***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.