Singapore	3061791	July 20, 2027
2	Progenitor Endothelial Cell Capturing With A Drug Eluting Implantable Medical Device	European Patent Convention	ONM Singapore	EP1753476	March 10, 2025
3	Progenitor Endothelial Cell Capturing With A Drug Eluting Implantable Medical Device	European Patent Convention	ONM Singapore	EP2671540	March 10, 2025
4	Progenitor Endothelial Cell Capturing With A Drug Eluting Implantable Medical Device	European Patent Convention	ONM Singapore	EP1948069	November 15, 2026

No.	Title	Place of registration	Name of registered proprietor	Patent no.	Expiry date*
5	Medical Device With Coating That Promotes Endothelial Cell Adherence And Differentiation	European Patent Convention	ONM Singapore	EP1471853	February 6, 2023
6	Balloon Catheter	European Patent Convention	ONM Singapore	1517720	July 2, 2023
7	Bioabsorbable Polymeric Composition For A Medical Device	European patent Convention	ONM Singapore	2044140	July 20, 2027
8	Bioabsorbable Polymeric Composition For A Medical Device	Germany	ONM Singapore	60 2007 051 053.8	July 20, 2027
9	Progenitor Endothelial Cell Capturing With A Drug Eluting Implantable Medical Device	Germany	ONM Singapore	60 2005 047 102.2	March 10, 2025
10	Medical Device With Coating That Promotes Endothelial Cell Adherence And Differentiation	Germany	ONM Singapore	603 50 032.3	February 6, 2023
11	Vorläufer-Endothelialzellen-Erfassung Mit Einer Implantierbaren Medizinischen Vorrichtung Zur Wirkstofffreisetzung	Germany	ONM Singapore	60 2006 059 087.3	November 15, 2026
12	Vorläufer-Endothelialzellen-Erfassung mit einer implantierbaren medizinischen Vorrichtung zur Wirkstofffreisetzung	Germany	ONM Singapore	60 2005 056 372.5	May 10, 2025
13	Balloon Catheter	Germany	ONM Singapore	60305494.3	July 2, 2023

* These patents cannot be extended after expiration.

No.	Title	Place of registration	Name of registered proprietor	Patent no.	Expiry date
14	Bioabsorbable polymer composition for a medical device	Germany	ONM Singapore	60 2007 057 469.2	July 20, 2027
15	Progenitor Endothelial Cell Capturing With A Drug Eluting Implantable Medical Device	Japan	ONM Singapore	5755395	March 10, 2025
16	Progenitor Endothelial Cell Capturing With A Drug Eluting Implantable Medical Device	Japan	ONM Singapore	5876173	March 10, 2025
17	Drug eluting balloon	Japan	ONM Singapore	7027319	February 8, 2037
18	Endothelial ligand binding and coating medical device	PRC	ONM Singapore	2005800040686 (Invention patent)	March 9, 2025
19	Endothelial ligand binding and coating medical device	PRC	ONM Singapore	2015103911947 (Invention patent)	March 9, 2025
20	A drug eluting transplantable instrument for capturing progenitor endothelial cells	PRC	ONM Singapore	2006800427176 (Invention patent)	November 14, 2026
21	A drug eluting transplantable instrument for capturing progenitor endothelial cells	PRC	ONM Singapore	2014100901794 (Invention patent)	November 14, 2026
22	Quick exchange balloon catheter structure	PRC	ONM Shenzhen	2013201867683 (Utility model)	April 14, 2023
23	Quick exchange balloon catheter structure	PRC	ONM Shenzhen	2013101288191 (Invention patent)	April 14, 2033
24	Balloon thermoforming device	PRC	ONM Shenzhen	2016213059440 (Utility model)	November 28, 2026

No.	Title	Place of registration	Name of registered proprietor	Patent no.	Expiry date
25	Balloon mold and molding system	PRC	ONM Shenzhen	2017200774228 (Utility model)	January 18, 2027
26	Drug Eluting Balloon Catheter	PRC	ONM Shenzhen	2017200917185 (Utility model)	January 21, 2027
27	Drug Eluting Balloon Catheter	PRC	ONM Shenzhen	2017200912891 (Utility model)	January 21, 2027
28	Bio-degradable Drug Eluting Stent	PRC	ONM Shenzhen	2018205019332 (Utility model)	April 9, 2028
29	A degradable material for double-layer stent	PRC	ONM Shenzhen	2018205019667 (Utility model)	April 9, 2028
30	A degradable stent with multiple layers of drug coating	PRC	ONM Shenzhen	2018205026406 (Utility model)	April 9, 2028
31	Balloon Catheter	PRC	ONM Shenzhen	2019203171325 (Utility model)	March 12, 2029
32	Microcatheter	PRC	ONM Shenzhen	201820637934X (Utility model)	April 27, 2028
33	Foley's tube	PRC	ONM Shenzhen	2019104153117 (Invention)	May 16, 2039
34	Catheter	PRC	ONM Shenzhen	2021203593841 (Utility model)	February 8, 2031
35	Adaptor device and catheter external members	PRC	ONM Shenzhen	202121896243X (Utility model)	August 12, 2031
36	Stent Delivery System with Raised Balloon	PRC	ONM Shenzhen	2013201259796 (Utility model)	March 19, 2023
37	Bioabsorbable Medical Device With Coating	United States	ONM Singapore	7,959,942	July 3, 2028
38	Bioabsorbable Medical Device With Coating	United States	ONM Singapore	8,642,068	October 20, 2027
39	Bioabsorbable Medical Device With Coating	United States	ONM Singapore	9,211,205	October 20, 2027

No.	Title	Place of registration	Name of registered proprietor	Patent no.	Expiry date
40	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	7,846,361	July 20, 2027
41	Bioabsorbable Polymeric Composition And Medical Device Background	United States	ONM Singapore	8,691,321	January 28, 2028
42	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	7,897,224	August 26, 2027
43	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	8,137,603	July 20, 2027
44	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	8,642,707	July 20, 2027
45	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	9,173,973	July 20, 2027
46	Bioabsorbable Polymeric Composition And Medical Device	United States	ONM Singapore	9,724,864	October 20, 2027
47	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	9,629,940	June 29, 2028
48	Bioabsorbable Polymeric Composition For A Medical Device	United States	ONM Singapore	9,662,416	June 29, 2028
49	Balloon Catheter	United States	ONM Singapore	7,169,162	June 21, 2024
50	Drug Eluting Balloon	United States	ONM Singapore	10,792,477	August 7, 2037

No.	Title	Place of registration	Name of registered proprietor	Patent no.	Expiry date
51	Drug Eluting Balloon	United States	ONM Singapore	10,737,075	February 8, 2037
52	Progenitor endothelial cell capturing with a drug eluting implantable medical device	United States	ONM Singapore	8,460,367	August 17, 2024

As of the Latest Practicable Date, we have applied for the registration of the following patents which have been published to the public and which we consider to be material to our business:

No.	Title	Place of filing	Name of applicant	Application no.	Application date
1	Drug Eluting Balloon	European Patent Convention	ONM Singapore	17750680.5	February 8, 2017
2	Bioabsorbable Polymeric Composition For A Medical Device	European Patent Convention	ONM Singapore	15003364.5	July 20, 2007
3	Bioabsorbable Polymeric Composition For A Medical Device	European Patent Convention	ONM Singapore	15003278.7	July 20, 2007
4.	Microcatheter	European Patent Convention	ONM Shenzhen	18903042.2	May 3, 2018
5	Bioabsorbable Polymeric Composition For A Medical Device	Hong Kong	ONM Singapore	16110924.2	July 20, 2007
6	Bioabsorbable Polymeric Composition For A Medical Device	Hong Kong	ONM Singapore	16112995.2	July 20, 2007
7	Microcatheter	Hong Kong	ONM Shenzhen	62020004861.4	May 3, 2018
8	Drug Eluting Balloon	Hong Kong	ONM Singapore	19123672.8	February 8, 2017
9	Microcatheter	Japan	ONM Shenzhen	2019-544055	May 3, 2018
10	Tip for foley's tube	PRC	ONM Shenzhen	201910189985X (Invention)	March 13, 2019
11	Microtubular	PRC	ONM Shenzhen	2018104049585 (Invention)	April 28, 2018
12	Anti-coagulation Coating and Preparation Method	PRC	ONM Shenzhen	2021111199466 (Invention)	September 24, 2021
13	A medical device	PRC	ONM Singapore	2019104875185	February 8, 2017
14	Microcatheter	United States	ONM Shenzhen	16/485,137	May 3, 2018
15	Drug Eluting Balloon	United States	ONM Singapore	16/912,957	June 26, 2020

(c) Domain Names

As of the Latest Practicable Date, our material domain names were as follows:

No.	Domain name	Registrant	Date of registration	Expiry date
1.	focusdb.cn	ONM Shenzhen	November 26, 2012	November 26, 2023
2.	genous.cn	ONM Shenzhen	September 16, 2010	September 16, 2023
3.	genous.com.cn	ONM Shenzhen	September 16, 2010	September 16, 2023
4.	onpf-hv.cn	ONM Shenzhen	July 2, 2020	July 2, 2023
5.	onpf-hv.com	ONM Shenzhen	July 2, 2020	July 2, 2023
6.	onpf-hv.net	ONM Shenzhen	July 2, 2020	July 2, 2023
7.	orbusneich.com.cn	ONM Shenzhen	November 24, 2014	November 24, 2023
8.	NEICH.COM	ONM BVI	June 23, 2000	June 23, 2022
9.	orbusbv.com	ONM BVI	December 11, 2003	December 10, 2023
10.	orbusmedical.com	ONM BVI	December 30, 2014	December 29, 2023
11.	orbusmt.com	ONM BVI	February 11, 1998	February 10, 2023
12.	orbusneich.cn	ONM Shenzhen	September 15, 2019	September 15, 2027
13.	orbusneich.co	ONM BVI	August 2, 2016	August 2, 2023
14.	orbusneich.com	ONM BVI	January 14, 2005	January 14, 2023
15.	orbusneich.eu	ONM BVI	August 23, 2006	September 1, 2023
16.	orbusneich.info	ONM BVI	August 2, 2016	August 2, 2023
17.	orbusneich.org	ONM BVI	August 2, 2016	August 2, 2023

Save as aforesaid, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our business.

C. FURTHER INFORMATION ABOUT DIRECTORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

(a) Interests and short positions of the Directors and chief executive of the Company in the Shares, underlying Shares and debentures of our Company and our associated corporations

The following table sets out the interests and short positions of our Directors and chief executive of our Company immediately following completion of the [**REDACTED**] in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of [**REDACTED**] contained in the Listing Rules, once our Shares are [**REDACTED**]:

Name of Director/ Chief Executive	Capacity/ nature of interest[(1)]	Name of company	Number of Shares immediately after the completion of the [REDACTED][(1)]	Approximate percentage of shareholding in the total share capital of our Company after the [REDACTED] (after taking into account the Share Consolidation and without taking into account any Shares which may be allotted and issued under the Share Incentive Schemes)
Mr. David CHIEN[(2)]	Interest of controlled corporation	The Company	[**REDACTED**]	[**REDACTED**]%
Ms. Kwai Ching Denise LAU[(2)]	Interest of controlled corporation	The Company	[**REDACTED**]	[**REDACTED**]%
Mr. Ching Chung John CHOW	Beneficial owner	The Company	[**REDACTED**]	[**REDACTED**]%

Notes:

(1) The calculation is based on the total number of [**REDACTED**] Shares in issue immediately after completion of the [**REDACTED**] (after taking into account the Share Consolidation without taking into account any Shares which may be issued under the Share Incentive Schemes).

(2) HART owns 2,607,619,221 Shares as of the date of this document and [521,523,844] Shares after the Share Consolidation. Mr. David CHIEN and Ms. Kwai Ching Denise LAU holds 55% and 45% of shareholdings of HART, respectively. As such, under the SFO, each of Mr. David CHIEN and Ms. Kwai Ching Denise LAU is deemed to be interested in the Shares held by HART.

(b) Interests of the substantial shareholders in the Shares

Save as disclosed in the section headed "Substantial Shareholders", immediately following the completion of the [**REDACTED**] and without taking into account any Shares which may be issued pursuant to the Share Incentive Schemes, our Directors are not aware of any other person (not being a Director or chief executive of our Company) who will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

2. Particulars of Directors' Service Contracts and Letters of Appointment

Each of our executive Directors has entered into a service contract with our Company on [●] and we have issued letters of appointment to our non-executive Director and each of our independent non-executive Directors. The principal particulars of these service contracts and letters of appointment are (a) for a term of 3 years commencing from the [**REDACTED**] and (b) are subject to termination in accordance with their respective terms. The term of the service contracts and the letters of appointment may be renewed in accordance with our Articles of Association and the applicable Listing Rules.

Save as disclosed above, none of our Directors has entered, or has proposed to enter, a service contract with any member of our Group (other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation)).

3. Emoluments of Directors

The aggregate amount of emoluments which was paid to our Directors for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 were approximately US$1.2 million, US$1.2 million, US$1.4 million and US$1.0 million, respectively.

It is estimated that emoluments and benefits in kind equivalent to approximately US$1.9 million (equivalent to HK$15.1 million) in aggregate will be paid and granted to our Directors by us in respect of the year ending December 31, 2022 under arrangements in force at the date of this document.

The aggregate amount of remuneration which were paid by the Group to our five highest paid individual (including both employees and Directors) for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 were US$2.5 million, US$1.9 million, US$2.3 million and US$1.5 million, respectively.

None of our Directors or any past directors of any member of the Group has been paid any sum of money for each of the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 as (a) an inducement to join or upon joining the Company; or (b) for loss of office as a director of any member of the Group or of any other office in connection with the management of the affairs of any member of the Group.

There has been no arrangement under which a Director has waived or agreed to waive any emoluments for each of the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022.

4. Disclaimers

Save as disclosed in this document:

(a) none of our Directors or our chief executive has any interest or short position in the Shares, underlying Shares or debentures of us or any of our associated corporations (within the meaning of Part XV the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO, or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to Model Code for Securities Transactions by Directors of Listed Issuers once the Shares are [**REDACTED**] on the Stock Exchange;

(b) none of our Directors is aware of any person (not being a Director or chief executive of the Company) who will, immediately following completion of the [**REDACTED**] (without taking into account any Shares which may be allotted and issued pursuant to the exercise of options which were granted under the Share Incentive Schemes), have an interest or short position in the Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group; and

(c) none of our Directors is interested in our promotion, or in any assets which, within the two years immediately preceding the date of this Document, have been acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to our Company;

(d) none of our Directors is materially interested in any contract or arrangement subsisting at the date of this Document which is significant in relation to our business; and

(e) so far as is known to our Directors, none of our Directors, their respective close associates (as defined under the Listing Rules) or Shareholders who own more than 5% of the number of issued shares of the Company have any interests in the five largest customers or the five largest suppliers of the Group.

D. SHARE INCENTIVE SCHEMES

1. Pre-[REDACTED] Share Option Scheme

(a) Purpose and Principal Terms

The purpose of the Pre-[**REDACTED**] Share Option Scheme is to enable our Group to grant options or awards to qualified persons (as determined by the sole opinion of our Board) including any director, employee, advisor and consultant of our Company or any of our associated companies as incentives, attraction, motivation or rewards by reason of their contribution or potential contribution to our Company and/or any of our associated companies. The principal terms of the Pre-[**REDACTED**] Share Option Scheme are as follows:

(i) Subject to any alterations set out under the Pre-[**REDACTED**] Share Option Scheme in the event of any capitalization issue, rights issue, sub-division, consolidation of shares, or reduction of capital of our Company that may take place after the [**REDACTED**], the maximum number of Shares in respect of which options or awards may be granted under the Pre-[**REDACTED**] Share Option Scheme shall be 200,000,000 Shares (40,000,000 Shares as adjusted after Share Consolidation).

(ii) An option shall be deemed to have been granted and accepted by the grantee and to have taken effect when a copy of the grant letter of the option ("**Grant Letter**") is duly signed by the grantee, together with other documents or undertakings to be signed by the grantees as a condition to acceptance (if applicable), are all duly received by our Company on or before the relevant acceptance date.

(iii) No option or award under the Pre-[**REDACTED**] Share Option Scheme will be granted after the [**REDACTED**], although provisions of the Pre-[**REDACTED**] Share Option Scheme will in all other respects remain in full force and effect to the extent necessary to give effect to the exercise of any options granted pursuant to the Pre-[**REDACTED**] Share Option Scheme on or prior to the [**REDACTED**] or otherwise as may be required in accordance with the provisions of the Pre-[**REDACTED**] Share Option Scheme and options granted prior thereto but not yet exercised shall continue to be valid and exercisable in accordance with this Scheme.

(iv) A grantee may subscribe for the Shares on the exercise of an option at the price approved by the Board in its absolute discretion with reference to factors which may include business performance and value of our Company and individual performance of the relevant grantee, and in any case, shall not be less than the par value of the Shares.

(v) An option is personal to the grantee and is not assignable and no grantee is permitted in any way to sell, transfer, charge, mortgage, encumber or create any interest (legal or beneficial) in favor of any third party over or in relation to any option or attempt to do so (with the exception that the grantee may nominate a nominee in whose name the Shares issued pursuant to the Pre-[**REDACTED**] Share Option Scheme may be registered). Any breach of the foregoing shall entitle our Company to cancel any outstanding options or any part thereof granted to such grantee without compensation.

(vi) The Shares to be allotted upon the exercise of an option is subject to the constitutional documents of our Company for the time being in force and, once issued, ranks *pari passu* in all respects with and has the same voting, dividend, transfer and other rights, including those arising on liquidation of our Company as attached to the fully-paid Shares in issue on the date of issue.

(vii) Each grantee to whom a share award has been granted shall be entitled to the Shares they are awarded in accordance with the terms (including any restrictions and vesting requirement that may be imposed) of the Pre-[**REDACTED**] Share Option Scheme and the respective grantee's offer document. However, unless otherwise waived by the Board and/or the committee (the "**Option Plan Committee**") authorized by the Board to administer the Pre-[**REDACTED**] Share Option Plan, a grantee is not entitled to exercise any Option until the [**REDACTED**].

(viii) The exercise of any Option under the Pre-[**REDACTED**] Share Option Scheme is subject to and conditional upon the commencement of dealings in these Shares on a Stock Exchange. If this condition is not fulfilled by December 31, 2022 (or such later date as the Board and/or the Option Plan Committee by resolution determines), the Pre-[**REDACTED**] Share Option Scheme and all options granted hereunder shall lapse automatically and cease to have any further effect.

(ix) In terms of rights on death or termination of employment:

(a) If the grantee ceases to be an eligible participant of the Pre-[**REDACTED**] Share Option Scheme as a result of death, ill-health, injury or disability (including permanent disability), provided that the grantee's relationship with the Group had not been otherwise terminated by the occurrence of events which would have caused his option(s) to lapse (as defined in the Pre-[**REDACTED**] Share Option Scheme), the grantee or his personal representatives is entitled within 12 months from the date of cessation of being an eligible participant or death to exercise his option in full (to the extent not already exercised);

(b) If the grantee ceases to be an eligible participant of the Pre-[**REDACTED**] Share Option Scheme as a result of termination of his relationship with the Group due to the occurrence of events which would have caused his option(s) to lapse (as defined in the Pre-[**REDACTED**] Share Option Scheme), the grantee's options will terminate on the date of such cessation without compensation, regardless of whether the options are exercisable or not;

(c) If the grantee's ceases to be an eligible participant of the Pre-[**REDACTED**] Share Option Scheme as a result of termination of his relationship with the Group for any reason other than those referred to in (a) and (b) above, the grantee may exercise his option up to his entitlement at the date of cessation of being an eligible participant (to the extent not already exercised) within 90 days following the date of such cessation.

(x) The Board may, at any time, alter in any respect the terms and conditions of the Pre-[**REDACTED**] Share Option Scheme and the regulations for the Pre-[**REDACTED**] Share Option Scheme's administration and operation, provided that the amended terms remain in compliance with the applicable laws and regulatory requirements and such alteration does not adversely affect the terms of issue of any Option granted or agreed to be granted prior to such alteration or to reduce the proportion of the equity capital to which any person was entitled pursuant to such Option prior to such alteration except with the grantee's written consent or by special resolution passed at a meeting of the grantees. Written notice of any alterations made in accordance with this paragraph (ix) shall be given to all grantees.

(xi) Our Company by ordinary resolution of the Board may at any time resolve to terminate the operation of the Pre-[**REDACTED**] Share Option Scheme and in such event no further options shall be offered but the provisions of the Pre-[**REDACTED**] Share Option Scheme shall remain in force to the extent necessary to give effect to the exercise of any Option granted prior to the termination or otherwise as may be required in accordance with the provisions of the Pre-[**REDACTED**] Share Option Scheme and options granted prior to such termination shall continue to be valid and exercisable in accordance with this Scheme.

(b) Outstanding Grants

As of the date of this document, outstanding options to subscribe for an aggregate of [9,274,900] Shares (as adjusted after Share Consolidation) have been granted to a total of 102 eligible participants by our Company under the Pre-[**REDACTED**] Share Option Scheme. The consideration paid by the grantees who have been granted options under the Pre-[**REDACTED**] Share Option Scheme was nil.

A summary of the grantees who have been granted options under the Pre-[**REDACTED**] Share Option Scheme is set forth below:

Grantee	Position/Relationship	Address	Number of Shares under outstanding options granted	Number of Shares under outstanding options granted (as adjusted after Share Consolidation)	Approximate percentage of enlarged issued share capital of the Company immediately after completion of the [REDACTED] (assuming no Shares are issued pursuant to the Pre-[REDACTED] Share Option Scheme)	*Note(s)*
Directors						
Wing Shing CHEN (陳泳成)	Executive Director, chief financial officer and company secretary	Flat A, 6/F, Tower 16, Mayfair by the Sea I, No. 23 Fo Chun Road, Tai Po, N.T., Hong Kong	2,000,000	[400,000]	[**REDACTED**]%	*1*
Ching Chung John CHOW (周靜忠)	Executive Director and head of business development	Flat 6 2/F, Block B, Villa Lotto, 18 Broadwood Road, Hong Kong	1,000,000	[200,000]	[**REDACTED**]%	*1*
Senior Management						
Alain Djamel KHAIR	Chief commercial officer	9 Thornton Road, Bromley, Kent BR1 5AP, United Kingdom	2,000,000	[400,000]	[**REDACTED**]%	2
Robert John COTTONE JR	Chief technical officer	13040 SW 30th CT, Davie, FL 33330, United States	2,000,000	[400,000]	[**REDACTED**]%	2
Other Grantees						
98 other option holders including consultants and current employees of our Group	Not applicable	Not applicable	39,374,500	[7,874,900]	[**REDACTED**]%	*1, 2, 3*
Total			46,374,500	[9,274,900]	[**REDACTED**]%	

Notes:

(1) With vesting commencement date on January 1, 2022 and a 48-month vesting period. Options are exercisable upon completion of the [**REDACTED**] until January 1, 2031, being the 10th anniversary of the date of the grant letter, at an exercise price of US$0.15 (US$0.75 as adjusted by Share Consolidation, which is equivalent to approximately HK$5.87).

(2) With vesting commencement date on January 1, 2022 and a 48-month vesting period. Options exercisable upon completion of the [**REDACTED**] until January 1, 2031, being the 10th anniversary of the date of the grant letter, at an exercise price of US$0.20 (US$1.0 as adjusted by Share Consolidation, which is equivalent to approximately HK$7.83).

(3) Options with exercise price of US$0.10 with no vesting period.

Save as disclosed above, no other options have been granted or agreed to be granted by our Company under the Pre-[**REDACTED**] Share Option Scheme.

Application has been made to the [**REDACTED**] for the [**REDACTED**] of and permission to [**REDACTED**] in the [9,274,900] Shares (as adjusted after Share Consolidation) that may be allotted and issued pursuant to the options granted under the Pre-[**REDACTED**] Share Option Scheme.

(c) Dilution Effect and impact on the earnings per Share

Subject to any alterations set out under the Pre-[**REDACTED**] Share Option Scheme in the event of any capitalization issue, rights issue, sub-division, consolidation of shares, or reduction of capital of our Company that may take place after the [**REDACTED**], the total number of shares subject to the options granted under the Pre-[**REDACTED**] Share Option Scheme shall be no more than [9,274,900] Shares (as adjusted after Share Consolidation), representing approximately [**REDACTED**]% of the issued share capital of our Company immediately upon completion of the [**REDACTED**] (excluding any Share which may fall to be allotted and issued under the Share Incentive Schemes). As such, taking into account the Shares to be allotted and issued under the Share Incentive Schemes, the shareholding of our Shareholders immediately following completion of the [**REDACTED**] will be diluted by approximately [**REDACTED**]%. There would be a maximum potential dilutive effect of [**REDACTED**]% on the earnings per share arising from exercise of the outstanding options.

2. Post-[REDACTED] Share Option Scheme

The following is a summary of the principal terms of the Post-[**REDACTED**] Share Option Scheme conditionally adopted by the resolutions in writing of all our Shareholders passed on [●].

(a) Purpose

The purpose of the Post-[**REDACTED**] Share Option Scheme is to enable our Group to grant options to selected participants as incentives or rewards for their contribution to our Group. Our Directors consider the Post-[**REDACTED**] Share Option Scheme, with its broadened basis of participation, will enable our Group to reward our employees, our Directors and other selected participants for their contributions to our Group. Given that our Directors are entitled to determine the performance targets to be achieved as well as the minimum period that an option must be held before an option can be exercised on a case by case basis, and that the exercise price of an option cannot in

any event fall below the price stipulated in the Listing Rules or such higher price as may be fixed by our Directors, it is expected that grantees of an option will make an effort to contribute to the development of our Group so as to bring about an increased market price of the Shares in order to capitalize on the benefits of the options granted.

(b) Who may join

Our Directors (which expression shall, for the purpose of this paragraph, include a duly authorized committee thereof) may, at their absolute discretion, invite any person belonging to any of the following classes of participants, who our Board considers, in its sole discretion, have contributed or will contribute to our Group, to take up options to subscribe for Shares:

(i) any directors (including executive Directors, non-executive Directors and independent non-executive Directors) and employees of any member of our Group; and

(ii) any advisors, consultants, distributors, contractors, customers, suppliers, agents, business partners, joint venture business partners, service providers of any member of our Group.

For the purposes of the Post-[**REDACTED**] Share Option Scheme, the options may be granted to any company wholly-owned by one or more persons belonging to any of these classes of participants. For the avoidance of doubt, the grant of any options by our Company for the subscription of Shares or other securities of our Group to any person who falls within any of these classes of participants shall not, by itself, unless our Directors otherwise so determine, be construed as a grant of option under the Post-[**REDACTED**] Share Option Scheme.

The eligibility of any of these class of participants to the grant of any option shall be determined by our Directors from time to time on the basis of our Directors' opinion as to the participant's contribution to the development and growth of our Group.

(c) Maximum number of Shares

(i) The maximum number of Shares which may be issued upon the exercise of all outstanding options granted and yet to be exercised under the Post-[**REDACTED**] Share Option Scheme and any other share option scheme(s) of our Group shall not in aggregate exceed 30% of the issued share capital of our Company from time to time.

(ii) The total number of Shares which may be issued upon exercise of all options to be granted under the Post-[**REDACTED**] Share Option Scheme and any other share option scheme of our Group shall not in aggregate exceed 10% of the Shares in issue on the day on which [**REDACTED**] of the Shares commence on the [**REDACTED**], such 10% limit represents [**REDACTED**] Shares (the "**General Scheme Limit**").

(iii) Subject to paragraph (i) above and without prejudice to paragraph (iv) below, our Company may issue a circular to its Shareholders and seek approval of its Shareholders in a general meeting to extend the General Scheme Limit provided that the total number of Shares which may be issued upon exercise of all options to be granted under the Post-[**REDACTED**] Share Option Scheme and any other share option scheme of our Group shall not exceed 10% of the Shares in issue as of the date of approval of the limit and, for the purpose of calculating the limit, options (including those outstanding, cancelled, lapsed or exercised in accordance with the Post-[**REDACTED**] Share Option Scheme and any other share option scheme of our Group) previously granted under the Post-[**REDACTED**] Share Option Scheme and any other share option scheme of our Group will not be counted. The circular sent by our Company to its Shareholders shall contain, among other information, the information required under Rule 17.02(2)(d) of the Listing Rules and the disclaimer required under Rule 17.02(4) of the Listing Rules.

(iv) Subject to paragraph (i) above and without prejudice to paragraph (iii) above, our Company may seek separate Shareholders' approval in a general meeting to grant options beyond the General Scheme Limit or, if applicable, the extended limit referred to in paragraph (iii) above to participants specifically identified by our Company before such approval is sought. In such event, our Company must send a circular to its Shareholders containing a general description of the specified participants, the number and terms of options to be granted, the purpose of granting options to the specified participants with an explanation as to how the terms of the options serve such purpose and such other information required under Rule 17.02(2)(d) of the Listing Rules and the disclaimer required under Rule 17.02(4) of the Listing Rules.

(d) Maximum entitlement of each participant

The total number of Shares issued and which may fall to be issued upon exercise of the options granted under the Post-[**REDACTED**] Share Option Scheme and any other share option scheme of our Company (including both exercised and outstanding options) to each participant in any 12-month period shall not exceed 1% of the issued share capital of our Company for the time being (the "**Individual Limit**"). Any further grant of options in aggregate in excess of the Individual Limit in any 12-month period up to and including the date of such further grant shall be subject to the issue of a circular to our Shareholders and our Shareholders' approval in general meeting of our Company with such participant and his close associates (or his associates if the participant is a connected person) abstaining from voting. The number and terms (including the exercise price) of options to be granted to such participant must be fixed before Shareholders' approval and the date of board meeting for proposing such further grant should be taken as the date of grant for the purpose of calculating the exercise price under note (1) to Rule 17.03(9) of the Listing Rules.

(e) Grant of options to connected persons

(i) Any grant of options under the Post-[**REDACTED**] Share Option Scheme to a director, chief executive or substantial shareholder of our Company or any of their respective associates must be approved by our independent non-executive Directors (excluding any independent non-executive Director who is the proposed grantee of the options).

(ii) Where any grant of options to a substantial Shareholder of our Company or an independent non-executive Director or any of their respective associates would result in the Shares issued and to be issued upon exercise of all options already granted and to be granted (including options exercised, cancelled and outstanding) to such person in the 12-month period up to and including the date of such grant:

1. representing in aggregate over 0.1% (or such other higher percentage as may from time to time be specified by the Stock Exchange) of the Shares in issue; and

2. having an aggregate value, based on the closing price of the Shares as stated in the Stock Exchange's daily quotations sheet the date of the offer of grant, in excess of HK$5 million (or such other higher amount as may from time to time be specified by the Stock Exchange);

such further grant of options must be approved by our Shareholders in a general meeting. Our Company must send a circular to its Shareholders. The grantee, his associates and all core connected persons of our Company must abstain from voting in favor of the relevant resolution at such general meeting. Any vote taken at the general meeting to approve the grant of such options must be taken on a poll. Any change in the terms of options granted to a substantial shareholder or an independent non-executive Director or any of their respective associates must be approved by our Shareholders in a general meeting.

(f) Time of acceptance and exercise of option

An option may be accepted by a participant within 5 Business Days from the date of the offer of grant of the option.

An option may be exercised in accordance with the terms of the Post-[**REDACTED**] Share Option Scheme at any time during a period to be determined and notified by our Directors to each grantee, which period may commence on a day after the date upon which the offer for the grant of options is made but shall end in any event not later than 10 years from the date of grant of the option subject to the provisions for early termination under the Post-[**REDACTED**] Share Option Scheme. Unless otherwise

determined by our Directors and stated in the offer of the grant of options to a grantee, there is no minimum period required under the Post-[**REDACTED**] Share Option Scheme for the holding of an option before it can be exercised.

(g) Performance targets

Unless our Directors otherwise determine and state in the offer of the grant of options to a grantee, a grantee is not required to achieve any performance targets before any options granted under the Post-[**REDACTED**] Share Option Scheme can be exercised.

(h) Subscription price for Shares and consideration for the option

The subscription price per Share under the Post-[**REDACTED**] Share Option Scheme will be a price determined by our Directors, but shall not be less than the highest of (i) the closing price of the Shares as stated in the Stock Exchange's daily quotations sheet on the date of the offer of grant; (ii) the average closing price of the Shares as stated in the Stock Exchange's daily quotations for the five Business Days immediately preceding the date of the offer of grant (provided that in the event that any option is proposed to be granted within a period of less than five Business Days after the [**REDACTED**] of the Shares first commences on the [**REDACTED**], the new [**REDACTED**] of the Shares for the [**REDACTED**] shall be used as the closing price for any Business Day falling within the period before [**REDACTED**]); and (iii) the nominal value of a Share on the date of grant.

A nominal consideration of HK$1.00 is payable upon acceptance of the grant of an option.

(i) Ranking of Shares

(i) Shares allotted and issued upon the exercise of an option will be identical to the then existing issued shares of our Company and subject to all the provisions of the Memorandum of Association and Articles of Association and will rank *pari passu* in all respects with the fully paid Shares in issue on the date the name of the grantee is registered on the register of members of our Company or, if that date falls on a day when the register of members of our Company is closed, the first day of the re-opening of the register of members ("**Exercise Date**") and accordingly will entitle the holders thereof to participate in all dividends or other distributions paid or made on or after the Exercise Date other than any dividend or other distribution previously declared or recommended or resolved to be paid or made if the record date thereof shall be before the Exercise Date. A Share allotted upon the exercise of an option shall not carry voting rights or rights to participate in any dividends or distributions (including those arising on a liquidation of our Company) declared or

recommended or resolved to be paid to the Shareholders on the register until the completion of the registration of the grantee on the register of members of our Company as the holder thereof.

(ii) Unless the context otherwise requires, references to "Shares" in this paragraph include references to shares in the ordinary equity share capital of our Company of such nominal amount as shall result from a subdivision, consolidation, re-classification or re-construction of the share capital of our Company from time to time.

(j) Restrictions on the time of grant of options

No offer for grant of options shall be made after inside information has come to our Company's knowledge until it has announced the information in accordance with the requirements of the Listing Rules. In particular, during the period commencing one month immediately preceding the earlier of (a) the date of the meeting of our Directors (as such date is first notified to the Stock Exchange in accordance with the requirements of the Listing Rules) for the approval of our Company's results for any year, half-year, quarter or any other interim period (whether or not required under the Listing Rules); and (b) the last date on which our Company must publish its announcement of its results for any year, half-year, quarter or any other interim period (whether or not required under the Listing Rules), and ending on the date of the announcement of the results, no offer for grant of options may be made.

Our Directors may not grant any option to a participant who is a Director during the period or time in which Directors are prohibited from dealing in shares pursuant to the Model Code for Securities Transactions by Directors of [**REDACTED**] prescribed by the Listing Rules or any corresponding code or securities dealing restrictions adopted by our Company.

(k) Period of the Post-*[**REDACTED**] *Share Option Scheme

The Post-[**REDACTED**] Share Option Scheme will remain in force for a period of 10 years commencing on the date on which the Post-[**REDACTED**] Share Option Scheme is adopted.

(l) Rights are personal to the grantee

An option is personal to the grantee and shall not be transferable or assignable and no grantee shall in any way sell, transfer, charge, mortgage, encumber or otherwise dispose of or create any interest in favor of or enter into any agreement with any other person over or in relation to any option, except for the transmission of an option on the death of the grantee to his personal representative(s) on the terms of the Post-[**REDACTED**] Share Option Scheme.

(m) Rights on ceasing employment

If the grantee of an option is an Eligible Employee and ceases to be an Eligible Employee for any reason other than death, or for serious misconduct or other grounds referred to in sub-paragraph (o) below before exercising his option in full, the option (to the extent not already exercised) will lapse on the date of cessation and will not be exercisable unless our Directors otherwise determine in which event the grantee may exercise the option (to the extent not already exercised) in whole or in part within such period as our Directors may determine following the date of such cessation, which will be taken to be the last day on which the grantee was physically at work with our Group whether salary is paid in lieu of notice or not.

(n) Rights on death

If the grantee of an option is an Eligible Employee and ceases to be an Eligible Employee by reason of his death, before exercising the option in full, provided that none of the events for termination of employment (as defined in the Post-[**REDACTED**] Share Option Scheme) then exists with respect to such grantee, his personal representative(s), or, as appropriate, the grantee may exercise the option (to the extent not already exercised) in whole or in part within a period of 12 months following the date of death of the grantee.

(o) Rights on dismissal

If the grantee of an option is an Eligible Employee and ceases to be an Eligible Employee by reason that he has been guilty of serious misconduct or has committed any act of bankruptcy or has become insolvent or has made any arrangements or composition with his creditors generally, or has been convicted of any criminal offence (other than an offence which in the opinion of our Directors does not bring the grantee or our Group into disrepute) or on any other ground on which an employer would be entitled to terminate his or her employment summarily, his option will lapse automatically and will not be exercisable on or after the date of ceasing to be an Eligible Employee.

(p) Rights on a general offer, a compromise or arrangement

If a general offer by way of takeover or otherwise (other than by way of scheme of arrangement) is made to our Shareholders (other than the offeror and/or any person controlled by the offeror and/or any person acting in concert with the offeror) and such offer becomes or is declared unconditional prior to the expiry date of the relevant option, our Company shall forthwith give notice thereof to the grantee and the grantee shall be entitled to exercise the option to its full extent or, if our Company shall give the relevant notification, to the extent notified by our Company, at any time within such period as shall be notified by our Company.

If a general offer for Shares by way of scheme of arrangement is made to our Shareholders and has been approved by the necessary number of Shareholders at the requisite meetings, our Company shall forthwith give notice thereof to the grantee and the grantee may at any time thereafter (but before such time as shall be notified by our Company) exercise the option to its full extent or, if our Company shall give the relevant notification, to the extent notified by our Company.

(q) Rights on winding up

In the event a notice is given by our Company to our Shareholders to convene a general meeting for the purpose of considering and, if thought fit, approving a resolution to voluntarily wind-up our Company, our Company shall forthwith give notice thereof to the grantee and the grantee (or in the case of the death of the grantee, his personal representatives(s)) may at any time within such period as shall be notified by our Company, subject to the provisions of all applicable laws, exercise the option to its full extent or, if our Company shall give the relevant notification, to the extent notified by our Company, and our Company shall as soon as possible and in any event no later than three days prior to the date of the proposed general meeting, allot, issue and register in the name of the Grantee such number of fully paid Shares which fall to be issued on exercise of such option.

(r) Adjustments to the subscription price

In the event of a capitalization issue, rights issue, subdivision or consolidation of Shares or reduction of capital of our Company whilst an option remains exercisable, such corresponding adjustment (if any) certified by the auditors for the time being of or an independent financial advisor to our Company as fair and reasonable will be made to (a) the number or nominal amount of Shares to which the Post-[**REDACTED**] Share Option Scheme or any option relates, so far as unexercised, and/or (b) the subscription price of the option concerned, and/or (c) the method of exercise of the Option, provided that (i) any adjustments shall give a grantee the same proportion of the issued share capital to which he was entitled prior to such alteration; (ii) the issue of Shares or other securities of our Group as consideration in a transaction may not be regarded as a circumstance requiring adjustment; and (iii) no adjustment shall be made the effect of which would be to enable a Share to be issued at less than its nominal value. In addition, in respect of any such adjustments, other than any adjustment made on a capitalization issue, such auditors or independent financial advisor must confirm to our Directors in writing that the adjustments satisfy the requirements of the relevant provision of the Listing Rules and such other applicable guidance and/or interpretation of the Listing Rules from time to time issued by the Stock Exchange (including, but not limited to, the "Supplementary Guidance on Main Board Listing Rule 17.03(13) and the Note immediately after the Rule" attached to the letter from the Stock Exchange dated September 5, 2005 to all issuers relating to share option schemes).

(s) Cancellation of options

Any options granted but not exercised may be cancelled if the grantee so agrees. Issuance of new options to the same grantee may only be made if there are unissued options available under the Post-[**REDACTED**] Share Option Scheme (excluding the cancelled options) and in compliance with the terms of the Post-[**REDACTED**] Share Option Scheme.

(t) Termination of the Post-[**REDACTED**] *Share Option Scheme*

Our Company may by ordinary resolution in a general meeting at any time resolve to terminate the Post-[**REDACTED**] Share Option Scheme prior to the expiry of the Post-[**REDACTED**] Share Option Scheme and in such event no further options shall be offered or granted but in all other respects the provisions of the Post-[**REDACTED**] Share Option Scheme shall remain in force to the extent necessary to give effect to the exercise of any options (to the extent not already exercised) granted prior to the termination or otherwise as may be required in accordance with the provisions of the Post-[**REDACTED**] Share Option Scheme. Options (to the extent not already exercised) granted prior to such termination shall continue to be valid and exercisable in accordance with the Post-[**REDACTED**] Share Option Scheme.

(u) Lapse of option

An option shall lapse automatically (to the extent not already exercised) on the earliest of:

(i) the expiry of the period referred to in sub-paragraph (f);

(ii) the expiry of the periods or dates referred to in sub-paragraphs (m), (n), (o), (p) and (q);

(iii) the date on which the grantee commits a breach of the provision which restricts the grantee to transfer or assign an option granted under the Post-[**REDACTED**] Share Option Scheme or sell, transfer, charge, mortgage, encumber or otherwise dispose of or create any interest in favor of or enter into any agreement with any other person over or in relation to any option except for the transmission of an Option on the death of the Grantee to his personal representative(s) on the terms of this Scheme;

(iv) the date on which the grantee (being an employee or a director of any member of our Group) ceases to be a participant of the Post-[**REDACTED**] Share Option Scheme by reason of the termination of his or her employment or engagement on the grounds that he or she has been guilty of serious misconduct, or appears either to be unable to pay or to have no reasonable prospect of being able to pay his or her debts or has become bankrupt or has made any arrangement or

(v) composition with his or her creditors generally, or has been convicted of any criminal offence involving his or her integrity or honesty or on any other ground on which an employer would be entitled to terminate his or her employment summarily;

(vi) the date on which the grantee joins a company which the board believes in its sole and reasonable opinion to be a competitor of our Company;

(vii) the date on which the grantee (being a corporation) appears either to be unable to pay or to have no reasonable prospect of being able to pay its debts or has become insolvent or has made any arrangement or composition with its creditors generally; and

(viii) unless our Board otherwise determines, and other than in the circumstances referred to in sub-paragraphs (m) or (n), the date the Grantee ceases to be a Participant (as determined by a Board resolution) for any other reason.

(v) Others

(i) The Post-[**REDACTED**] Share Option Scheme is conditional on the [**REDACTED**] granting or agreeing to grant approval of (subject to such condition as the Stock Exchange may impose) the [**REDACTED**] of and permission to [**REDACTED**] in such number of Shares to be issued pursuant to the exercise of any options which may be granted under the Post-[**REDACTED**] Share Option Scheme, such number representing the General Scheme Limit. Application has been made to the [**REDACTED**] for the [**REDACTED**] of and permission to [**REDACTED**] in the Shares to be issued within the General Scheme Limit pursuant to the exercise of any options which may be granted under the Post-[**REDACTED**] Share Option Scheme.

(ii) The terms and conditions of the Post-[**REDACTED**] Share Option Scheme relating to the matters set forth in Rule 17.03 of the Listing Rules shall not be altered to the advantage of grantees of the options except with the approval of our Shareholders in a general meeting.

(iii) Any alterations to the terms and conditions of the Post-[**REDACTED**] Share Option Scheme which are of a material nature or any change to the terms of options granted must be approved by our Shareholders in a general meeting and the Stock Exchange, except where the alterations take effect automatically under the existing terms of the Post-[**REDACTED**] Share Option Scheme.

(iv) The amended terms of the Post-[**REDACTED**] Share Option Scheme or the options shall comply with the relevant requirements of Chapter 17 of the Listing Rules.

(v) Any change to the authority of our Directors or the scheme administrators in relation to any alteration to the terms of the Post-[**REDACTED**] Share Option Scheme shall be approved by our Shareholders in a general meeting.

(w) Value of options

Our Directors consider it inappropriate to disclose the value of options which may be granted under the Post-[**REDACTED**] Share Option Scheme as if they had been granted as of the Latest Practicable Date. Any such valuation will have to be made on the basis of a certain option pricing model or other method that depends on various assumptions including the exercise price, the exercise period, interest rate, expected volatility and other variables. As no options have been granted, certain variables are not available for calculating the value of options. Our Directors believe that any calculation of the value of options granted as of the Latest Practicable Date would be based on a number of speculative assumptions that are not meaningful and would be misleading to investors.

(x) Grant of options

As of the date of this document, no options have been granted or agreed to be granted under the Post-[**REDACTED**] Share Option Scheme.

Application has been made to the [**REDACTED**] for the [**REDACTED**] of, and permission to [**REDACTED**] in, the Shares which may fall to be issued pursuant to the exercise of the options to be granted under the Post-[**REDACTED**] Share Option Scheme.

E. OTHER INFORMATION

1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries.

2. Litigation

Except as disclosed in this document, as of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened by or against any member of our Group, that would have a material adverse effect on our Group's results of operations or financial condition, taken as a whole.

3. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

4. Promoter

Our Company has no promoter for the purpose of the [**REDACTED**]. Within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any promoter in connection with the [**REDACTED**] and the related transactions described in this document.

5. Taxation of Holders of Shares

(1) Hong Kong

[**REDACTED**] in Shares registered on our Company's Hong Kong branch register of members will be subject to Hong Kong stamp duty. The sale, purchase and transfer of Shares are subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.13% of the consideration or, if higher, the value of the Shares being sold or transferred. Dividends paid on Shares will not be subject to tax in Hong Kong and no tax is imposed in Hong Kong in respect of capital gains. However, profits from [**REDACTED**] in the Shares derived by persons carrying on a business of trading or dealings in securities in Hong Kong arising in or derived from Hong Kong may be subject to Hong Kong profits tax. The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong. No Hong Kong estate duty is payable and no estate duty clearance papers are needed for a grant of representation in respect of holders of Shares whose death occurs on or after February 11, 2006.

(2) Cayman Islands

There is no stamp duty payable in the Cayman Islands on transfers of shares of Cayman Islands companies save for those which hold interests in land in the Cayman Islands.

(3) Consultation with professional advisors

Potential investors in the [**REDACTED**] are urged to consult their professional tax advisors if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or dealing in our Shares (or exercising rights attached to them). None of us, the Joint Sponsors, the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], or any other person or party involved in the [**REDACTED**] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the subscription, purchase, holding or disposal of, dealing in or the exercise of any rights in relation to our Shares.

6. Application for [REDACTED]

The Joint Sponsors has made an application on behalf of our Company to the [**REDACTED**] of the [**REDACTED**] for the [**REDACTED**] of, and permission to [**REDACTED**] in, the Shares in issue and to be [**REDACTED**] as mentioned in this document. All necessary arrangements have been made to enable the securities to be admitted into [**REDACTED**].

7. No Material Adverse Change

Our Directors confirm that up to the date of this document, there has been no material adverse change in the financial or trading position or prospect of our Group since June 30, 2022 (being the date to which the latest audited consolidated financial statements of our Group were prepared).

8. Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given their opinion and/or advice in this document are as follows:

Name	Qualifications
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation under the SFO to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
CCB International Capital Limited	A licensed corporation under the SFO to conduct Type 1 (dealing in securities), Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
PricewaterhouseCoopers	Certified Public Accountants under Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong) Registered Public Interest Entity Auditor under Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
King & Wood Mallesons	PRC legal advisors

Name	Qualifications
Conyers Dill & Pearman	Cayman Islands attorneys-at-law
China Insights Industry Consultancy Limited	Industry consultant
Herbert Smith Freehills	Legal advisors as to international sanctions laws
Stibbe	Dutch legal advisors as to the Investigation

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

9. Consents

Each of the experts named in paragraph headed "8. Qualifications of Experts" above has given and has not withdrawn their respective written consents to the issue of this document with the inclusion of their reports and/or letters and/or the references to their names included herein in the form and context in which they are respectively included.

10. Joint Sponsors' Independence

China International Capital Corporation Hong Kong Securities Limited is not considered as an independent sponsor according to the independence criteria applicable to sponsors as set out in Rule 3A.07 of the Listing Rules, as CICC Biomedical Fund is one of our Pre-[**REDACTED**] Investors and its [former] nominee director serving on our Board has also been a non-executive director of certain companies within the same group as that of China International Capital Corporation Hong Kong Securities Limited.

CCB International Capital Limited satisfies the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

The Joint Sponsors' fees payable by us in respect of the Joint Sponsors' services as sponsor for the [**REDACTED**] are HK$9,360,000.

11. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

12. Agency Fees and Commissions Received

The [**REDACTED**] will receive an [**REDACTED**] commission as referred to in the section headed " [**REDACTED**]."

13. Bilingual Document

The English language and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

14. Miscellaneous

Save as otherwise disclosed in this document:

(a) none of our Directors or experts referred to in the paragraph headed "E. Other Information – 8. Qualifications of Experts" of this appendix has any direct or indirect interest in the promotion of us, or in any assets which have within two years immediately preceding the date of this document been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;

(b) none of our Directors or experts referred to in the paragraph headed "E. Other Information – 8. Qualifications of Experts" of this appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group taken as a whole;

(c) within the two years preceding the date of this document, no share or loan capital of the Company or any of its subsidiaries has been issued or has been agreed to be issued fully or partly paid either for cash or for a consideration other than cash;

(d) within the two years preceding the date of this document, no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any capital of any member of the Group;

(e) the two years preceding the date of this document, no commission has been paid or is payable (except commissions to sub-[**REDACTED**]) for subscribing or agreeing to subscribe, or procuring or agreeing to procure the subscriptions, for any Shares in our Company;

(f) no share or loan capital of the Company or any of its subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;

(g) no founder, management or deferred shares of the Company or any of its subsidiaries have been issued or have been agreed to be issued;

(h) none of the equity and debt securities of the Company is listed or dealt in on any stock exchange (other than the Stock Exchange) nor is any listing or permission to deal being or proposed to be sought;

(i) the Group has no outstanding convertible debt securities or debentures;

(j) there is no arrangement under which future dividends are waived or agreed to be waived;

(k) the English text of this document and the [**REDACTED**] shall prevail over their respective Chinese text; and

(l) there has not been any interruption in the business of the Group which may have or has had a significant effect on the financial position of the Group in the 12 months preceding the date of this document.

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were (i) a copy of the [**REDACTED**]; (ii) copies of each of the material contracts referred to in the section headed "Statutory and General Information – B. Further Information about the Business of the Company – 1. Summary of Material Contracts" in Appendix IV to this document; and (iii) the written consents issued by each of the experts and referred to in section headed "Statutory and General Information – E. Other information – 8. Qualifications of Experts" in Appendix IV to this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Hong Kong Stock Exchange at www.hkexnews.hk and our website at https://orbusneich.com during a period of 14 days from the date of this document:

(a) the Memorandum and Articles of Association;

(b) the Accountant's Report of the Group for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 prepared by PricewaterhouseCoopers, the text of which is set out in Appendix I to this document;

(c) the report received from PricewaterhouseCoopers on the unaudited pro forma financial information of our Group, the text of which is set out in Appendix II to this document;

(d) the audited consolidated financial statements of our Group for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022;

(e) the PRC legal opinions issued by King & Wood Mallesons, our PRC legal advisors in respect of general matters and property interests of our Group in the PRC;

(f) the letter issued by Conyers Dill & Pearman, our legal advisors on Cayman Islands laws, summarizing certain aspects of Companies Law referred to in the section headed "Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law";

(g) the Companies Act (2021 Revision) of the Cayman Islands;

(h) the legal memorandum issued by Stibbe, our Dutch legal advisors as to the investigation of OIBV conducted by the DPPS, in respect of such investigation;

(i) the industry report prepared by China Insights Industry Consultancy Limited referred to in the section headed "Industry Overview" in this document;

(j) the material contracts referred to in the paragraph headed "Statutory and General Information – B. Further Information about the Business of the Company – 1. Summary of Material Contracts" in Appendix IV to this document;

(k) the service agreements and letters of appointment referred to in the paragraph headed "Statutory and General Information – C. Further Information about Directors and Substantial Shareholders – 2. Particulars of Directors' Service Contracts and Letters of Appointment" in Appendix IV to this document;

(l) the written consents referred to in the paragraph headed "Statutory and General Information – E. Other Information – 9. Consents" in Appendix IV to this document;

(m) the rules of the Pre-[**REDACTED**] Share Option Scheme;

(n) the rules of the Post-[**REDACTED**] Share Option Scheme; and

(o) a full list of all the grantees under the Pre-[**REDACTED**] Share Option Scheme.